

### 16.2.7.1 Adverse Events Legend Page

Category	Abbreviation	Text
Action - Study Vaccine Dose	NA	Not applicable
	P	Investigational product withdrawn
Action - Subject	TC	Concomitant drug treatment given
	TCN	Concomitant non-drug treatment given
	W	Withdrawn from study
Cause of AE	CD	Concomitant drug treatment
	CND	Concomitant non-drug treatment
	O	Other
Outcome	F	Fatal
	N	Not recovered/not resolved
	R	Recovered/resolved
	RS	Recovered/resolved with sequelae
	RG	Recovering/resolving
	UNK	Unknown
Toxicity Grade	1	Mild
	2	Moderate
	3	Severe
	4	Life-threatening
System Organ Class	BLOOD	Blood and lymphatic system disorders
	CARD	Cardiac disorders
	CONG	Congenital, familial and genetic disorders
	EAR	Ear and labyrinth disorders
	ENDO	Endocrine disorders
	EYE	Eye disorders
	GASTR	Gastrointestinal disorders
	GENRL	General disorders and administration site conditions
HEPAT	Hepatobiliary disorders	

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	IMMUN	Immune system disorders
	INFEC	Infections and infestations
	INJ&P	Injury poisoning and procedural complications
	INV	Investigations
	METAB	Metabolism and nutrition disorders
	MUSC	Musculoskeletal and connective tissue disorders
	NEOPL	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
	NERV	Nervous system disorders
	PREG	Pregnancy, puerperium and perinatal conditions
	PSYCH	Psychiatric disorders
	RENAL	Renal and urinary disorders
	REPRO	Reproductive system and breast disorders
	RESP	Respiratory, thoracic and mediastinal disorders
	SKIN	Skin and subcutaneous tissue disorders
	SOCCI	Social circumstances
	SURG	Surgical and medical procedures
	VASC	Vascular disorders

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**16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction <sup>b</sup>	Rel Day <sup>a</sup>							Stop Date <sup>c</sup>	Dur (Days) <sup>d</sup>
					1	2	3	4	5	6	7		
16-55	C4591001 1007 10071111	1	03AUG2020	Pain at the injection site	Mod	Sev	Mild	N		N	N	05AUG2020	3
	C4591001 1008 10081782	2	30DEC2020	Redness (cu)			21	21				02JAN2021	2
				Redness (svt)	N	N	Sev	Sev	N	N			
	C4591001 1013 10131180	1	13AUG2020	Pain at the injection site	Mod	Sev	Mild	Mild	N	Mild		19AUG2020	7
		2	03SEP2020	Redness (cu)	21							03SEP2020	1
				Redness (svt)	Sev	N							
	C4591001 1015 10151015	2	04SEP2020	Redness (cu)			18	21	21	14	13	10SEP2020	5
				Redness (svt)	N	N	Mod	Sev	Sev	Mod	Mod		
				Swelling (cu)			11	21				07SEP2020	2
				Swelling (svt)	N	N	Mod	Sev	N	N	N		
	C4591001 1015 10151030	1	15AUG2020	Pain at the injection site	Mild	Sev	Mild	Mild	N	N	N	18AUG2020	4
		2	04SEP2020	Pain at the injection site	Mod	Sev		Mild	N	Mild			
	C4591001 1016 10161087	1	10AUG2020	Swelling (cu)	9	15	>21	19			9	21AUG2020	12
				Swelling (svt)	Mild	Mod	Sev	Mod		N	Mild		
				Pain at the injection site	Mod	Mod	Sev	Mod		N	N	13AUG2020	4
C4591001 1016 10161106	1	12AUG2020	Pain at the injection site	Mild	Sev	Mild	Mild	Mild	N		16AUG2020	5	
C4591001 1056 10561108	1	01SEP2020	Swelling (cu)		11	20	21				05SEP2020	4	

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					1	2	3	4	5	6	7			
				Swelling (svt)		Mod	Mod	Sev						
	C4591001 1057 10571368	1	23NOV2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	24NOV2020	2	
	C4591001 1077 10771013	2	31AUG2020	Redness (cu)				>21				03SEP2020	1	
				Redness (svt)	N	N	N	Sev		N	N			
				Swelling (cu)		20	20	>21		18		05SEP2020	5	
				Swelling (svt)	N	Mod	Mod	Sev		Mod	N			
	C4591001 1083 10831020	2	24AUG2020	Pain at the injection site	Mild	Sev	N	N		N	N	25AUG2020	2	
	C4591001 1089 10891025	2	20AUG2020	Pain at the injection site	Mild	Sev	Mod	Mild	Mild		N	24AUG2020	5	
	C4591001 1089 10891107	2	02SEP2020	Redness (cu)		18	21					04SEP2020	2	
				Redness (svt)	N	Mod	Sev			N	N	N		
				Swelling (cu)		18	21					04SEP2020	2	
				Swelling (svt)	N	Mod	Sev			N	N	N		
	C4591001 1089 10891131	1	17AUG2020	Swelling (cu)	21							17AUG2020	1	
				Swelling (svt)	Sev	N	N	N	N	N	N			
	C4591001 1090 10901043	2	24AUG2020	Pain at the injection site	Sev	Sev	Mild	N		N	Mild	01NOV2020	70	
	C4591001 1091 10911046	2	25AUG2020	Redness (cu)		16	21	21				28AUG2020	3	
				Redness (svt)	N	Mod	Sev	Sev	N	N	N			
	C4591001 1109 11091102	2	21AUG2020	Pain at the injection site	Sev	Mod	N	N	N	N	N	22AUG2020	2	

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					1	2	3	4	5	6	7		
	C4591001 1109 11091204	1	11AUG2020	Pain at the injection site	Mod	Sev	Mild	N	N	N	N	13AUG2020	3
	C4591001 1120 11201130	2	03SEP2020	Pain at the injection site	Sev	Mod	Mild	Mild	Mild		N	07SEP2020	5
	C4591001 1120 11201238	1	21AUG2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	22AUG2020	2
	C4591001 1124 11241039	2	03SEP2020	Swelling (cu)		21	1					04SEP2020	1
				Swelling (svt)	N	Sev	N	N	N	N	N		
				Pain at the injection site	N	Sev	Mod	N	N	N	N	05SEP2020	2
	C4591001 1125 11251243	1	08DEC2020	Pain at the injection site	Mild	Sev	Sev	Mild	N	N		11DEC2020	4
	C4591001 1127 11271014	2	19AUG2020	Pain at the injection site		Sev	Mod	Mild	Mild	Mild	N	24AUG2020	5
	C4591001 1127 11271022	1	30JUL2020	Pain at the injection site		Sev	Mod		Mild	N	N	03AUG2020	4
	C4591001 1127 11271032	1	31JUL2020	Pain at the injection site	Mod	Sev	Mild	Mild	Mild	N	N	04AUG2020	5
	C4591001 1129 11291045	2	25AUG2020	Redness (cu)		7	21					27AUG2020	2
				Redness (svt)	N	Mild	Sev		N	N			
	C4591001 1135 11351060	2	28AUG2020	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	30AUG2020	3
	C4591001 1135 11351105	2	31AUG2020	Pain at the injection site	N	Sev	Mod	Mild	Mild	N	N	04SEP2020	4
	C4591001 1140 11401051	1	06AUG2020	Pain at the injection site	Sev	Mod	N	N	N	N	N	07AUG2020	2

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					1	2	3	4	5	6	7			
	C4591001 1140 11401065	1	06AUG2020	Swelling (cu)		21	10	5					09AUG2020	3
				Swelling (svt)	N	Sev	Mild	Mild	N		N			
				Pain at the injection site	Mild	Sev	Mod	Mild	Mild		N		10AUG2020	5
		2	28AUG2020	Pain at the injection site	N	Sev	Mod	Mod	Mild	Mild			03SEP2020	6
	C4591001 1142 11421316	1	24NOV2020	Pain at the injection site	Mild	Sev	N	N	N	N	N		25NOV2020	2
	C4591001 1147 11471019	2	24AUG2020	Pain at the injection site	Mod	Sev	Mild	Mild	N	N	N		27AUG2020	4
	C4591001 1150 11501152	2	23DEC2020	Pain at the injection site	Sev	Mod	Mild				N		25DEC2020	3
	C4591001 1152 11521076	2	03SEP2020	Pain at the injection site	Mild	Sev	Mild	Mild	Mild	N	N		07SEP2020	5
	C4591001 1162 11621019	1	03AUG2020	Pain at the injection site	N	Sev	N	N	N		N		04AUG2020	1
	C4591001 1163 11631036	2	25AUG2020	Redness (cu)				21					03SEP2020	7
				Redness (svt)		N		Sev						
				Pain at the injection site		N		Sev					03SEP2020	7
	C4591001 1194 11941069	1	20OCT2020	Pain at the injection site	Sev	Mod	Mild	N	N	N	N		22OCT2020	3
	C4591001 1194 11941091	1	22OCT2020	Pain at the injection site	Mod	Sev	Mild	Mild	Mild	N			26OCT2020	5
	C4591001 1195 11951119	1	19OCT2020	Redness (cu)	20	21	21	20	20				23OCT2020	5

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					1	2	3	4	5	6	7		
				Redness (svt)	Mod	Sev	Sev	Mod	Mod	N	N		
				Swelling (cu)	21	21	21	20	20			23OCT2020	5
				Swelling (svt)	Sev	Sev	Sev	Mod	Mod	N	N		
	C4591001 1197 11971019	2	04NOV2020	Pain at the injection site	N	Sev	Mild	Mild	N	N	N	07NOV2020	3
	C4591001 1203 12031010	1	19OCT2020	Pain at the injection site	N	Sev		Mod	Mod	Mild		25OCT2020	6
	C4591001 1203 12031064	2	16NOV2020	Pain at the injection site	Sev	Mod	Mild	Mild	N	N	N	19NOV2020	4
	C4591001 1205 12051079	1	11NOV2020	Pain at the injection site	Sev	Mod	Mild	N	N	N	N	13NOV2020	3
		2	02DEC2020	Pain at the injection site	Mod	Sev	Mod	Mild	Mild	Mild	Mild	09DEC2020	8
	C4591001 1205 12051080	2	02DEC2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	03DEC2020	2
	C4591001 1210 12101005	2	12NOV2020	Pain at the injection site		Sev	N	N	N		N	13NOV2020	1
	C4591001 1210 12101006	2	13NOV2020	Pain at the injection site	N	Sev	Mild	N	N	N	N	15NOV2020	2
	C4591001 1210 12101028	1	30OCT2020	Pain at the injection site	Sev	Mild	N	N		N	N	31OCT2020	2
		2	20NOV2020	Pain at the injection site	Sev	Mild	N			N	N	21NOV2020	2
	C4591001 1210 12101033	1	02NOV2020	Pain at the injection site	Sev	Mild	Mild	Mild	Mild	N		06NOV2020	5
	C4591001 1210 12101050	2	26NOV2020	Pain at the injection site	Sev	Mild	N	N	N	N	N	27NOV2020	2

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					1	2	3	4	5	6	7		
	C4591001 1212 12121007	2	17NOV2020	Pain at the injection site	Mod	Sev	Mild	Mild	N	N	N	20NOV2020	4
	C4591001 1212 12121015	2	18NOV2020	Pain at the injection site	Sev	Mod	Mod	N	N	N	N	20NOV2020	3
	C4591001 1212 12121016	2	18NOV2020	Pain at the injection site	Sev	Mild	Mild	N	N	N	N	20NOV2020	3
	C4591001 1213 12131013	2	17NOV2020	Pain at the injection site	Sev	Sev	Mod	N	N			19NOV2020	3
	C4591001 1213 12131059	1	09NOV2020	Pain at the injection site	Mod	Sev	Mild	N	N	N	N	11NOV2020	3
	C4591001 1214 12141025	1	03NOV2020	Pain at the injection site	Sev	Mod	N	N	N		N	04NOV2020	2
	C4591001 1214 12141043	1	09NOV2020	Pain at the injection site	Sev	Mild	Mild	N	N	N	N	11NOV2020	3
	C4591001 1214 12141045	1	09NOV2020	Pain at the injection site	Sev	Mild	N	N	N	N	N	10NOV2020	2
	C4591001 1217 12171002	1	22OCT2020	Pain at the injection site	Sev	Mod		Mild	Mild	N	N	26OCT2020	5
	C4591001 1217 12171011	1	23OCT2020	Pain at the injection site	Sev	N	N		N	N	N	23OCT2020	1
	C4591001 1217 12171012	1	23OCT2020	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	25OCT2020	3
	C4591001 1217 12171016	2	16NOV2020	Pain at the injection site	Sev	Mild	N	N	N	N	N	17NOV2020	2
	C4591001 1226 12261008	2	24AUG2020	Pain at the injection site		Sev	N	N	N	N	N	25AUG2020	1
	C4591001 1226 12261011	1	05AUG2020	Pain at the injection site	Sev	Mod	N	N	N	N		06AUG2020	2



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					1	2	3	4	5	6	7		
	C4591001 1226 12261044	1	07AUG2020	Pain at the injection site	N		N	Sev	Mild	Mild	N	12AUG2020	3
	C4591001 1226 12261089	2	01SEP2020	Redness (cu)			21	21	12			05SEP2020	3
				Redness (svt)	N	N	Sev	Sev	Mod	N	N		
				Swelling (cu)			21	21				04SEP2020	2
				Swelling (svt)	N	N	Sev	Sev	N	N	N		
	C4591001 1226 12261096	1	11AUG2020	Pain at the injection site	Mild	Sev	Mild	N	N	Mild	N	16AUG2020	6
	C4591001 1226 12261140	1	12AUG2020	Pain at the injection site	N	Sev	N	N	N	N	N	13AUG2020	1
	C4591001 1226 12262255†	2	06NOV2020	Pain at the injection site		Sev		N	N	N	N	07NOV2020	1
	C4591001 1229 12291001	2	14OCT2020	Pain at the injection site		Sev	Mod	N	N	N	N	16OCT2020	2
	C4591001 1229 12291002	1	22SEP2020	Pain at the injection site	N	Sev	N	N	N	N	N	23SEP2020	1
	C4591001 1229 12291008	2	15OCT2020	Swelling (cu)	12	21						16OCT2020	2
				Swelling (svt)	Mod	Sev	N	N	N	N	N		
	C4591001 1229 12291024†	1	28SEP2020	Redness (cu)	21							28SEP2020	1
				Redness (svt)	Sev	N	N	N	N	N	N		
				Swelling (cu)		21						29SEP2020	1
				Swelling (svt)	N	Sev	N	N	N	N	N		
	C4591001 1229 12291032	1	28SEP2020	Redness (cu)	21							28SEP2020	1

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					1	2	3	4	5	6	7		
				Redness (svt)	Sev	N	N	N	N	N	N		
	C4591001 1229 12291047	1	29SEP2020	Pain at the injection site	Sev	Mild		N	N	N	N	30SEP2020	2
	C4591001 1229 12291082	1	01OCT2020	Redness (cu)	21							01OCT2020	1
	C4591001 1229 12291104	1	05OCT2020	Redness (svt) Pain at the injection site	Sev	N		N	N	N		26OCT2020	22
	C4591001 1229 12291105	2	26OCT2020	Pain at the injection site	Mod	Sev	N	Mod	N	N	N	29OCT2020	4
	C4591001 1229 12291108	1	05OCT2020	Redness (cu)		21		21				08OCT2020	3
				Redness (svt)	N	Sev	N	Sev	N	N	N		
				Swelling (cu)				21				08OCT2020	1
				Swelling (svt)	N	N	N	Sev	N	N	N		
	C4591001 1229 12291109	1	05OCT2020	Redness (cu)		21						06OCT2020	1
				Redness (svt)	N	Sev	N	N	N		N		
	C4591001 1229 12291114	1	06OCT2020	Redness (cu)	21							06OCT2020	1
				Redness (svt)	Sev	N	N	N	N		N		
	C4591001 1229 12291124	1	06OCT2020	Pain at the injection site	Mod	Sev	Mild	N			N	08OCT2020	3
	C4591001 1229 12291127	2	27OCT2020	Redness (cu)		21						28OCT2020	1
				Redness (svt)		Sev							

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					1	2	3	4	5	6	7		
	C4591001 1230 12301018	1	24SEP2020	Pain at the injection site	Sev	Sev	Mild	N	N	N	N	26SEP2020	3
	C4591001 1230 12301021	1	24SEP2020	Redness (cu)	21							24SEP2020	1
				Redness (svt)	Sev	N	N		N	N	N		
	C4591001 1230 12301072	1	29SEP2020	Redness (cu)	21							29SEP2020	1
				Redness (svt)	Sev	N	N	N	N	N	N		
	C4591001 1230 12301133	1	05OCT2020	Redness (cu)		2	21					07OCT2020	1
				Redness (svt)		N	Sev	N	N	N	N		
	C4591001 1231 12311018	2	27AUG2020	Pain at the injection site	N	Sev	Mild	Mild	Mild	N	N	31AUG2020	4
	C4591001 1231 12311055	1	11AUG2020	Pain at the injection site	Mild	Sev	Mod	Mild	Mild	Mild	Mild	17AUG2020	7
	C4591001 1231 12311162	1	13AUG2020	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	15AUG2020	3
	C4591001 1231 12311231	2	03SEP2020	Pain at the injection site	Mod	Sev	Mod	Mod	Mod	Mild	N	08SEP2020	6
	C4591001 1231 12311295	2	03SEP2020	Pain at the injection site	N	Mild	Sev	Mod	Mild	Mild		10SEP2020	7
	C4591001 1231 12311304	2	04SEP2020	Pain at the injection site		Sev	N	Mild	N	N	N	07SEP2020	3
	C4591001 1231 12311386	1	15AUG2020	Pain at the injection site	Mod	Sev	N	N	N	N	N	16AUG2020	2
	C4591001 1231 12311494	2	06SEP2020	Pain at the injection site	Sev	Mod	Mild	Mild	N	N		09SEP2020	4

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					1	2	3	4	5	6	7		
	C4591001 1231 12311513	2	08SEP2020	Pain at the injection site	N	Sev	Mild	N	N	N	N	10SEP2020	2
	C4591001 1232 12321010	2	02SEP2020	Pain at the injection site		Sev	N	Mild	N	N	N	05SEP2020	3
	C4591001 1246 12461025	1	28SEP2020	Pain at the injection site	Mod	Sev	Mild	N	N	N	N	30SEP2020	3
	C4591001 1246 12461055†	1	02OCT2020	Redness (cu)	21							02OCT2020	1
				Redness (svt)	Sev	N	N	N	N	N	N		
	C4591001 1247 12471033	2	15OCT2020	Pain at the injection site	N			Sev	Sev	N	N	19OCT2020	2
	C4591001 1247 12471071	1	28SEP2020	Swelling (cu)		21						29SEP2020	1
				Swelling (svt)	N	Sev	N	N	N	N	N		
	C4591001 1247 12471156	2	22OCT2020	Redness (cu)		21						23OCT2020	1
				Redness (svt)	N	Sev	N		N	N	N		
				Swelling (cu)		21						23OCT2020	1
				Swelling (svt)	N	Sev	N		N	N	N		
	C4591001 1247 12471159	1	05OCT2020	Pain at the injection site	Sev	Mild	N	N		N	N	06OCT2020	2
	C4591001 1247 12471199	1	06OCT2020	Redness (cu)	21	21						07OCT2020	2
				Redness (svt)	Sev	Sev		N			N		
				Swelling (cu)	21							06OCT2020	1
				Swelling (svt)	Sev	N		N			N		

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					1	2	3	4	5	6	7		
18-55	C4591001 1001 10011034 <sup>^</sup>	1	20MAY2020	Pain at the injection site	Sev	Mod	Mild	Mild	Mild	N	N	24MAY2020	5
	C4591001 1003 10031061 <sup>^</sup>	1	22JUN2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	23JUN2020	2
>55	C4591001 1001 10011084	1	28JUL2020	Pain at the injection site	Mod	Sev	N	N	N	N	N	29JUL2020	2
	C4591001 1055 10551017	1	10AUG2020	Pain at the injection site	Mild	Sev	N		N	N	N	11AUG2020	2
	C4591001 1085 10851059	2	02SEP2020	Redness (cu)		21	15	15				05SEP2020	3
				Redness (svt)	N	Sev	Mod	Mod	N	N	N		
				Swelling (cu)		21		15				05SEP2020	3
				Swelling (svt)	N	Sev	N	Mod	N	N	N		
	C4591001 1087 10871040	1	08AUG2020	Swelling (cu)		21	12	20				11AUG2020	3
				Swelling (svt)	N	Sev	Mod	Mod	N	N	N		
	C4591001 1090 10901155	2	31AUG2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	01SEP2020	2
	C4591001 1090 10901158	2	31AUG2020	Pain at the injection site	Mod	Sev	Mod	Sev	Mod	Mod	Mod	15SEP2020	16
	C4591001 1091 10911024	2	24AUG2020	Redness (cu)		3	21	15	>21			28AUG2020	3
				Redness (svt)	N	N	Sev	Mod	Sev	N	N		
	C4591001 1109 11091008	2	18AUG2020	Redness (cu)			15		21			22AUG2020	3
				Redness (svt)	N	N	Mod	N	Sev	N	N		

**16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction <sup>b</sup>	Rel Day <sup>a</sup>							Stop Date <sup>c</sup>	Dur (Days) <sup>d</sup>
					1	2	3	4	5	6	7		
	C4591001 1109 11091093	2	24AUG2020	Pain at the injection site	Mod	Sev	Mod		Mild	Mild			
	C4591001 1110 11101015	1	01AUG2020	Redness (cu)		21						02AUG2020	1
				Redness (svt)	N	Sev	N	N	N	N	N		
	C4591001 1123 11231012	2	19AUG2020	Pain at the injection site		Sev	Mod	Mod	N	N	N	22AUG2020	3
	C4591001 1124 11241031	2	03SEP2020	Redness (cu)			21	20	15			07SEP2020	3
				Redness (svt)	N	N	Sev	Mod	Mod	N	N		
	C4591001 1140 11401034	1	04AUG2020	Pain at the injection site	N	Sev	N	N	N	N		05AUG2020	1
	C4591001 1142 11421044	2	29AUG2020	Swelling (cu)			21	10				01SEP2020	2
				Swelling (svt)	N		Sev	Mild		N	N		
	C4591001 1142 11421093	2	04SEP2020	Redness (cu)				21	21	16	16	13SEP2020	7
				Redness (svt)		N	N	Sev	Sev	Mod	Mod		
	C4591001 1145 11451012	2	02SEP2020	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	04SEP2020	3
	C4591001 1146 11461025	2	03SEP2020	Pain at the injection site	Sev	Mod		N	N	N	N	04SEP2020	2
	C4591001 1194 11941074	2	12NOV2020	Redness (cu)					21	>21		17NOV2020	2
				Redness (svt)					Sev	Sev	N		
				Swelling (cu)					21	>21		17NOV2020	2
				Swelling (svt)					Sev	Sev	N		

**16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction <sup>b</sup>	Rel Day <sup>a</sup>							Stop Date <sup>c</sup>	Dur (Days) <sup>d</sup>
					1	2	3	4	5	6	7		
	C4591001 1195 11951046	2	05NOV2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	06NOV2020	2
	C4591001 1197 11971090	1	19OCT2020	Redness (cu)			21	9	5			23OCT2020	3
				Redness (svt)	N	N	Sev	Mild	Mild	N	N		
	C4591001 1197 11971095	2	07NOV2020	Pain at the injection site	Mod	Mod	Sev	Mild	Mild	N	N	11NOV2020	5
	C4591001 1205 12051018	2	16NOV2020	Redness (cu)		21						17NOV2020	1
				Redness (svt)		Sev	N	N		N	N		
	C4591001 1207 12071004	1	23OCT2020	Redness (cu)		11	21	5				26OCT2020	3
				Redness (svt)	N	Mod	Sev	Mild	N	N	N		
	C4591001 1224 12241016	2	02SEP2020	Redness (cu)		19	17	21	21	20	20	08SEP2020	6
				Redness (svt)	N	Mod	Mod	Sev	Sev	Mod	Mod		
	C4591001 1224 12241019	2	02SEP2020	Redness (cu)		6	21	21				05SEP2020	3
				Redness (svt)	N	Mild	Sev	Sev	N	N	N		
	C4591001 1226 12261033	1	06AUG2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	07AUG2020	2
	C4591001 1226 12261149	1	13AUG2020	Redness (cu)		21	10					15AUG2020	2
				Redness (svt)		Sev	Mild	N	N	N	N		
	C4591001 1229 12291040	2	21OCT2020	Swelling (cu)		20	21					23OCT2020	2
				Swelling (svt)	N	Mod	Sev	N	N	N	N		

**16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction <sup>b</sup>	Rel Day <sup>a</sup>							Stop Date <sup>c</sup>	Dur (Days) <sup>d</sup>	
					1	2	3	4	5	6	7			
	C4591001 1229 12291056	2	21OCT2020	Swelling (cu)		21							22OCT2020	1
				Swelling (svt)	N	Sev	N	N	N	N	N			
	C4591001 1229 12291067	1	30SEP2020	Redness (cu)		10		21					03OCT2020	3
				Redness (svt)	N	Mild	N	Sev		N	N			
		2	21OCT2020	Redness (cu)						21			26OCT2020	1
				Redness (svt)						Sev	N			
	C4591001 1229 12291084	2	23OCT2020	Pain at the injection site	Sev								25OCT2020	3
	C4591001 1229 12291087	1	02OCT2020	Redness (cu)			21						04OCT2020	1
				Redness (svt)		N	Sev	N		N	N			
				Swelling (cu)		21	21						04OCT2020	2
				Swelling (svt)		Sev	Sev	N		N	N			
	C4591001 1229 12291097	1	05OCT2020	Redness (cu)	21								05OCT2020	1
				Redness (svt)	Sev	N	N	N	N	N	N			
	C4591001 1246 12461056	2	23OCT2020	Redness (cu)		21	4						24OCT2020	1
				Redness (svt)	N	Sev	N	N	N	N	N			
	C4591001 1247 12471056	2	15OCT2020	Pain at the injection site	Mod	Sev	Mod	Mild	Mild	N	N		19OCT2020	5

Abbreviations: cu = caliper units; Dur = duration; Mod = moderate; N = none; Sev = severe; svt = severity.

Note: † = Human immunodeficiency virus (HIV)-positive subject, ^ = Phase 1 subjects.

a. Relative day (Rel Day) = date of reaction - date of last vaccination + 1.

b. The maximum measurable size for redness and swelling in the electronic diary (e-diary) was 21 caliper units. Redness and swelling exceeding 21



**16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction <sup>b</sup>	Rel Day <sup>a</sup>							Stop Date <sup>c</sup>	Dur (Days) <sup>d</sup>
					1	2	3	4	5	6	7		
<p>caliper units are reported as &gt;21. Study sites recorded injection site redness or swelling in centimeters. These were converted to caliper units (1 caliper unit = 0.5 centimeters).</p> <p>c. Stop date is the date the reaction was last reported.</p> <p>d. Duration (days) was calculated as the difference from the start of the first reported reaction to resolution of the last reported reaction, inclusive. If the reaction continued beyond Day 7, the calculation includes all days from the last e-diary day until the date of resolution collected on the case report form. If the reaction was ongoing at the time of the subsequent vaccination, the end date/day for the reaction is the date/day that the next vaccine was administered, which was used for the duration calculation.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_1004_sevlr_all</p>													

### 16.2.7.2.2 Listing of Severe and Grade 4 Local Reactions – Subjects Enrolled in Multiple Sites

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction <sup>b</sup>	Rel Day <sup>a</sup>							Stop Date <sup>c</sup>	Dur (Days) <sup>d</sup>
					1	2	3	4	5	6	7		
No subject meets the reporting criteria.													
<p>Abbreviation: Dur = duration.</p> <p>a. Relative day (Rel Day) = date of reaction - date of last vaccination + 1.</p> <p>b. The maximum measurable size for redness and swelling in the electronic diary (e-diary) was 21 caliper units. Redness and swelling exceeding 21 caliper units are reported as &gt;21. Study sites recorded injection site redness or swelling in centimeters. These were converted to caliper units (1 caliper unit = 0.5 centimeters).</p> <p>c. Stop date is the date the reaction was last reported.</p> <p>d. Duration (days) was calculated as the difference from the start of the first reported reaction to resolution of the last reported reaction, inclusive. If the reaction continued beyond Day 7, the calculation includes all days from the last e-diary day until the date of resolution collected on the case report form. If the reaction was ongoing at the time of the subsequent vaccination, the end date/day for the reaction is the date/day that the next vaccine was administered, which was used for the duration calculation.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)            (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_1004_sevlr_menrol_all</p>													

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>	
					1	2	3	4	5	6	7			
16-55	C4591001 1001 10011125	1	04AUG2020	Fatigue	Mod	Mod	Sev	Mild				N	07AUG2020	4
				Headache	Mod	Mod	Sev	Mod				N	07AUG2020	4
				New or worsened muscle pain	N	N	Sev	N				N	06AUG2020	1
				New or worsened joint pain	N	Mild	Sev	N				N	06AUG2020	2
	C4591001 1003 10031160	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	N	28AUG2020	1
	C4591001 1003 10031191	2	02SEP2020	Headache	Mild	Sev	Mild	N	N	Mild	N		07SEP2020	6
	C4591001 1005 10051024	2	31AUG2020	Fatigue		Sev	N	N	N			N	01SEP2020	1
	C4591001 1005 10051066	2	02SEP2020	Fatigue	N	Sev	N	N	N	N			03SEP2020	1
				Chills	N	Sev	N	N	N	N			03SEP2020	1
	C4591001 1005 10051434	2	12JAN2021	Chills	N	Sev	N		N	N			13JAN2021	1
	C4591001 1005 10051442	1	22DEC2020	Fatigue	N	Sev	Mild	Mild	N	Mild	N		27DEC2020	5
	C4591001 1006 10061024	2	31AUG2020	Fatigue	N	Sev	Mod	N	N	N	N		02SEP2020	2
	C4591001 1006 10061037	2	04SEP2020	Fatigue	N	Sev	N		Mod	Mod	N		09SEP2020	5
	C4591001 1006 10061040	1	14AUG2020	Headache	Mild	Mild	Sev	N	N	N	Mod		21AUG2020	8
C4591001 1006 10061053	2	09SEP2020	Fatigue	Mod	Sev	Mild	Mild	Mild	Mild	Mild		16SEP2020	8	

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
				Chills	Mod	Sev	Mild	N	N	N	N	11SEP2020	3
	C4591001 1006 10061084	2	10SEP2020	Fatigue	Sev	N				N	Mild	17SEP2020	8
	C4591001 1006 10061185	2	21DEC2020	Chills	N	Sev	N	N	N	N	N	22DEC2020	1
	C4591001 1006 10061192	2	22DEC2020	Headache	N	Sev	N	Mild	N	N	N	25DEC2020	3
	C4591001 1006 10061210	2	23DEC2020	Headache	N	Sev	N	N	N	N	N	24DEC2020	1
	C4591001 1006 10061246	1	10DEC2020	Fatigue	N	N	Sev	N	N	N	N	12DEC2020	1
	C4591001 1007 10071097	2	20AUG2020	New or worsened muscle pain	N	Sev	Mod	Mod	Mod	Mod	Mod	01SEP2020	12
	C4591001 1007 10071111	1	03AUG2020	Chills	N	Sev	N	N		N	N	04AUG2020	1
				New or worsened muscle pain	N	Sev	N	N		N	N	04AUG2020	1
	C4591001 1007 10071130	2	26AUG2020	Chills	N	Sev	N	N	N	N	N	27AUG2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	27AUG2020	1
	C4591001 1007 10071146	2	27AUG2020	New or worsened muscle pain	N	Sev	N		N	N	N	28AUG2020	1
	C4591001 1007 10071157	2	31AUG2020	Fatigue	N	Sev	N	N	N	N	N	01SEP2020	1
				Chills	N	Sev	N	N	N	N	N	01SEP2020	1
	C4591001 1007 10071487	1	01DEC2020	Headache	N	Sev	Mild		N	N		03DEC2020	2

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>	
					1	2	3	4	5	6	7			
	C4591001 1007 10071503	1	03DEC2020	New or worsened muscle pain	Sev	Mod		N				N	04DEC2020	2
	C4591001 1009 10091028	2	31AUG2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	N	01SEP2020	1
	C4591001 1011 10111035	2	03SEP2020	Fatigue	Sev	Sev	Sev	Mild	Mild	N	N	N	07SEP2020	5
				Headache	N	Sev	Mod	N	Mild	N	N	N	07SEP2020	4
				Chills	N	Sev	Mod	N	N	N	N	N	05SEP2020	2
				New or worsened muscle pain	N	Sev	N	N	N	N	N	N	04SEP2020	1
	C4591001 1011 10111129	2	21SEP2020	Headache	Sev	N	N	N	N			N	21SEP2020	1
	C4591001 1012 10121001	1	03AUG2020	Headache	Mild	Sev		N	N	N	N	N	04AUG2020	2
	C4591001 1013 10131005	1	28JUL2020	Headache	N	N	N	N	Sev			N	01AUG2020	1
	C4591001 1013 10131013	2	18AUG2020	Headache	N	Sev	Mild	Mild	Mod	Mild	N	N	23AUG2020	5
	C4591001 1013 10131030	2	18AUG2020	Chills	N	Sev	N	N	N	N	N	N	19AUG2020	1
	C4591001 1013 10131055	2	24AUG2020	New or worsened muscle pain		N	Sev	N	N			N	26AUG2020	1
	C4591001 1013 10131059	2	25AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	N	27AUG2020	2
	C4591001 1013 10131062	2	24AUG2020	Fatigue	N	Sev	N	N	N	N	N	N	25AUG2020	1
	C4591001 1013 10131084	2	26AUG2020	Vomiting	N	N	N	N	N	Mod	Sev	N	01SEP2020	2

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>	
					1	2	3	4	5	6	7			
	C4591001 1013 10131180	2	03SEP2020	New or worsened muscle pain	N	Sev							06SEP2020	2
				New or worsened joint pain	N	Sev							06SEP2020	2
	C4591001 1015 10151030	1	15AUG2020	Fatigue	N	Sev	Mod	Mild	Mild	Sev	Mod		21AUG2020	6
		2	04SEP2020	Fatigue	N	Sev		Mod	Mod	N			08SEP2020	4
				Headache	N	Sev		Mod	Mod	N			08SEP2020	4
				New or worsened muscle pain	N	Sev		Mod	N	N			07SEP2020	3
	C4591001 1015 10151035	2	04SEP2020	Fatigue		Sev	N	N	N	N	N		05SEP2020	1
				New or worsened muscle pain		Sev	N	N	N	N	N		05SEP2020	1
				New or worsened joint pain		Sev	N	N	N	N	N		05SEP2020	1
	C4591001 1016 10161004	2	19AUG2020	Oral temperature (°C)	36.4	39.6	37.1	36.8	36.4	36.2	35.7		20AUG2020	1
	C4591001 1016 10161078	2	28AUG2020	Headache	N	Sev	N	N	N	N	N		29AUG2020	1
				Chills	N	Sev	N	N	N	N	N		29AUG2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N		29AUG2020	1
	C4591001 1016 10161349	2	25NOV2020	Headache	Mod	Sev	Mild	N	N	N	N		27NOV2020	3
	C4591001 1018 10181013	1	30JUL2020	Fatigue	N	N	N	N	N	Sev	N		04AUG2020	1

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1018 10181055	2	25AUG2020	Fatigue	N	Sev	Mod	N	Mild	Mild	Mild	31AUG2020	6
				New or worsened muscle pain	N	Sev	Mild	N	Mild	Mild	N	30AUG2020	5
	C4591001 1018 10181089	2	27AUG2020	New or worsened joint pain	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1018 10181151	2	03SEP2020	Fatigue	Sev	Mild	N	N	N		N	04SEP2020	2
	C4591001 1042 10421070	2	31AUG2020	Fatigue	Mod	Sev	Mod	N	N	N	N	02SEP2020	3
	C4591001 1042 10421105	2	02SEP2020	Oral temperature (°C)	36.7	38.9	36.7	36.7	36.8	36.6	36.1	03SEP2020	1
	C4591001 1044 10441244	2	14DEC2020	Fatigue	N	Sev	Mild	Mild	Mild	Mild	N	19DEC2020	5
				New or worsened muscle pain	N	Sev	Mild	N	N	N	N	16DEC2020	2
	C4591001 1044 10441245	2	14DEC2020	Fatigue		Sev	Mild	N	N		N	16DEC2020	2
	C4591001 1044 10441287	1	11DEC2020	Fatigue	Mod	Sev	Mild	Mild	N	Mild	Mild		
	C4591001 1052 10521017	1	21AUG2020	Diarrhea	N	Mild	Mod	Mod	Mod	Sev	Mod	27AUG2020	6
	C4591001 1052 10521036	1	26AUG2020	Fatigue	Mod	Sev	N	N	N		N	27AUG2020	2
	C4591001 1055 10551003	2	27AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	29AUG2020	2
	C4591001 1057 10571028	2	08SEP2020	Fatigue	N	Sev	N	N	N	N	N	09SEP2020	1

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1057 10571362†	1	30OCT2020	Oral temperature (°C)	38.9	38.5	38.3	37.8	37.9	37.4		01NOV2020	3
				Fatigue	Mod	Mod	Sev	Mild	Mod	Sev		05NOV2020	7
				Headache	Mod	Mod	Sev	Mild	Mod	Mod		05NOV2020	7
				Vomiting	N	N	Mod	Sev	Mod	N		03NOV2020	3
	C4591001 1066 10661027	1	13AUG2020	Fatigue	Mild	N			Sev	Mod	Mod	20AUG2020	8
	C4591001 1071 10711019	2	02SEP2020	Fatigue	N	Sev			N	N	N	03SEP2020	1
	C4591001 1071 10711039	2	04SEP2020	Headache	N	N	Mod	Sev		Mild	Mild	21SEP2020	16
	C4591001 1071 10711065	2	09SEP2020	Headache	Sev	Sev	N	N	N	N	Mild	17SEP2020	9
	C4591001 1073 10731021	1	31JUL2020	Fatigue	Mild	Sev	Mod	N		N	N	02AUG2020	3
		2	24AUG2020	Fatigue	N	Sev	Mod	N	N	N	N	26AUG2020	2
	C4591001 1073 10731064	2	01SEP2020	Fatigue	Mod	Mod	Mod	Sev	N	N	N	04SEP2020	4
				Headache	N	Mod	N	Sev	N	N	N	04SEP2020	3
	C4591001 1073 10731083	2	02SEP2020	Fatigue	Mod	Sev	N	N	N		N	03SEP2020	2
				Chills	N	Sev	N	N	N		N	03SEP2020	1
	C4591001 1077 10771013	2	31AUG2020	Fatigue	N	Sev	N	Mod		Mod	N	05SEP2020	5
				Chills	N	Sev	N	N		N	N	01SEP2020	1
	C4591001 1079 10791039	2	25AUG2020	Headache	N	Mild	N	N	Mod	Sev		02SEP2020	8



**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1079 10791040	2	24AUG2020	Headache					Sev		N	28AUG2020	1
	C4591001 1079 10791097	2	31AUG2020	Chills		Sev	N	N	N		N	01SEP2020	1
	C4591001 1079 10791112	1	12AUG2020	Headache	Mild	Sev	N	N	N	N	N	13AUG2020	2
	C4591001 1079 10791115	1	12AUG2020	Headache	Mild	Mild		Mild	Sev	Mod	Mild	18AUG2020	7
	C4591001 1079 10791127	2	03SEP2020	Oral temperature (°C)	36.8	39	37.2	36.9	36.8	36.6	36.6	04SEP2020	1
	C4591001 1080 10801009	2	03SEP2020	Headache		Sev	Mod	N			N	05SEP2020	2
	C4591001 1081 10811033	2	03SEP2020	Fatigue	N	Sev	N	N	N	N		04SEP2020	1
	C4591001 1082 10821036	1	04AUG2020	Headache	Mod	N	Mild	N	N	N	Sev	11AUG2020	8
		2	25AUG2020	Headache	N	Sev	Sev	N	N	N	Mod	31AUG2020	6
	C4591001 1083 10831020	2	24AUG2020	Fatigue	N	Sev	N	N		N	N	25AUG2020	1
	C4591001 1083 10831060	1	06AUG2020	Oral temperature (°C)	36.5	37.8	37.8	38.6	38.6	38.9	38.7	13AUG2020	5
	C4591001 1084 10841068	2	28AUG2020	Chills	N	Sev	N					29AUG2020	1
	C4591001 1084 10841091	2	28AUG2020	Fatigue	N	Sev	N	N	N	N	N	29AUG2020	1
	C4591001 1084 10841102	2	31AUG2020	Headache	N	Sev	Mod	Mod	Mild	N	N	04SEP2020	4

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>	
					1	2	3	4	5	6	7			
	C4591001 1084 10841118	1	10AUG2020	Fatigue	N	Sev	N	N	N	N	N	N	11AUG2020	1
	C4591001 1084 10841146	2	02SEP2020	Fatigue	N	Sev	Mild	N	N	N	N	N	04SEP2020	2
	C4591001 1084 10841187	1	14AUG2020	Fatigue	Mild	Sev	Mild	N		N	N	N	16AUG2020	3
	C4591001 1084 10841188	1	14AUG2020	Headache	N	N	Mod	Sev	N	N	N	N	17AUG2020	2
		2	04SEP2020	Headache	N	N	N	N	N	N	Sev	N	10SEP2020	1
	C4591001 1085 10851018	1	01AUG2020	Diarrhea	N	N	N	Mod	N	Mod	Sev	N	07AUG2020	4
	C4591001 1085 10851075	2	29AUG2020	Fatigue	Sev	Mod	Mild	N	N	N	N	N	31AUG2020	3
	C4591001 1087 10871045	1	10AUG2020	Fatigue	Sev	Sev	Sev	Sev	Sev	Sev	Sev	Sev	24AUG2020	15
				New or worsened muscle pain	N	N	N	N	Mod	Mod	Sev	N	24AUG2020	11
		2	31AUG2020	Fatigue	Mild	Mod		Sev	Sev	Sev	Sev	N		
				Headache	Mild	Mod		Mod	Mod	Mod	Sev	N		
	C4591001 1088 10881010	1	12AUG2020	Chills	N	Mild	Sev	N	N	N	N	N	14AUG2020	2
				Diarrhea	N	Mild	Sev	Sev	Mild	Mild	N	N	17AUG2020	5
	C4591001 1088 10881012	2	04SEP2020	Fatigue	N	Sev	N	N	N	N	N	N	05SEP2020	1
	C4591001 1089 10891025	2	20AUG2020	Headache	N	Sev	Mod	Mod	Mild		Mild	N	26AUG2020	6
	C4591001 1089 10891054	1	04AUG2020	Fatigue	N	Mild	Mod		Sev		Sev	N	14AUG2020	10

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1089 10891078	2	27AUG2020	Fatigue		Sev	N	N	N	N	N	28AUG2020	1
				Diarrhea		N	Sev	N	N	N	N	29AUG2020	1
	C4591001 1089 10891082	1	07AUG2020	Headache	N	Sev				N	N	08AUG2020	1
	C4591001 1089 10891103	2	31AUG2020	New or worsened joint pain	N	N	Sev	N			N	02SEP2020	1
	C4591001 1090 10901015	2	24AUG2020	Fatigue	N	Sev	N	N		N	N	25AUG2020	1
	C4591001 1090 10901022	2	28AUG2020	Headache		Sev	Mod	N	N	N	N	30AUG2020	2
	C4591001 1090 10901043	2	24AUG2020	Headache	Mild	Sev	N	N		N	Mild	30AUG2020	7
				Chills	N	Sev	N	N		N	N	25AUG2020	1
	C4591001 1090 10901045	2	24AUG2020	Headache	N	Sev	N	Mild	N	N		27AUG2020	3
				Chills	N	Sev	Mild	N	N	N		26AUG2020	2
	C4591001 1090 10901050	2	24AUG2020	Fatigue	N	Sev		N	N	N	N	25AUG2020	1
				Headache	N	Sev		N	N	N	N	25AUG2020	1
				Chills	N	Sev		N	N	N	N	25AUG2020	1
				New or worsened muscle pain	N	Sev		N	N	N	N	25AUG2020	1
	C4591001 1090 10901095	1	07AUG2020	Oral temperature (°C)	36.7	37.6	39.3	36.7	36.7	37.2	36.7	09AUG2020	1
		2	28AUG2020	Oral temperature (°C)	37	39.7	38	37.3	37.1	36.4	37	30AUG2020	2

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1090 10901104	1	07AUG2020	Fatigue	N	Mild	Sev	Mod	Mild	N	N	11AUG2020	4
				New or worsened muscle pain	N	Mod	Sev	Mod	N	N	N	10AUG2020	3
	C4591001 1091 10911037	1	04AUG2020	Fatigue	N	Sev	N	N	N	N	N	05AUG2020	1
	C4591001 1091 10911051	2	26AUG2020	Oral temperature (°C)	38.4	38.9	36.6	36.5	36.6	36.7		27AUG2020	2
	C4591001 1091 10911107	2	02SEP2020	Fatigue	Mod	Sev	N	N	N	N	N	03SEP2020	2
				Headache	Mod	Sev	N	N	N	N	N	03SEP2020	2
				Chills	N	Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1091 10911121	2	01SEP2020	Headache		Sev	N	N	N	Mild	N	06SEP2020	5
	C4591001 1094 10941016	1	14AUG2020	Fatigue	Sev	Mild	N	N		N	Sev	27AUG2020	14
	C4591001 1095 10951093	2	28AUG2020	Fatigue	Mod	Sev	Mod	Mod	Mod	N	N	01SEP2020	5
	C4591001 1107 11071010	2	18AUG2020	Headache	Mod	N		Mod	Sev	Mod		23AUG2020	6
	C4591001 1107 11071055	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1107 11071065	1	06AUG2020	Oral temperature (°C)	37.1	37.3	39.6	37.1	37.2	38.2	37.8	11AUG2020	4
	C4591001 1107 11071087	2	01SEP2020	Headache	Mod	Sev	Mild	N	N	N	N	03SEP2020	3
	C4591001 1109 11091020	2	18AUG2020	Headache	Mod	Sev	N	N		N	N	19AUG2020	2

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>	
					1	2	3	4	5	6	7			
	C4591001 1109 11091027	2	21AUG2020	Fatigue		Sev	Mod	N				N	23AUG2020	2
	C4591001 1109 11091060	2	20AUG2020	Oral temperature (°C)		38.9	37	38.6	38.3	38.4			26AUG2020	6
	C4591001 1109 11091102	2	21AUG2020	Fatigue	N	Sev	N	N	N	N	N	N	22AUG2020	1
				Headache	N	Sev	N	N	N	N	N	N	22AUG2020	1
				Vomiting	N	Sev	N	N	N	Mild	N	N	26AUG2020	5
				New or worsened joint pain	N	Sev	N	N	N	N	N	N	22AUG2020	1
	C4591001 1109 11091178	2	28AUG2020	Fatigue		Sev	N	N		Mod	N	N	02SEP2020	5
	C4591001 1109 11091228	2	03SEP2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	N	04SEP2020	1
	C4591001 1109 11091246	2	08SEP2020	New or worsened muscle pain					Sev		Mod	N	15SEP2020	4
	C4591001 1109 11091258	2	08SEP2020	Headache		Sev	N	Mod	Mod			N	12SEP2020	4
	C4591001 1109 11091267	1	16AUG2020	Fatigue	Mod	Mod	Sev	Mod	Mod				21AUG2020	6
		2	08SEP2020	Fatigue	Sev	N	N	N	N	Mod	N	N	13SEP2020	6
	C4591001 1110 11101027	2	24AUG2020	Oral temperature (°C)		39.4	38.1		37.9	37.2	37.2		26AUG2020	2
				Fatigue		Sev	Mod		Mod	N	N	N	28AUG2020	4
				New or worsened muscle pain		Sev	Mod		N	N	N	N	26AUG2020	2
				New or worsened joint pain		Sev	Mod		N	N	N	N	26AUG2020	2

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1110 11101033	2	25AUG2020	Fatigue	Mild	Sev		N	N	N	N	26AUG2020	2
	C4591001 1110 11101095	2	03SEP2020	Chills	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1111 11111072	2	31AUG2020	New or worsened joint pain	N	Sev	N	N	N	N	N	01SEP2020	1
	C4591001 1111 11111115	2	04SEP2020	Fatigue	Mild	N	N	Mod	Sev	Mod	Mod	10SEP2020	7
	C4591001 1112 11121045	1	03AUG2020	Oral temperature (°C)	36.9	39	37	37.1	36.9	36.8	36.6	04AUG2020	1
	C4591001 1112 11121180	2	16SEP2020	New or worsened joint pain		Sev	Sev	Mild	Mild	Mild	Mild	22SEP2020	6
	C4591001 1120 11201039	2	24AUG2020	Fatigue	Mod	Sev	Mild	Mild	N	N	N	27AUG2020	4
	C4591001 1120 11201082	2	25AUG2020	Fatigue	Mild	Mild	N	Mod	Mild	Mod	Sev	02SEP2020	9
	C4591001 1120 11201103	2	25AUG2020	Fatigue	N	Sev	N	N	N	N	N	26AUG2020	1
	C4591001 1120 11201148	1	12AUG2020	Fatigue	Mild	Mod	Mild	Sev	Mild	Mod	Mild	19AUG2020	8
		2	31AUG2020	Headache	N	Sev	N	Mild	N		N	03SEP2020	3
	C4591001 1120 11201172	1	13AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	15AUG2020	2
	C4591001 1120 11201244	2	09SEP2020	Headache		Sev	N	N	N	N	N	10SEP2020	1
	C4591001 1120 11201250	2	11SEP2020	Headache	N	Sev	N	N	N	N	N	12SEP2020	1

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
				New or worsened joint pain	N	Sev	N	N	N	Mod	Mild		
	C4591001 1120 11201278	2	02OCT2020	Chills		Sev	N	N	N	N	N	03OCT2020	1
	C4591001 1120 11201281	2	12OCT2020	New or worsened joint pain	N	N	Sev	N	N	N	N	14OCT2020	1
	C4591001 1120 11201320	2	16NOV2020	Oral temperature (°C)	32.2	38		39.6				20NOV2020	4
				Diarrhea	N	Sev		Mild				20NOV2020	4
	C4591001 1120 11201322	2	05NOV2020	Chills	N	Sev	N	N	N	N	N	06NOV2020	1
	C4591001 1120 11201331	1	16OCT2020	Oral temperature (°C)	37.1	37.4	39.6		36.7	36.7		18OCT2020	1
				Headache	Mod	Mod	Sev		N	N		18OCT2020	3
				Chills	N	N	Sev		N	N		18OCT2020	1
		2	05NOV2020	Oral temperature (°C)	37.1	39.3	38.5	36.7	36.8	36.6	36.8	07NOV2020	2
	C4591001 1120 11201404	2	16NOV2020	Oral temperature (°C)	37.9	39	37.2	37.1		37.1	37.3	17NOV2020	1
				Chills	Mild	Sev	N	N		N	N	17NOV2020	2
	C4591001 1123 11231090	2	03SEP2020	Fatigue	N	Sev	N		N	N	N	04SEP2020	1
	C4591001 1124 11241019	1	12AUG2020	Fatigue	N	Sev	N	N	N	Mod	N	17AUG2020	5
	C4591001 1125 11251024	2	01SEP2020	Fatigue	N	Sev	N	N	N	N	N	02SEP2020	1
	C4591001 1125 11251243	1	08DEC2020	Fatigue	N	Mod	Sev	N	N	N		10DEC2020	2

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
				Headache	N	Sev	Sev	N	N	N		10DEC2020	2
	C4591001 1126 11261208	2	04DEC2020	Headache	N	Sev	N	N	N	N	N	05DEC2020	1
	C4591001 1127 11271014	2	19AUG2020	Fatigue		Sev	Mod	N	Mild	Mild	N	24AUG2020	5
				Headache		Sev	N	N	N	N	N	20AUG2020	1
				New or worsened muscle pain		Sev	Mod	N	N	N	N	21AUG2020	2
	C4591001 1127 11271022	1	30JUL2020	Fatigue		Mild	Mod		Sev	Mod	Mild	16AUG2020	17
				Headache		Sev	Mod		Sev	Mod	Mild	16AUG2020	17
	C4591001 1127 11271032	1	31JUL2020	Fatigue	N	Sev	Mild	N	N	N	N	02AUG2020	2
				New or worsened muscle pain	N	Sev	N	N	N	N	N	01AUG2020	1
		2	19AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	21AUG2020	2
				New or worsened muscle pain	N	Sev	N	N	N	N	N	20AUG2020	1
	C4591001 1128 11281021	2	21AUG2020	Fatigue	N	Sev	Mod	N	N	N	N	23AUG2020	2
				Chills	N	Sev	N	N	N	N	N	22AUG2020	1
	C4591001 1128 11281024	2	20AUG2020	Fatigue	N	Sev	N	N	N	N	N	21AUG2020	1
				Headache	N	Sev	N	N	N	N	N	21AUG2020	1
	C4591001 1128 11281054	2	26AUG2020	Fatigue	Mod	Sev	N	Mod	Mod	Mod	Mod		



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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1128 11281119	2	03SEP2020	New or worsened muscle pain	Mod	Sev	N	N		N	N	04SEP2020	2
				New or worsened joint pain	Mild	Sev	N	N		N	N	04SEP2020	2
	C4591001 1129 11291006	2	17AUG2020	Fatigue		Sev	Mod	N	N	N	N	19AUG2020	2
				Chills		Sev	N	N	N	N	N	18AUG2020	1
	C4591001 1129 11291061	1	07AUG2020	Fatigue	Mod	Sev	Mod	Mild		N	N	10AUG2020	4
	C4591001 1129 11291089	1	11AUG2020	Fatigue	N	Mod	Sev		N	Mild	N	16AUG2020	5
				Headache	N	N	Sev		N	Mild	N	16AUG2020	4
	C4591001 1129 11291261	2	14DEC2020	Headache	Sev	Sev	N	N	N	N	N	15DEC2020	2
	C4591001 1129 11291262	2	14DEC2020	Fatigue	Sev	Mild	Mild	N	N	N	N	16DEC2020	3
	C4591001 1133 11331051	2	24AUG2020	Oral temperature (°C)	37.1	39.4	37.4	37.2	37.2	37.3	37.2	25AUG2020	1
				Headache	N	Sev	N	N	N	N	N	25AUG2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	25AUG2020	1
	C4591001 1133 11331152	2	09SEP2020	Diarrhea	N	Sev		N	N	N		10SEP2020	1
	C4591001 1133 11331180	1	14AUG2020	Oral temperature (°C)	32.2	39.2	33.3	37.3	37.4	37.5		15AUG2020	1
		2	04SEP2020	Oral temperature (°C)	37.3	39	38.8	38.8	37.3	38	37.4	09SEP2020	5

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1135 11351036	1	05AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	07AUG2020	2
	C4591001 1135 11351088	2	28AUG2020	Fatigue	Mild	Sev	N	N	N	N	N	29AUG2020	2
	C4591001 1135 11351114	2	01SEP2020	Fatigue	Mod	Sev		N	Mild	N	N	05SEP2020	5
				Chills	N	Sev		N	N	N	N	02SEP2020	1
				New or worsened muscle pain	N	Sev		N	N	N	N	02SEP2020	1
	C4591001 1139 11391015	2	21AUG2020	Fatigue	N	Sev	N	N	N	N	N	22AUG2020	1
	C4591001 1139 11391062	2	26AUG2020	Fatigue	N	Sev	N	N	N	Mild	N	31AUG2020	5
	C4591001 1139 11391070	1	07AUG2020	Fatigue	N	Sev	N	N	N	N	N	08AUG2020	1
	C4591001 1139 11391160	2	29DEC2020	Oral temperature (°C)	36.3	38.9	36.2			36.8		30DEC2020	1
	C4591001 1140 11401022	1	03AUG2020	Fatigue	N	Sev	Mod	N	N	N	N	05AUG2020	2
				New or worsened muscle pain	Mild	Sev	Mod	N	N	N	N	05AUG2020	3
		2	25AUG2020	Oral temperature (°C)	37.8	39.8	37.3	37.1	37.2	37.2	37.1	26AUG2020	1
				Fatigue	N	Sev	Mod	N	N	N	N	27AUG2020	2
				Chills	N	Sev	N	N	N	N	N	26AUG2020	1
				New or worsened muscle pain	Mild	Sev	N	Mild	N	N	N	28AUG2020	4

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1140 11401031	2	24AUG2020	Oral temperature (°C)	37.1	39	36.6	36.6	36.1	36.4	36.1	25AUG2020	1
				Headache	N	Sev	N	N	N	N	N	25AUG2020	1
	C4591001 1140 11401037	2	27AUG2020	Oral temperature (°C)	36.6	39.4	36.6	36.2		35.9	35.9	28AUG2020	1
				Fatigue	Mild	Sev	Mod	N		N	N	29AUG2020	3
	C4591001 1140 11401045	2	24AUG2020	Headache	Sev	Mild	N	N	N	N	Mild	30AUG2020	7
	C4591001 1140 11401049	1	05AUG2020	Headache	N	N	N	N	N	N	Sev	12AUG2020	2
	C4591001 1140 11401065	1	06AUG2020	New or worsened muscle pain	N	Sev	N	N	N		N	07AUG2020	1
		2	28AUG2020	New or worsened muscle pain	N	Sev	Mild	N	N	N		30AUG2020	2
				New or worsened joint pain	N	Sev	N	N	N	N		29AUG2020	1
	C4591001 1140 11401316	2	14DEC2020	Headache	Mild	Sev	N	N	N	N	N	15DEC2020	2
				Chills	N	Sev	N	N	N	N	N	15DEC2020	1
	C4591001 1140 11401320	2	23DEC2020	Fatigue	Mild	Sev	N	N	N	N	N	24DEC2020	2
	C4591001 1140 11401321	1	04DEC2020	Fatigue	Mod	Sev	Mod	N	N	N	N	06DEC2020	3
	C4591001 1140 11401322	2	23DEC2020	Fatigue	Mod	Sev	Mod	Mild	N			26DEC2020	4
				Headache	Mod	Sev	Mild	N	N			25DEC2020	3
	C4591001 1141 11411026	2	24AUG2020	Fatigue		Sev	N	N	N	N	N	25AUG2020	1

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>	
					1	2	3	4	5	6	7			
				Chills		Sev	N	N	N	N	N	25AUG2020	1	
				New or worsened muscle pain		Sev	N	N	N	N	N	25AUG2020	1	
				New or worsened joint pain		Sev	N	N	N	N	N	25AUG2020	1	
	C4591001 1141 11411057	2	01SEP2020	Fatigue		Sev	Mild	N		N	N	03SEP2020	2	
	C4591001 1141 11411081	1	14AUG2020	Fatigue	N	Sev	N	N	N	N	N	15AUG2020	1	
	C4591001 1142 11421014	2	19AUG2020	Fatigue	N	Sev		N	N	N	Mild	26AUG2020	7	
	C4591001 1142 11421015	2	18AUG2020	Oral temperature (°C)				39.1		36.9	36.7	36.9	20AUG2020	1
				Headache				Sev		Mild	Mild	Mild		
				Chills				Sev		Mild	N	N	22AUG2020	3
	C4591001 1142 11421050	2	28AUG2020	Headache	N	Sev	Mild		N				30AUG2020	2
				Chills	N	Sev	N		N				29AUG2020	1
				New or worsened muscle pain	N	Sev	N		N				29AUG2020	1
	C4591001 1142 11421081	2	02SEP2020	Fatigue	N		Sev	N		N	N		04SEP2020	1
	C4591001 1142 11421336	2	23DEC2020	Headache		N	N	N	N	Sev	N		28DEC2020	1
	C4591001 1145 11451010	2	02SEP2020	Fatigue	N	Sev	Mild	N	N	N			04SEP2020	2
	C4591001 1146 11461043	2	09SEP2020	Fatigue	Sev	Mild	N	N	N	N			10SEP2020	2

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1147 11471013	2	25AUG2020	Headache	N	N		Sev	Mod	Mild	N	30AUG2020	3
				Chills	N	N		Sev	Mod	N	N	29AUG2020	2
	C4591001 1147 11471019	2	24AUG2020	Fatigue	N	Sev	N	N	N	N	N	25AUG2020	1
				Headache	N	Sev	N	N	N	N	N	25AUG2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	25AUG2020	1
				New or worsened joint pain	N	Sev	N	N	N	N	N	25AUG2020	1
	C4591001 1147 11471255	2	05DEC2020	Oral temperature (°C)	37.1	39.5	37.1	37.1	37.2	37.1	37	06DEC2020	1
				Chills	N	Sev	N	N	N	N	N	06DEC2020	1
	C4591001 1149 11491016	1	07AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	09AUG2020	2
	C4591001 1149 11491049	2	01SEP2020	Oral temperature (°C)	36.6	39.4	37.9	37.3	37.1	37	37.2	02SEP2020	1
				Headache	N	Sev	N	N	N	N	N	02SEP2020	1
	C4591001 1149 11491063	2	02SEP2020	Oral temperature (°C)	37.3	39.3	37.7	37.7	37.7	37	36.8	03SEP2020	1
	C4591001 1152 11521029	2	02SEP2020	Headache	N	Sev	Mod	Mild	N	N	N	05SEP2020	3
	C4591001 1152 11521072	2	01SEP2020	Diarrhea	N	N	Sev	Mild		N	N	04SEP2020	2
	C4591001 1152 11521076	2	03SEP2020	Fatigue	Mild	Sev	N	N	N	N	N	04SEP2020	2
				New or worsened muscle pain	N	Sev	N	N	N	N	N	04SEP2020	1

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
				New or worsened joint pain	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1152 11521600	2	15DEC2020	Oral temperature (°C)	36.8	37.3	39	36.7	36.6	36.8	36.9	17DEC2020	1
	C4591001 1152 11521630	2	28DEC2020	Headache	N	Sev	N	N	N	N	N	29DEC2020	1
	C4591001 1152 11521632	1	07DEC2020	Chills	Mod	Sev	Mild	N			N	09DEC2020	3
		2	28DEC2020	Fatigue	N	Sev	Mild	N	N		N	30DEC2020	2
				Headache	N	Sev	Mild	N	N		N	30DEC2020	2
	C4591001 1156 11561299	1	11NOV2020	Fatigue	N	Mild	Mod	N	N	Sev	N	16NOV2020	5
	C4591001 1156 11561300	1	17NOV2020	Oral temperature (°C)	36.9	38.9	35.4	36.5	37.1		36.4	18NOV2020	1
	C4591001 1157 11571006	2	04SEP2020	Fatigue		Sev	Mild	Mild	Mild	N	N	08SEP2020	4
				Chills		Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1157 11571040	2	09SEP2020	Chills	N	Sev	N	N	N	N	N	10SEP2020	1
	C4591001 1162 11621044	1	06AUG2020	Oral temperature (°C)			36.1			40	37.6	11AUG2020	1
				Fatigue			N			Sev	Sev	13AUG2020	3
				Headache			N			Sev	Sev	13AUG2020	3
				Chills			Mild			Sev	Mod	13AUG2020	6
				New or worsened muscle pain			N			Sev	N	11AUG2020	1

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1162 11621080	2	02SEP2020	Headache	N	Sev	Mod	N	N	N		04SEP2020	2
				Chills	N	Sev	Mod	N	N	N		04SEP2020	2
	C4591001 1162 11621103	1	13AUG2020	Headache	Sev	Mild	Mod	Mild	Mild	N	N	17AUG2020	5
	C4591001 1162 11621110	2	02SEP2020	Fatigue		Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1162 11621115	2	01SEP2020	Headache			N	N	Sev			05SEP2020	1
	C4591001 1163 11631036	2	25AUG2020	Fatigue		N		Sev				03SEP2020	7
				Headache		N		Sev				03SEP2020	7
				Chills		N		Sev				03SEP2020	7
				Vomiting		N		Sev				03SEP2020	7
				Diarrhea		N		Sev				03SEP2020	7
				New or worsened muscle pain		N		Sev				03SEP2020	7
				New or worsened joint pain		N		Sev				03SEP2020	7
	C4591001 1163 11631060	1	07AUG2020	Fatigue	N	N	N	N		Sev	N	12AUG2020	1
	C4591001 1163 11631087	2	01SEP2020	Fatigue				Sev	Mild	N	N	05SEP2020	2
	C4591001 1167 11671001	2	02SEP2020	Oral temperature (°C)		39.6	36.8	36.8	36.8	36.8	36.9	03SEP2020	1
				Fatigue		Sev	N	N	N	N	N	03SEP2020	1
				Chills		Sev	N	N	N	N	N	03SEP2020	1

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
				New or worsened muscle pain		Sev	N	N	N	N	N	03SEP2020	1
				New or worsened joint pain		Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1167 11671002	2	04SEP2020	New or worsened muscle pain	N	Mod	Sev	N		N	N	06SEP2020	2
	C4591001 1167 11671006	2	02SEP2020	Fatigue	N	Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1170 11701002	2	02SEP2020	Oral temperature (°C)	37.8	41.2	37.2	36.7	37.1	36.9	36.7	03SEP2020	1
	C4591001 1171 11711020	2	04SEP2020	Fatigue		Sev	Mild	N	N	N	N	06SEP2020	2
	C4591001 1171 11711027	1	14AUG2020	Chills	N	Sev	N	N	N	N	N	15AUG2020	1
	C4591001 1177 11771039	2	09SEP2020	Chills	N	Sev	N	N	N	N	N	10SEP2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	10SEP2020	1
	C4591001 1185 11851066	2	19NOV2020	Fatigue		Sev	Mild	N		N	N	21NOV2020	2
				Headache		Sev	Mild	Mild		N	N	22NOV2020	3
				Chills		Sev	Mild	N		N	N	21NOV2020	2
				New or worsened joint pain		Sev	N	N		N	N	20NOV2020	1
	C4591001 1194 11941003	2	05NOV2020	Oral temperature (°C)	39	36.7	36.7		36.6	36.7		05NOV2020	1
	C4591001 1194 11941012	2	04NOV2020	Fatigue	N	Sev	Sev	Sev	N	N	N	07NOV2020	3



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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
				Chills	N	Sev	Mild	N	N	N	N	06NOV2020	2
	C4591001 1194 11941030	2	07NOV2020	Oral temperature (°C)	36.8	39.1	39.1	37.4	36.8	37.1	36.2	09NOV2020	2
				Fatigue	Mild	Sev	Sev	Mild	N	N	N	10NOV2020	4
				Headache	N	Sev	Sev	Mild	N	N	N	10NOV2020	3
				Chills	Mod	Sev	Sev	N	N	N	N	09NOV2020	3
				New or worsened muscle pain	N	Mod	Sev	Mild	N	N	N	10NOV2020	3
	C4591001 1194 11941052	1	19OCT2020	Chills	N	Mild	Sev	N	N	Mild	N	24OCT2020	5
		2	09NOV2020	Chills	N	Sev	N	N	N	N	N	10NOV2020	1
	C4591001 1194 11941062	2	11NOV2020	Fatigue	Mod	Sev	Mild	Mild	N	N	N	14NOV2020	4
	C4591001 1194 11941069	2	11NOV2020	Fatigue	Sev	Sev	Mild	N	N	N	N	13NOV2020	3
	C4591001 1194 11941071	2	11NOV2020	Chills	Sev	N	N	N	N	N	N	11NOV2020	1
	C4591001 1194 11941087	1	21OCT2020	Fatigue	N	Mod	Mod	Mod	Mod	Sev	Sev	04NOV2020	14
				Headache	N	Sev	Mod	Mild	Mild	N	Mild	27OCT2020	6
	C4591001 1195 11951001	2	05NOV2020	Headache	N	Sev		N	N	N	N	06NOV2020	1
	C4591001 1195 11951010	2	03NOV2020	Fatigue	Mod	Sev	N	N	N	N	N	04NOV2020	2
	C4591001 1195 11951100	1	18OCT2020	Vomiting	Sev	N	N		N	N	N	18OCT2020	1

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1195 11951106	2	08NOV2020	Oral temperature (°C)	36.2	39.2	38.1	37	36.2	36.2	36.1	10NOV2020	2
				Fatigue	N	Sev	Mild	N	N	N	N	10NOV2020	2
	C4591001 1195 11951137	2	07NOV2020	Oral temperature (°C)	38.2	38.9	37.2	39.2	38.5	37.9	37.4	11NOV2020	5
				Fatigue	Mild	Mod	Mild	Sev	Mod	Mild	Mild	14NOV2020	8
				Headache	N	N	Mild	Mod	Sev	Mod	Mod	14NOV2020	6
	C4591001 1195 11951138	2	11NOV2020	Fatigue	N	Sev	N	N	N	N	N	12NOV2020	1
	C4591001 1197 11971096	2	07NOV2020	Headache	N	Mod	Sev	Mod	N	N	N	10NOV2020	3
	C4591001 1203 12031010	1	19OCT2020	Headache	N	Sev		Mod	Mod	N		23OCT2020	4
		2	09NOV2020	Fatigue	Mod	Sev	Mod	Mod		N		12NOV2020	4
	C4591001 1203 12031044	1	21OCT2020	Fatigue	Mild	Sev	Mild	Mild	Mild	Mild	Mod	30OCT2020	10
	C4591001 1203 12031045	2	11NOV2020	Fatigue	Mild	Sev	Mild	N		N	N	13NOV2020	3
				New or worsened muscle pain	N	Sev	Mild	N		N	N	13NOV2020	2
				New or worsened joint pain	N	Sev	Mild	N		N	N	13NOV2020	2
	C4591001 1203 12031064	1	26OCT2020	Headache	Mod	Sev	Mild	N	Mild	Mild	N	31OCT2020	6
		2	16NOV2020	Headache	Mod	Sev	Mod	Mod	N	N	N	19NOV2020	4
				New or worsened muscle pain	Sev	Mod	Mild	Mild	N	N	N	19NOV2020	4

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1205 12051003	2	13NOV2020	Headache	Sev	N	N	N		N		13NOV2020	1
	C4591001 1205 12051004	2	13NOV2020	Chills	N	N	N	N	N	Sev		25NOV2020	8
	C4591001 1205 12051010	2	13NOV2020	Diarrhea	N	N	Mild	Sev	Sev	N	N	17NOV2020	3
	C4591001 1205 12051017	1	27OCT2020	Diarrhea	N	N	N	Sev	N	N	Mod	02NOV2020	4
	C4591001 1205 12051021	2	17NOV2020	Fatigue		Sev	N	N		N	N	18NOV2020	1
				Chills		Sev	Mod	N		N	N	19NOV2020	2
	C4591001 1205 12051054	2	26NOV2020	Fatigue		Sev	N	N		N	N	27NOV2020	1
	C4591001 1205 12051077	2	02DEC2020	Fatigue	N	Sev	N	N	N		N	03DEC2020	1
	C4591001 1205 12051079	1	11NOV2020	Headache	Mild	Sev	N	N	Mild	N	Mod	18NOV2020	8
		2	02DEC2020	Headache	Mod	Sev	N	N	N	N	N	03DEC2020	2
				Chills	Mild	Sev	N	N	N	N	N	03DEC2020	2
				New or worsened muscle pain	N	Sev	N	N	N	N	N	03DEC2020	1
				New or worsened joint pain	N	Sev	N	N	N	N	N	03DEC2020	1
	C4591001 1207 12071002	2	13NOV2020	New or worsened muscle pain	N	Sev	N	N		N	N	14NOV2020	1
	C4591001 1207 12071007	2	16NOV2020	Chills	Mod	Sev	N	N	N	N	N	17NOV2020	2

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
				New or worsened muscle pain	Mod	Sev	N	N	N	N	N	17NOV2020	2
				New or worsened joint pain	Mod	Sev	N	N	N	N	N	17NOV2020	2
	C4591001 1207 12071008	2	16NOV2020	Fatigue	N	Sev	N		N	N	N	17NOV2020	1
	C4591001 1207 12071013	1	26OCT2020	Headache	N	Sev	N	N	N	N	N	27OCT2020	1
		2	16NOV2020	Fatigue	N	Sev	Mod	N	N	N	N	18NOV2020	2
				Chills	N	Sev	N	N	N	N	N	17NOV2020	1
	C4591001 1207 12071041	2	24NOV2020	Fatigue	Mod	Sev	Mild	N	N	Mild	N	29NOV2020	6
	C4591001 1207 12071057	2	26NOV2020	Fatigue	N	Sev	N	N	N	N	N	27NOV2020	1
	C4591001 1208 12081020	1	02NOV2020	Headache	N	Mod		N	Mod	Mod	Sev	12NOV2020	10
	C4591001 1208 12081026	2	26NOV2020	Fatigue	N	Sev	Mod	N	N	N	N	28NOV2020	2
	C4591001 1208 12081034	2	26NOV2020	Fatigue		Sev	Mild	N	N	N	N	28NOV2020	2
	C4591001 1208 12081035	2	26NOV2020	Fatigue	N	Sev	N	N	N	N	N	27NOV2020	1
	C4591001 1208 12081045	2	27NOV2020	Fatigue	Mild	Sev	Mild	Sev	N	N	N	30NOV2020	4
				New or worsened muscle pain	N	Sev	Mod	Sev	N	N	N	30NOV2020	3
	C4591001 1208 12081051	2	01DEC2020	Fatigue	Mod	Sev	Mod	N		N	N	03DEC2020	3

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1208 12081052	1	10NOV2020	Headache	N	N	N	Sev	N	Mild	Mild	16NOV2020	4
	C4591001 1210 12101005	2	12NOV2020	Fatigue		Sev	N	N	N		N	13NOV2020	1
				Chills		Sev	N	N	N		N	13NOV2020	1
	C4591001 1210 12101024	1	28OCT2020	Headache	N	Sev	Mod	N	N	Mild	N	02NOV2020	5
		2	18NOV2020	Fatigue	N	Sev	Sev	Mod	Mild	N	N	22NOV2020	4
				Headache	N	Sev	Mod	Mild	N	N	N	21NOV2020	3
				Chills	N	Sev	N	N	N	N	N	19NOV2020	1
	C4591001 1210 12101028	2	20NOV2020	Fatigue	Sev	Mild	N			N	N	21NOV2020	2
	C4591001 1210 12101029	1	30OCT2020	New or worsened joint pain	N	N	N	N		Sev	N	04NOV2020	1
	C4591001 1210 12101036	2	24NOV2020	Chills	N	Sev	N	N	N	N	N	25NOV2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	25NOV2020	1
				New or worsened joint pain	N	Sev	N	N	N	N	N	25NOV2020	1
	C4591001 1210 12101038	2	24NOV2020	Oral temperature (°C)		39.8	37.7	35.8	35.2	35.2	35.3	25NOV2020	1
				Fatigue		Sev	Mild	N	N	N	N	26NOV2020	2
				Headache		Sev	Mod	Mild	N	N	N	27NOV2020	3
				New or worsened joint pain		Sev	Mild	N	N	N	N	26NOV2020	2

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1210 12101047	2	24NOV2020	Fatigue	N	Sev	N	N	N	N	N	25NOV2020	1
				Headache	N	Sev	N	N	N	Mild	N	29NOV2020	5
	C4591001 1210 12101055	2	26NOV2020	Fatigue	Mod	Sev	N			N		27NOV2020	2
				Chills	Sev	Mild	N			N		27NOV2020	2
				New or worsened muscle pain	Mod	Sev	N			N		27NOV2020	2
	C4591001 1212 12121007	2	17NOV2020	Oral temperature (°C)	36.9	39.5	37.5	36.9	36.8	36.6	37	18NOV2020	1
				Fatigue	Mod	Sev	Mod	N	N	N	N	19NOV2020	3
				New or worsened muscle pain	N	Sev	Mod	N	N	N	N	19NOV2020	2
	C4591001 1213 12131001	2	13NOV2020	Oral temperature (°C)	39	37.8	36.7	37	36.8	36	37.2	13NOV2020	1
				Fatigue	Sev	N	N	N	N	N	N	13NOV2020	1
	C4591001 1213 12131008	1	23OCT2020	Fatigue	N	Sev	N	N	N	N	N	24OCT2020	1
		2	12NOV2020	Fatigue	Mod	Sev	N	N	N		N	13NOV2020	2
				Headache	Mod	Sev	N	N	N		N	13NOV2020	2
				New or worsened muscle pain	Mod	Sev	N	N	N		N	13NOV2020	2
	C4591001 1213 12131015	2	23NOV2020	Chills	Sev	Mild	N	Mild	N	N	N	26NOV2020	4
	C4591001 1213 12131028	2	27NOV2020	Fatigue	N	Sev	N	N	N	N	N	29NOV2020	1
				Chills	N	Sev	N	N	N	N	N	29NOV2020	1

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1213 12131037	2	26NOV2020	Fatigue	Mod	Sev	N	N	N	N	N	27NOV2020	2
	C4591001 1213 12131038	2	24NOV2020	Headache	Mild	Sev	Mod	Mild	Mild	Mild	Mild	30NOV2020	7
	C4591001 1213 12131042	2	27NOV2020	Fatigue	Mild	Sev	N	N	N	N	N	28NOV2020	2
				Headache	N	Sev	N	N	N	N	N	28NOV2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	28NOV2020	1
	C4591001 1213 12131054	2	30NOV2020	Fatigue	N	Sev	Mild	N	N	N	N	02DEC2020	2
				Chills	N	Sev	N	N	N	N	N	01DEC2020	1
	C4591001 1214 12141004	1	23OCT2020	Fatigue	Mild	Mod	Sev	Mild	Mild	N		27OCT2020	5
	C4591001 1214 12141042	1	06NOV2020	Chills	N	Sev		N	N	N		07NOV2020	1
	C4591001 1214 12141052	2	01DEC2020	Headache	N	Mod		N	N	N	Sev	07DEC2020	6
	C4591001 1214 12141053	2	02DEC2020	Headache	N	N	N	N	N	N	Sev	08DEC2020	1
	C4591001 1217 12171002	2	12NOV2020	Fatigue	Mild	Sev	Mild	N	N	N		14NOV2020	3
	C4591001 1217 12171010	1	23OCT2020	Headache	N	N	N	Sev	N	N	N	26OCT2020	1
	C4591001 1217 12171013	1	26OCT2020	Headache	N	Mod	Sev	N	N	N	N	28OCT2020	2
				New or worsened muscle pain	N	N	Sev	N	N	N	N	28OCT2020	1

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1217 12171031	1	30OCT2020	Headache	N	N	N	Sev	N	N	N	02NOV2020	1
	C4591001 1217 12171034	2	24NOV2020	Fatigue	Mod	Sev	Mod	Mild	N	N	N	27NOV2020	4
				Chills	Mild	Sev	N	N	N	N	N	25NOV2020	2
				New or worsened muscle pain	N	Sev	N	N	N	N	N	25NOV2020	1
	C4591001 1217 12171051	1	06NOV2020	Fatigue	N	N	N		Sev	N	N	10NOV2020	1
	C4591001 1217 12171053	1	06NOV2020	Fatigue	N	Sev		N	N	N	N	07NOV2020	1
		2	26NOV2020	Fatigue	N	Sev	N	N	N	N		27NOV2020	1
	C4591001 1223 12231027	1	28AUG2020	Fatigue	Mild	Sev	Mild	N	N	N	N	30AUG2020	3
	C4591001 1223 12231057	1	01SEP2020	Headache	N	Sev	Mild	N	N	N	N	03SEP2020	2
	C4591001 1223 12231074	2	23SEP2020	Fatigue		Sev	N		N	N		24SEP2020	1
	C4591001 1224 12241005	1	12AUG2020	Headache	N	Mod	Sev	N	N	N	N	14AUG2020	2
	C4591001 1224 12241168	2	10DEC2020	Chills	Mod	Sev	N	N	N	N	N	11DEC2020	2
	C4591001 1224 12241171	1	23NOV2020	Fatigue	N	Sev	N	N	N	N	N	24NOV2020	1
				Headache	N	Sev	N	N	N	N	N	24NOV2020	1
	C4591001 1224 12241173	2	21DEC2020	New or worsened muscle pain	N	Sev		N	N		N	22DEC2020	1



**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1224 12241176	1	30NOV2020	Chills	N	Sev	N	N	N	N	N	01DEC2020	1
	C4591001 1224 12241178	1	30NOV2020	Fatigue	Mild	Sev	N	N	N	N	N	01DEC2020	2
				Chills	N	Sev	N	N	N	N	N	01DEC2020	1
		2	29DEC2020	Chills	Mild	Sev	Mild	N	N	N	N	31DEC2020	3
	C4591001 1226 12261001	2	25AUG2020	New or worsened muscle pain	Mod	Sev		N	N	N		26AUG2020	2
	C4591001 1226 12261008	1	05AUG2020	Headache	N	Sev	N	N	N	N	N	06AUG2020	1
		2	24AUG2020	Headache		Sev	N	N	N	Mild	N	29AUG2020	5
	C4591001 1226 12261019	1	06AUG2020	Fatigue	N	N	N	N	Sev	N	N	10AUG2020	1
	C4591001 1226 12261025	2	25AUG2020	Fatigue		Mild	Mod	Sev	Mild	Mod	N	30AUG2020	5
				Headache		Mild	N	Mod	Mild	Sev	N	30AUG2020	5
				New or worsened muscle pain		N	N	N	N	Sev	N	30AUG2020	1
	C4591001 1226 12261055	1	10AUG2020	Fatigue	N	N	Mild	N	Sev	Mod		16AUG2020	5
	C4591001 1226 12261066	1	10AUG2020	Headache	N	Mod	Sev	N	N	N	N	12AUG2020	2
	C4591001 1226 12261072	1	11AUG2020	New or worsened muscle pain	N	N	Sev	N	N	N	N	13AUG2020	1
	C4591001 1226 12261089	1	11AUG2020	Headache	Sev	Mild	Mild	N	Mild	N	N	15AUG2020	5
	C4591001 1226 12261096	1	11AUG2020	Fatigue	N	Sev	Mod	N	N	N	N	13AUG2020	2

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
				Headache	N	Sev	Mod	N	N	N	N	13AUG2020	2
				New or worsened muscle pain	N	Sev	Mild	N	N	N	N	13AUG2020	2
				New or worsened joint pain	N	Sev	Mild	Mild	N	N	N	14AUG2020	3
		2	01SEP2020	Fatigue	N	Sev	N	N	N	N	N	02SEP2020	1
	C4591001 1226 12261104	1	11AUG2020	Headache	Mod	Sev	Mod	Mild	Mild	N	N	15AUG2020	5
	C4591001 1226 12261106	2	01SEP2020	Fatigue	N	Sev		Mild	N			04SEP2020	3
				Headache	N	Sev		Mild	N			04SEP2020	3
				New or worsened muscle pain	N	Sev		N	N			02SEP2020	1
				New or worsened joint pain	N	Sev		N	N			02SEP2020	1
	C4591001 1226 12261124	2	04SEP2020	Fatigue	N	Sev	N	N	N	N		05SEP2020	1
	C4591001 1226 12261154	1	13AUG2020	Fatigue	Sev	Sev	Mild	N	N	N		15AUG2020	3
		2	16SEP2020	Headache			Sev	Mild	Mod	N	N	20SEP2020	3
	C4591001 1226 12261156	2	03SEP2020	Fatigue	N	Mod	Mod	Sev	N	N	N	06SEP2020	3
				New or worsened joint pain	N	Mod	Mild	Sev	Mild	Mod	N	08SEP2020	5
	C4591001 1226 12261208	2	08SEP2020	Headache	Sev	Mild	N	Mild	N	N	N	11SEP2020	4
	C4591001 1226 12261215	1	17AUG2020	Headache	N	Sev		N	Mild		N	21AUG2020	4

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1226 12261232	2	09SEP2020	Fatigue	N	Sev	Mild	N	N	N	N	11SEP2020	2
	C4591001 1226 12261243	1	18AUG2020	Headache	N	N	Sev	N	N	N	N	20AUG2020	1
	C4591001 1226 12261248	2	07SEP2020	Fatigue	Mild	Sev	Mild			N	N	09SEP2020	3
	C4591001 1226 12262255†	2	06NOV2020	Fatigue		Sev		Mild	N	N	N	09NOV2020	3
	C4591001 1229 12291011	2	14OCT2020	Headache		Sev	Mod	Mod	N	N	N	17OCT2020	3
	C4591001 1229 12291016	1	25SEP2020	Headache			N	Mod	Sev	Mild	Mod	01OCT2020	4
	C4591001 1229 12291024†	1	28SEP2020	Vomiting	N	Mod	Sev	N	N	N	N	30SEP2020	2
				Diarrhea	N	Sev	Mod	Mild	N	N	N	01OCT2020	3
	C4591001 1229 12291029	1	28SEP2020	Oral temperature (°C)		39.7	33.2	35.2	35.4	35.4	35.4	29SEP2020	1
	C4591001 1229 12291042†	2	20OCT2020	Headache	Mod	Sev	N	N	N	N	N	21OCT2020	2
	C4591001 1229 12291046	2	20OCT2020	Fatigue	N	Sev	Mild		N	N	N	22OCT2020	2
	C4591001 1229 12291047	1	29SEP2020	New or worsened muscle pain	Sev	Mod		N	N	N	N	30SEP2020	2
	C4591001 1229 12291057	1	30SEP2020	Headache	N	N	N	Sev	Mild	N	N	04OCT2020	2
	C4591001 1229 12291065	1	30SEP2020	Chills	Mod	Mild	Mild	Mod	Sev	N	N	04OCT2020	5
		2	21OCT2020	Fatigue	Mild	N	Mod	N	N	Sev	N	26OCT2020	6

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
				New or worsened muscle pain	N	Mild	N	N	N	Sev	Mod	27OCT2020	6
	C4591001 1229 12291082	1	01OCT2020	Fatigue	Mild	Sev		N	N	N		02OCT2020	2
				New or worsened muscle pain	Sev	Mod		N	N	N		02OCT2020	2
	C4591001 1229 12291094	1	02OCT2020	Oral temperature (°C)	35.3	36.6	36.7	36.7	35.6	37.7	39.2	08OCT2020	1
	C4591001 1229 12291096†	2	23OCT2020	Headache						Mod	Sev	29OCT2020	2
	C4591001 1229 12291100	2	26OCT2020	Headache	Mod		Mild	Mild	Mild	Sev		31OCT2020	6
	C4591001 1229 12291105	2	26OCT2020	Fatigue	Sev	Sev	Mod	Mod	Mod	Mod	Mod	03NOV2020	9
				Headache	Mod	Sev	Mod	Mod	Mod	Mod	Mod	03NOV2020	9
				Vomiting	Sev	N	N	N	N	N	N	26OCT2020	1
				New or worsened muscle pain	N	Sev	Mod	N	N	Sev	Mod	03NOV2020	8
	C4591001 1229 12291109	1	05OCT2020	Chills	N	N	N	N	N		Sev	11OCT2020	1
		2	26OCT2020	Fatigue	N	N		N	N	Sev	N	31OCT2020	1
	C4591001 1229 12291113†	2	27OCT2020	Oral temperature (°C)	40	40	40	36.4	36.1	36.4	36.6	29OCT2020	3
	C4591001 1229 12291122	1	06OCT2020	Oral temperature (°C)	39.6	39.9	39.5	39.6	39.4	39.6	39.6	12OCT2020	7
		2	27OCT2020	Oral temperature (°C)	32.6	32.8	39.2	32.5	32.8	32.9	32.7	29OCT2020	1
				Headache	Sev	Mild	N	Mild	N	N	N	30OCT2020	4

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1230 12301001	1	23SEP2020	Headache	Sev	Sev	Mild		Mild	N	N	27SEP2020	5
	C4591001 1230 12301018	1	24SEP2020	New or worsened muscle pain	Mod	Sev	N	N	N	N	N	25SEP2020	2
				New or worsened joint pain	N	Sev	N	N	N	N	N	25SEP2020	1
	C4591001 1230 12301058	2	19OCT2020	Headache	N	Sev	N	N	N	N	N	20OCT2020	1
	C4591001 1230 12301074	1	30SEP2020	Headache	N	N	N	N	Sev	Mod	N	05OCT2020	2
	C4591001 1230 12301084	2	21OCT2020	Oral temperature (°C)	35.3	39.4	37.2	35.9	36.3	35.6	36.4	22OCT2020	1
				Fatigue	N	Sev	Sev	N	N	N	N	23OCT2020	2
	C4591001 1230 12301094	1	01OCT2020	Headache	N	Sev	Sev	N	N	N	N	03OCT2020	2
	C4591001 1230 12301102	2	23OCT2020	Headache	N	Mod	N	Mod	N	Sev	N	28OCT2020	5
	C4591001 1230 12301117	1	03OCT2020	Headache	N	Sev	N	N	N	N	N	04OCT2020	1
	C4591001 1230 12301124	2	27OCT2020	Headache	N	N	N	Sev	N	N	N	30OCT2020	1
	C4591001 1230 12301129	1	05OCT2020	Headache	Mild	Mild	Mild	Sev	Mild	Mild	Mild	12OCT2020	8
	C4591001 1231 12311002	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1231 12311012	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	28AUG2020	1

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1231 12311018	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1231 12311034	2	02SEP2020	Oral temperature (°C)	36.5	39.9	36.8	36.4	37	36.8	36.3	03SEP2020	1
	C4591001 1231 12311055	2	01SEP2020	Oral temperature (°C)	36.7	39	37.2	36.7		36.5	36.6	02SEP2020	1
				Fatigue	N	Sev	N	N		Mod	N	06SEP2020	5
				Chills	N	Sev	N	N		N	N	02SEP2020	1
	C4591001 1231 12311082	1	12AUG2020	Fatigue	N	Sev	Mild	Mild	Mild	Mild	Mild	19AUG2020	7
				Chills	N	Sev	N	N	N	N	N	13AUG2020	1
		2	01SEP2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	02SEP2020	1
	C4591001 1231 12311092	2	02SEP2020	Headache	N	Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1231 12311099	2	01SEP2020	Fatigue	Mod	Mod	Sev	Mod	Mod	Mod	Mod	12SEP2020	12
	C4591001 1231 12311124	1	13AUG2020	Headache	Mild	Sev	N	N	N	N	N	14AUG2020	2
		2	01SEP2020	Fatigue	Mild	Sev	Mod	Mild	N	N	N	04SEP2020	4
	C4591001 1231 12311125	1	13AUG2020	Headache	Mod	Sev	N	N	N	N	N	14AUG2020	2
				Chills	N	Sev	Mild	Mild	N	N	N	16AUG2020	3
	C4591001 1231 12311144	2	02SEP2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1231 12311164	2	02SEP2020	Fatigue	N	Sev	Mild	Mild	N	Mild	Mild	09SEP2020	7

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>	
					1	2	3	4	5	6	7			
				Chills	N	Sev	N	N	N	N	N	N	03SEP2020	1
	C4591001 1231 12311169	2	03SEP2020	Headache	N	Sev	N	N	N		N		04SEP2020	1
	C4591001 1231 12311172	2	04SEP2020	Fatigue	N	Sev	N	N	N	N	N		05SEP2020	1
	C4591001 1231 12311179	1	14AUG2020	Headache	N	Sev	Mild	Mild	Mild	Mild	Mild		21AUG2020	7
	C4591001 1231 12311185	1	14AUG2020	Fatigue	N	Mod	Sev	Mod	Mod	Mod	Mod		21AUG2020	7
				Chills	N	Sev	Mod	Mod	Mod	Mod	Mod		21AUG2020	7
		2	02SEP2020	Headache	Mod	Sev	N	N	N	N	N		03SEP2020	2
	C4591001 1231 12311190	2	03SEP2020	Oral temperature (°C)	36.8	39	37	36.5	36.7	36.7	36.5		04SEP2020	1
	C4591001 1231 12311193	2	04SEP2020	Chills	N	Sev	N	N	N	N	N		05SEP2020	1
	C4591001 1231 12311208	2	04SEP2020	Headache	Mild	Sev	Mild	Mild	Mild	N	N		08SEP2020	5
	C4591001 1231 12311211	2	21SEP2020	New or worsened muscle pain	Mod	Sev	N	Sev	Mod	N	N		25SEP2020	5
				New or worsened joint pain	Mod	Sev	Mod	Mod	Mod	N	N		25SEP2020	5
	C4591001 1231 12311221	2	04SEP2020	Headache	N	Sev	Mild	N	N	Mild	N		09SEP2020	5
	C4591001 1231 12311243	2	04SEP2020	New or worsened muscle pain	N	Sev	N	N	N	N	N		05SEP2020	1
	C4591001 1231 12311246	2	02SEP2020	Oral temperature (°C)	37	39	37.4	36.6	36.7	36.6	37.1		03SEP2020	1
				Fatigue	N	Sev	N	N	N	N	N		03SEP2020	1

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1231 12311252	2	04SEP2020	Headache	N	Sev	Mild	Mild	N	N	N	07SEP2020	3
	C4591001 1231 12311266	2	02SEP2020	Oral temperature (°C)	37.4	39.1	37.9	36.2	36.4	36.3	36.2	03SEP2020	1
	C4591001 1231 12311272	2	02SEP2020	Headache	N	Sev	Mod	N	Mild	Mod	N	07SEP2020	5
	C4591001 1231 12311281	2	04SEP2020	New or worsened muscle pain	Mild	Sev	N	N	N	N	N	05SEP2020	2
	C4591001 1231 12311289	1	15AUG2020	Headache	N	Sev	N	N	N	N	N	16AUG2020	1
	C4591001 1231 12311290	1	15AUG2020	Headache	N	Sev	N	N	N	N	N	16AUG2020	1
		2	03SEP2020	Fatigue	N	Sev	N	N	N	N	N	04SEP2020	1
				Headache	N	Sev	N	Mod	Mod	N	N	07SEP2020	4
				Chills	N	Sev	N	N	N	N	N	04SEP2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1231 12311294	1	15AUG2020	New or worsened joint pain	N	N	N	N	Sev	Mild	N	20AUG2020	2
		2	07SEP2020	Fatigue	N	N	N	N	N		Sev	14SEP2020	2
				New or worsened muscle pain	N	N	Sev	N	N		N	09SEP2020	1
	C4591001 1231 12311303	2	04SEP2020	Headache	N	Sev	N	N	N	N	N	05SEP2020	1
				Chills	Mod	Sev	N	N	N	N	N	05SEP2020	2
	C4591001 1231 12311304	2	04SEP2020	Fatigue		Sev	Mild	Mild	Mild	Mild	N	09SEP2020	5



**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
				Chills		Sev	N	N	N	N	N	05SEP2020	1
				New or worsened muscle pain		Sev	Mild	Mild	Mild	Mild	N	09SEP2020	5
	C4591001 1231 12311306	1	15AUG2020	Headache	N	Mod	N	Sev	N	N	N	18AUG2020	3
	C4591001 1231 12311312	2	03SEP2020	Headache	Mild	Sev	N	N	N	N	N	04SEP2020	2
				Chills	Mod	Sev	N	N	N	N	N	04SEP2020	2
	C4591001 1231 12311317	2	07SEP2020	Headache	Sev	N	N	N	N	N	N	07SEP2020	1
	C4591001 1231 12311327	2	03SEP2020	Fatigue	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1231 12311331	2	03SEP2020	Headache	Mod	Sev	Mild	N	N	N	N	05SEP2020	3
	C4591001 1231 12311361	2	04SEP2020	Oral temperature (°C)	36.4	39	36.2	36.2	36.1	36.2	36.1	05SEP2020	1
				Fatigue	Mild	Sev	Mild	Mild	N	N	N	07SEP2020	4
				Chills	Mild	Sev	Mild	N	N	N	N	06SEP2020	3
				New or worsened joint pain	N	Sev	Mild	N	N	N	N	06SEP2020	2
	C4591001 1231 12311365	2	04SEP2020	Headache	Mild	Sev	N	N	N	N	N	05SEP2020	2
				Chills	N	Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1231 12311368	2	04SEP2020	Oral temperature (°C)	36	39.1	39.2	35.8	35.9	36.6	35.9	06SEP2020	2
	C4591001 1231 12311370	2	03SEP2020	Headache	Mod	Sev	Mild	Mild	N	N	N	06SEP2020	4

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
				New or worsened muscle pain	Mild	Sev	Mod	Mild	Mild	Mild	N	08SEP2020	6
	C4591001 1231 12311375	2	03SEP2020	New or worsened muscle pain	N	Mild	N	Sev	Mild	N	N	07SEP2020	4
	C4591001 1231 12311386	1	15AUG2020	Headache	N	Sev	N	N	N	N	N	16AUG2020	1
	C4591001 1231 12311410	1	15AUG2020	Fatigue	Mod	Mild	N	N	Mild	Sev		22AUG2020	8
				Chills	N	N	Mild	N	N	Sev		22AUG2020	6
				New or worsened muscle pain	N	N	N	N	N	Sev		22AUG2020	3
		2	06SEP2020	Fatigue	N	N	N	Sev	Mod	N	Mod	12SEP2020	4
				Headache	N	Mod	Sev	N	Mod	N	Mod	12SEP2020	6
	C4591001 1231 12311425	2	04SEP2020	Fatigue	Mild	Sev		N		N		05SEP2020	2
				New or worsened muscle pain	N	Sev		N		N		05SEP2020	1
	C4591001 1231 12311432	1	15AUG2020	Headache	N	Sev	Mild	Mild	Mild	N	N	19AUG2020	4
	C4591001 1231 12311454	2	03SEP2020	Fatigue	Mild	Sev	N	N	N	N	N	04SEP2020	2
	C4591001 1231 12311463	1	15AUG2020	Fatigue	Mild	Mod	Mild	N	N	Sev	Mild	23AUG2020	9
	C4591001 1231 12311468	2	03SEP2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1231 12311486	2	07SEP2020	Fatigue	N	Sev	N	N	N	N	N	08SEP2020	1

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
				New or worsened muscle pain	N	Sev	Mild	Mild	Mod	Mild	Mod	14SEP2020	7
	C4591001 1231 12311507	2	07SEP2020	Fatigue	Mild	Sev	N	N	N	N	N	08SEP2020	2
	C4591001 1231 12311509	2	08SEP2020	Fatigue	N	Sev	N	N	N	N	N	09SEP2020	1
	C4591001 1232 12321010	1	13AUG2020	Headache	Mild	Sev	N	N	N	N	N	09SEP2020	2
		2	02SEP2020	Fatigue		Sev	Mild	Mild	Mild	N	Mild	08SEP2020	6
				Chills		Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1235 12351237	2	28DEC2020	New or worsened joint pain	N	Sev	N	N	N	N	N	29DEC2020	1
	C4591001 1235 12351241	2	28DEC2020	Headache	Mild	Sev	Mild	Mild	Mild	N	N	01JAN2021	5
	C4591001 1241 12411005	2	26AUG2020	Oral temperature (°C)		39	38.1	37.3	37.2			28AUG2020	2
	C4591001 1241 12411097	1	13AUG2020	Fatigue	N	N	N	N	Mild	Sev	Mod	20AUG2020	4
				Headache	N	N	N	N	Mod	Sev	Sev	20AUG2020	4
	C4591001 1241 12411158	2	08SEP2020	Chills	N	Sev	N	N	N	N	N	09SEP2020	1
	C4591001 1241 12411207	2	09SEP2020	Headache	N	Sev	Mod	N	N	N	N	11SEP2020	2
				New or worsened joint pain	N	Sev	N	N	N	N	N	10SEP2020	1
	C4591001 1241 12411262	2	14SEP2020	New or worsened joint pain	N	Mild	Mild	N	Sev	Mild		26SEP2020	12

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>	
					1	2	3	4	5	6	7			
	C4591001 1246 12461002	2	15OCT2020	Fatigue	N	Sev	N	N	N	N	N	N	16OCT2020	1
				Headache	N	Sev	N	N	N	N	N	N	16OCT2020	1
				Chills	N	Sev	N	N	N	N	N	N	16OCT2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	N	16OCT2020	1
				New or worsened joint pain	N	Sev	N	N	N	N	N	N	16OCT2020	1
	C4591001 1246 12461025	1	28SEP2020	Fatigue	N	Sev	Mild	Mod	Mild	N	Mod			
				Headache	N	Sev	Mod	Mod	Mild	N	Mod			
				Chills	N	Sev	N	N	N	N	N	29SEP2020	1	
				New or worsened muscle pain	N	Sev	N	N	N	N	N	29SEP2020	1	
				New or worsened joint pain	N	Sev	N	N	N	N	N	29SEP2020	1	
	C4591001 1246 12461038	2	20OCT2020	Diarrhea	N	Sev	Mild			N	N	22OCT2020	2	
	C4591001 1246 12461050	2	22OCT2020	Fatigue	Mod	N	Sev	N	N	Mod		02NOV2020	12	
	C4591001 1246 12461052	2	22OCT2020	Headache	N	Sev	Mod	N	N	N		24OCT2020	2	
	C4591001 1246 12461055†	1	02OCT2020	Oral temperature (°C)	39.8	36.3	36	36	36.2	37.2	37	02OCT2020	1	
	C4591001 1246 12461068	2	23OCT2020	Oral temperature (°C)	36.6	39.2	36.6	36.3	36.2	36.2	36.2	24OCT2020	1	
	C4591001 1246 12461090	1	06OCT2020	Fatigue	Mild	Mod	Sev	N	N	N	N	08OCT2020	3	

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1247 12471010	1	23SEP2020	Headache	Mild	Mild	Mod	N	Mod	Mild	Sev	29SEP2020	7
	C4591001 1247 12471016	2	14OCT2020	Fatigue	N	Sev		N	N			15OCT2020	1
	C4591001 1247 12471033	2	15OCT2020	New or worsened muscle pain	N			Sev	Sev	N	N	19OCT2020	2
	C4591001 1247 12471054	1	29SEP2020	Fatigue	Mod	Mod	Sev	Mod	Mod	Mod	N	04OCT2020	6
	C4591001 1247 12471099	2	20OCT2020	Fatigue	Mild	Sev	N	N	Mild	N	N	24OCT2020	5
	C4591001 1247 12471120	2	21OCT2020	Chills	N	Sev	N	N	N	N	N	22OCT2020	1
	C4591001 1247 12471121	1	30SEP2020	Oral temperature (°C)	39.2	39.8	39.1	39.2	39	38.8	38.9	06OCT2020	7
				Fatigue	Mod	Mod	Mod	Sev	Mod	Mod	Mod	06OCT2020	7
				Headache	Mod	Sev	Mod	Mod	Mod	Mild	Mod	06OCT2020	7
		2	21OCT2020	Oral temperature (°C)	38.9	40	39.6	39.3	38.2	38.9	38.8		
				Fatigue	Mod	Mod	Mod	Mod	Mod	Mod	Sev		
	C4591001 1247 12471145	2	22OCT2020	Headache		Mild	N		Sev	N	N	26OCT2020	4
	C4591001 1247 12471172	2	26OCT2020	Fatigue	Mild	Sev	Mild	N	Mild	N	N	30OCT2020	5
				Chills	N	Sev	N	N	N	N	N	27OCT2020	1
	C4591001 1265 12651006	2	14SEP2020	Fatigue	N	Sev	N		Mild	Mild	N	19SEP2020	5
	C4591001 1270 12701165	1	23NOV2020	Fatigue	N	Sev	N	N	N	N	N	24NOV2020	1

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
18-55	C4591001 1001 10011009^	2	27MAY2020	Fatigue	N	Sev	Mild	N	N	N	N	29MAY2020	2
	C4591001 1001 10011071^	2	22JUL2020	Fatigue	Mod	Sev	Mild	Mild	N	N	N	25JUL2020	4
	C4591001 1002 10021015^	2	02JUN2020	Chills	Sev	Mod	N	N	N	N	N	03JUN2020	2
	C4591001 1002 10021023^	1	18MAY2020	Fatigue	Mild	Sev	N	N	N	N	N	19MAY2020	2
				Chills	Mild	Sev	N	N	N	N	N	19MAY2020	2
				New or worsened joint pain	Mild	Sev	N	N	N	N	N	19MAY2020	2
	C4591001 1002 10021024^	1	18MAY2020	Fatigue	Mod	Sev	Mild	Mild	Mild	Mild	Mild	31MAY2020	14
				Headache	Mod	Sev	Mild	N	N	N	N	20MAY2020	3
				New or worsened muscle pain	Mod	Sev	N	N	N	N	N	19MAY2020	2
	C4591001 1003 10031061^	1	22JUN2020	Fatigue	Mod	Sev	N	N	N	N	N	23JUN2020	2
				Headache	N	Sev	N	N	N	N	N	23JUN2020	1
				Chills	N	Sev	N	N	N	N	N	23JUN2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	23JUN2020	1
				New or worsened joint pain	N	Sev	N	N	N	N	N	23JUN2020	1
	C4591001 1003 10031065^	2	15JUL2020	Fatigue	N	Sev	Mild	N	N	N	N	17JUL2020	2
	C4591001 1007 10071027^	2	08JUL2020	Fatigue	Mod	Sev		Mild	N	N		11JUL2020	4

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>	
					1	2	3	4	5	6	7			
65-85	C4591001 1007 10071046^	1	22JUN2020	Headache	N	Mild	N		N	N	Sev	29JUN2020	7	
	C4591001 1001 10011043^	2	08JUL2020	Fatigue	N	Sev	N		N	N		09JUL2020	1	
				Headache	N	Sev	N		N	N		09JUL2020	1	
	C4591001 1001 10011048^	1	16JUN2020	Fatigue	N	Sev	Mild	N	N	N	N		18JUN2020	2
2		08JUL2020	Oral temperature (°C)	37.1	38.9	37.6	36.7	36.7	36.5	36.7		09JUL2020	1	
>55	C4591001 1002 10021060^	1	15JUN2020	Fatigue	Mild	Sev	Mild	N	N	Mild	Mild	05AUG2020	29	
				New or worsened muscle pain	N	Sev	Sev	N	N	N	N		17JUN2020	2
	C4591001 1003 10031083^	1	01JUL2020	New or worsened muscle pain	N	Mod	Sev	N	Mod	Mod	Sev	08JUL2020	7	
	C4591001 1001 10011084	2	18AUG2020	New or worsened muscle pain	N	Sev	N	N	N	N	N		19AUG2020	1
		2	19AUG2020	Fatigue	N	Sev	N	N	N	N	N		20AUG2020	1
	C4591001 1001 10011142	2	25AUG2020	Diarrhea	N	Sev	Mild	Mod	N	Mild	Mild	03SEP2020	9	
	C4591001 1005 10051060	2	02SEP2020	Fatigue	N	Sev	N	N	N	N	N	03SEP2020	1	
	C4591001 1005 10051063	2	01SEP2020	Chills	N	N	Sev	N	N	N	N	03SEP2020	1	
	C4591001 1006 10061035	1	14AUG2020	Headache	N	Sev	N	Mild	N	N	N		17AUG2020	3
	C4591001 1007 10071114	1	03AUG2020	Fatigue	Mod	Mild	Sev	Sev	Mod	Mod	Mod		22AUG2020	20

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
				Chills	N	N	Sev	N	Mild	N	N	07AUG2020	3
	C4591001 1007 10071120	2	26AUG2020	Fatigue	Mod	Sev	Mod	Mild	N	N	N	29AUG2020	4
	C4591001 1007 10071127	1	05AUG2020	Headache	N	Mild	N	N	N	N	Sev	12AUG2020	7
	C4591001 1009 10091019	2	31AUG2020	Fatigue	N	Sev	N	N	N	N	N	01SEP2020	1
	C4591001 1011 10111014	2	03SEP2020	Fatigue	N	Sev	N	N	N			04SEP2020	1
	C4591001 1011 10111037	2	02SEP2020	Fatigue	N	Sev	Mild	N	N	N	N	04SEP2020	2
	C4591001 1013 10131184	2	03SEP2020	Fatigue	Mod	Sev	Mild	N	N	N	N	05SEP2020	3
	C4591001 1015 10151019	2	02SEP2020	New or worsened muscle pain		Mod	Sev	N	N	N		04SEP2020	2
	C4591001 1016 10161035	2	24AUG2020	Headache	N		Sev	N	Mild	Mild	N	29AUG2020	4
	C4591001 1021 10211004	2	02SEP2020	Fatigue		Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1021 10211020	1	12AUG2020	New or worsened muscle pain	N	N	N	Mod	Mod	Sev	N	17AUG2020	3
				New or worsened joint pain	N	N	N	N	N	Sev	N	17AUG2020	1
	C4591001 1022 10221006	2	04SEP2020	Chills		Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1046 10461038	2	05SEP2020	Fatigue	N	Mod	Mod	Mild	Sev	Mod	Mild	11SEP2020	6



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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1055 10551017	1	10AUG2020	Fatigue	Mild	Sev	Mild		N	N	N	12AUG2020	3
	C4591001 1057 10571330†	2	09NOV2020	Fatigue		Sev		Sev	N	N		12NOV2020	3
	C4591001 1073 10731052	2	31AUG2020	Vomiting	N	N	N	N	N	N	Sev	06SEP2020	1
	C4591001 1073 10731072	2	03SEP2020	Chills	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1073 10731078	1	12AUG2020	Diarrhea	N	Sev	Mild	N	N	N	N	14AUG2020	2
		2	03SEP2020	Fatigue	Mod	Sev	Mod	N	N	N	N	05SEP2020	3
	C4591001 1079 10791065	2	26AUG2020	Fatigue		Sev	N	N		N	N	27AUG2020	1
				New or worsened muscle pain		Sev	N	N		N	N	27AUG2020	1
	C4591001 1079 10791084	2	26AUG2020	Fatigue		Sev					N	27AUG2020	1
				Chills		Sev					N	27AUG2020	1
	C4591001 1079 10791111	2	04SEP2020	Headache		N	Sev	Mod	Mod	Mod	Mod	10SEP2020	5
	C4591001 1080 10801006	1	10AUG2020	New or worsened muscle pain	N	N	N	N	Sev	Mod	Mod	31AUG2020	18
	C4591001 1080 10801008	2	31AUG2020	Headache	Mild	Sev	Mod	Mild	N	N	N	03SEP2020	3
	C4591001 1084 10841022	2	24AUG2020	Chills	N	Sev	N	N	N	N	N	25AUG2020	1
	C4591001 1084 10841080	2	28AUG2020	Fatigue	N	Sev	N	N	N	N	N	29AUG2020	1

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
				New or worsened muscle pain	N	Sev	N	N	N	N	N	29AUG2020	1
	C4591001 1084 10841167	2	04SEP2020	Fatigue	N	Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1084 10841183	2	04SEP2020	New or worsened muscle pain	N	Sev	Mod	Mod	N	N	N	07SEP2020	3
	C4591001 1085 10851074	2	27AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	29AUG2020	2
	C4591001 1087 10871001	2	25AUG2020	New or worsened joint pain	N	Mod	N	Sev	N	N	N	28AUG2020	3
	C4591001 1087 10871024	1	07AUG2020	New or worsened joint pain	N	N	N	N	N	N	Sev	13AUG2020	1
	C4591001 1087 10871039	2	31AUG2020	Fatigue	N	Sev	Mod	N	N	N	N	02SEP2020	2
	C4591001 1087 10871044	2	31AUG2020	Oral temperature (°C)	36.4	39.4	37.4	36.8		36.7	37.1	01SEP2020	1
	C4591001 1088 10881032	1	14AUG2020	New or worsened muscle pain	N	N	N	N	Sev	N	N	18AUG2020	1
	C4591001 1089 10891046	2	27AUG2020	Fatigue	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1090 10901117	2	31AUG2020	Fatigue	Mod	Sev	Mild	Mild	Mild	Mild	N	05SEP2020	6
	C4591001 1090 10901124	2	31AUG2020	Chills	N	Sev	N	N	N	N	N	01SEP2020	1
	C4591001 1090 10901127	2	31AUG2020	Fatigue	Mod	Sev	Mod	Mild	Mild	Mild	Mild		
	C4591001 1090 10901171	1	13AUG2020	Diarrhea		Mild	Sev	Sev	Sev		N	17AUG2020	4

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1091 10911059	2	27AUG2020	New or worsened muscle pain	N	N	N	Sev	N	N		30AUG2020	1
	C4591001 1096 10961002	2	04SEP2020	Diarrhea		N	N	Sev	Mild		N	08SEP2020	2
	C4591001 1107 11071043	1	05AUG2020	Fatigue	N	N	N	N	N	Sev	Mild	11AUG2020	2
				New or worsened joint pain	N	N	N	N	N	Sev	N	10AUG2020	1
	C4591001 1107 11071044	2	26AUG2020	Oral temperature (°C)	37.3	39.9	37.3	37.2	37.2	37.2	37.1	27AUG2020	1
				Fatigue	N	Sev	Mild	Mod	Mod	N	N	30AUG2020	4
				Chills	N	Sev	N	N	Mild	N	N	30AUG2020	4
	C4591001 1107 11071048	2	26AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	28AUG2020	2
	C4591001 1107 11071050	2	26AUG2020	Headache	N	Sev	Mod	Mild	N	N	N	29AUG2020	3
	C4591001 1109 11091008	2	18AUG2020	Chills	N	Sev	Mild	N	N	N	N	20AUG2020	2
	C4591001 1109 11091038	2	18AUG2020	Headache	N	Sev	Sev	Mod	Mild	N	N	22AUG2020	4
	C4591001 1109 11091093	2	24AUG2020	Fatigue	N	Sev	Mild		N	N		26AUG2020	2
				Chills	N	Sev	N		N	N		25AUG2020	1
	C4591001 1109 11091166	2	24AUG2020	Diarrhea	Mild		N	Sev	N	N	N	27AUG2020	4
	C4591001 1109 11091198	2	31AUG2020	Oral temperature (°C)	38.9	37.3	37.2	37.2	37.1	37.4	37.2	31AUG2020	1

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1110 11101056	2	28AUG2020	Fatigue	N	Sev	N	N	N		N	29AUG2020	1
	C4591001 1111 11111041	2	27AUG2020	New or worsened joint pain	N	N	N	N	Sev	N	N	31AUG2020	1
	C4591001 1111 11111073	2	31AUG2020	Fatigue	N	Sev	N	N	N	N	N	01SEP2020	1
	C4591001 1111 11111110	2	04SEP2020	Headache	N	Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1112 11121129	2	08SEP2020	Fatigue	N	Sev	Mod	Mild	Mild	Mild	Mild	15SEP2020	7
	C4591001 1112 11121145	2	08SEP2020	Fatigue	N	Sev	Mod	Mild	N	N	N	11SEP2020	3
	C4591001 1118 11181020	2	04SEP2020	Chills New or worsened joint pain	N	Sev	N	N	N	N	N	09SEP2020	1
	C4591001 1120 11201018	1	31JUL2020	New or worsened joint pain	N	Sev	Mod		N		N	06SEP2020	2
	C4591001 1120 11201018	1	31JUL2020	Fatigue	N	N	N	N	Sev	N	N	04AUG2020	1
	C4591001 1120 11201020	2	26AUG2020	Fatigue	N	Sev	N	N	N	N	N	27AUG2020	1
	C4591001 1120 11201059	2	26AUG2020	Fatigue	N	Sev	N	N	N	N	N	27AUG2020	1
	C4591001 1120 11201059	2	26AUG2020	New or worsened muscle pain	N	N	N	N	Sev	N	N	30AUG2020	1
	C4591001 1120 11201073	1	05AUG2020	Oral temperature (°C)	37.4	38	38.5	37.9	37.9	39.1	38.1	13AUG2020	8
	C4591001 1120 11201127	1	11AUG2020	Diarrhea	N	Mod	Sev						
	C4591001 1120 11201160	2	02SEP2020	New or worsened muscle pain		Sev	N	N	N	N	N	03SEP2020	1

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Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1120 11201214	2	08SEP2020	Headache	Mod	Mild	Mod	Mod	Sev	N	N	12SEP2020	5
	C4591001 1120 11201276	2	01OCT2020	New or worsened muscle pain		Sev	N	N	N	N		02OCT2020	1
	C4591001 1120 11201378	2	11NOV2020	Fatigue	N	Sev	N	N	N	N	N	12NOV2020	1
	C4591001 1120 11201408	1	28OCT2020	Headache	N	Sev	N	N	N	N	N	12NOV2020	1
		1	28OCT2020	Fatigue	Sev	Mild	Mild	Mild			Mod	13NOV2020	17
		2	02DEC2020	New or worsened muscle pain					Sev	Mild	Mild		
		2	02DEC2020	New or worsened joint pain					Sev	Mild	Mild		
	C4591001 1123 11231012	2	19AUG2020	New or worsened muscle pain		Sev	N	N	N	N	N	20AUG2020	1
	C4591001 1124 11241031	2	03SEP2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1124 11241033	2	01SEP2020	Fatigue		Sev	Mod	N	N	Mild	Mild	10SEP2020	9
				Chills		Sev	N	N	N	N	N	02SEP2020	1
				New or worsened muscle pain		Sev	N	N	N	N	N	02SEP2020	1
				New or worsened joint pain		Sev	N	N	N	N	N	02SEP2020	1
	C4591001 1125 11251001	2	01SEP2020	Diarrhea	N	N	N	Mod	Sev	N	N	05SEP2020	2
	C4591001 1129 11291038	2	24AUG2020	Oral temperature (°C)	36.7	38.9	36.9	36.4	36.4	36.3	36.4	25AUG2020	1

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1129 11291099	2	31AUG2020	Fatigue	N	Mod	Sev	N	N	N	N	02SEP2020	2
	C4591001 1134 11341016	2	31AUG2020	Fatigue	Mild	Sev	Mild	Mild	Mild	Mod	Mild	08SEP2020	9
	C4591001 1135 11351028	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1135 11351046	2	27AUG2020	Fatigue	Mild	Sev	N	Mild	N	N	N	30AUG2020	4
	C4591001 1135 11351074	2	28AUG2020	Fatigue		Sev	N	N	N		N	29AUG2020	1
				Headache		Sev	N	N	N		N	29AUG2020	1
				New or worsened muscle pain		Sev	N	N	N		N	29AUG2020	1
	C4591001 1135 11351079	2	27AUG2020	Fatigue	N	Sev	N	N	N	N	N	28AUG2020	1
				Chills	N	Sev	N	N	N	N	N	28AUG2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	28AUG2020	1
				New or worsened joint pain	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1135 11351087	1	08AUG2020	Headache	Sev	N	N	N	N	N		08AUG2020	1
	C4591001 1135 11351116	2	01SEP2020	Chills	N	Sev	N	N	N	N		02SEP2020	1
	C4591001 1139 11391057	1	06AUG2020	Fatigue	Mild	Sev	Mild	N	N	N	N	08AUG2020	3
	C4591001 1139 11391088	2	02SEP2020	Fatigue	Mild	Sev	N	N	N		N	03SEP2020	2

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1141 11411028	2	26AUG2020	New or worsened muscle pain	N	Mod	Sev	Mod	Mod	N	N	30AUG2020	4
	C4591001 1142 11421012	2	18AUG2020	Fatigue	N	Sev	N	N	N	N	N	19AUG2020	1
				Headache	N	Sev	Mod	N	N	N	N	20AUG2020	2
	C4591001 1145 11451009	2	02SEP2020	Fatigue	Mod	Sev	Mild	N	N	N	N	04SEP2020	3
				New or worsened muscle pain	Mild	Sev	N	N	N	N	N	03SEP2020	2
	C4591001 1147 11471009	2	24AUG2020	Fatigue	N	Mild		Mod	Sev	Mod	Mild		
	C4591001 1147 11471020	2	25AUG2020	Fatigue	N	Sev	N	N	N	N	N	26AUG2020	1
	C4591001 1147 11471082	2	01SEP2020	Diarrhea		Mild	Mod	Mild	Mod	Sev	Mod	27SEP2020	26
	C4591001 1147 11471084	2	31AUG2020	Fatigue	N	Sev	N	N	N	N	Mod	07SEP2020	7
	C4591001 1147 11471116	2	01SEP2020	Oral temperature (°C)	36.9	38.9	37.7	37.1	37.6	37.2	37	02SEP2020	1
				Chills	N	Sev	Mild	N	N	N	N	03SEP2020	2
	C4591001 1147 11471124	2	04SEP2020	Fatigue	N	Mod	Mod	Mod	Sev	Mod	N	09SEP2020	5
	C4591001 1163 11631131	2	08SEP2020	New or worsened joint pain		Mild	Sev	N	N	N	N	10SEP2020	2
	C4591001 1185 11851034	2	16NOV2020	Headache	N	Mod	Sev	N	N	N	N	18NOV2020	2
	C4591001 1185 11851035	2	17NOV2020	Fatigue	N	Sev	Mild	N	N	N	N	19NOV2020	2

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1185 11851046	1	29OCT2020	Diarrhea	N	N	Sev	Mild	N	N	N	01NOV2020	2
	C4591001 1185 11851047	2	19NOV2020	Fatigue	Mild	Sev	Mild	N	Mild	N	Mild	26NOV2020	8
	C4591001 1185 11851058	2	18NOV2020	Fatigue	N	Sev	N	N		N	N	19NOV2020	1
	C4591001 1194 11941015	2	06NOV2020	Fatigue	Mild	Sev	Mild	Mild	Mild	N	N	10NOV2020	5
	C4591001 1194 11941021	2	04NOV2020	Chills	N	Sev	N	N	N	N	N	07NOV2020	1
Oral temperature (°C)				37	39.4	37.8	36.4	36.6	36.6	36.4	05NOV2020	1	
Fatigue				N	Sev	Mod	Mod	Mild	N	N	08NOV2020	4	
	C4591001 1194 11941036	2	06NOV2020	Fatigue	N	Sev	N	N	N	N	N	07NOV2020	1
	C4591001 1194 11941055	2	09NOV2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	10NOV2020	1
	C4591001 1194 11941073†	2	11NOV2020	Fatigue	N	N	N	N	N	N	Sev	18NOV2020	2
Chills				N	N	N	N	N	N	Sev	18NOV2020	2	
Diarrhea				N	N	Mild	N	N	Mild	Sev	18NOV2020	6	
	C4591001 1195 11951033	2	04NOV2020	Vomiting	N	Sev	N	N	N	N	N	05NOV2020	1
	C4591001 1195 11951057	2	05NOV2020	Fatigue	N	Sev	N	N	N	N	N	06NOV2020	1
	C4591001 1195 11951096	2	08NOV2020	Fatigue	N	Sev	N	N	N	N	N	09NOV2020	1
	C4591001 1197 11971006	1	15OCT2020	New or worsened joint pain	N	N	Sev	N	N	N	N	17OCT2020	1



**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
		2	04NOV2020	Headache	N	Sev	N	N	N	N	N	05NOV2020	1
				Chills	N	Sev	N	N	N	N	N	05NOV2020	1
	C4591001 1197 11971027	2	06NOV2020	Chills	Sev	N	N	N	N	N	N	06NOV2020	1
	C4591001 1197 11971055	2	05NOV2020	Headache	Sev	Mild	N	N	N	N	N	06NOV2020	2
	C4591001 1197 11971095	2	07NOV2020	Fatigue	N	Sev	GRADE 4	Mod	N	N	N	10NOV2020	3
				Headache	N	Mod	Sev	Mod	N	N	N	10NOV2020	3
				New or worsened muscle pain	N	Mod	Sev	N	N	N	N	09NOV2020	2
				New or worsened joint pain	N	Mod	Sev	N	N	N	N	09NOV2020	2
	C4591001 1203 12031025	2	10NOV2020	Fatigue	N	Sev	N		N	N	N	11NOV2020	1
	C4591001 1205 12051018	2	16NOV2020	Fatigue		Mod	Sev	N		N	N	18NOV2020	2
	C4591001 1205 12051057	2	27NOV2020	Fatigue	N	Sev	Mild	N	Mild	N		01DEC2020	4
	C4591001 1207 12071001	2	13NOV2020	Fatigue	N	Sev	N	N	N	N	N	14NOV2020	1
	C4591001 1207 12071068	2	27NOV2020	Chills	N	Sev	Mild	N	N	N	N	29NOV2020	2
	C4591001 1213 12131027	2	23NOV2020	Oral temperature (°C)	37.9	39.5	37.6	36.7	36.7	36.5	36.5	24NOV2020	1
	C4591001 1213 12131031	2	25NOV2020	Fatigue	Mild	Sev	N	N	N	N	N	26NOV2020	2

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1217 12171036	2	24NOV2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	25NOV2020	1
	C4591001 1224 12241003	1	12AUG2020	Diarrhea	N	N	N	Sev	N	N	N	15AUG2020	1
	C4591001 1226 12261033	2	25AUG2020	Fatigue		Sev	N	N	N	N		26AUG2020	1
	C4591001 1226 12261099	2	01SEP2020	Chills		Sev	N	N	N	N		26AUG2020	1
	C4591001 1226 12261099	2	01SEP2020	Oral temperature (°C)	36.3	39.1	36.8		36.8	36.6	36.7	02SEP2020	1
	C4591001 1226 12261099	2	01SEP2020	Fatigue	N	Sev	N		N	N	N	02SEP2020	1
	C4591001 1226 12261099	2	01SEP2020	Headache	N	Sev	Mild		N	N	N	03SEP2020	2
	C4591001 1229 12291023	1	25SEP2020	Oral temperature (°C)	33.2	36.2	33.1	39.6	35.8	36.1	32.4	28SEP2020	1
	C4591001 1229 12291067	2	21OCT2020	Fatigue						Sev	N	26OCT2020	1
	C4591001 1229 12291067	2	21OCT2020	Diarrhea						Sev	N	26OCT2020	1
	C4591001 1229 12291084	2	23OCT2020	Fatigue	Sev							26OCT2020	4
	C4591001 1229 12291084	2	23OCT2020	New or worsened muscle pain	Sev							26OCT2020	4
	C4591001 1229 12291123	1	06OCT2020	Oral temperature (°C)	38.2	39.3	37.2	36.8	37.5		36.9	07OCT2020	2
	C4591001 1230 12301096	1	01OCT2020	New or worsened muscle pain	N	N	N	N	N	Sev	N	06OCT2020	1
	C4591001 1231 12311007	2	26AUG2020	Fatigue	N	Sev	N	N	N	N	N	27AUG2020	1
	C4591001 1231 12311007	2	26AUG2020	Chills	N	Sev	N	N	N	N	N	27AUG2020	1

**16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) –  
All Subjects ≥16 Years of Age – Safety Population**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1231 12311038	1	11AUG2020	Headache	N	Sev	N	Mild	Mild	N	N	15AUG2020	4
	C4591001 1231 12311146	2	03SEP2020	Fatigue	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1231 12311150	2	01SEP2020	Chills	N	Sev	N	N	N	N	N	04SEP2020	1
Fatigue				N	Sev	Mod	N	N	N	N	03SEP2020	2	
Headache				N	Sev	Mod	Mild	N	N	N	04SEP2020	3	
	C4591001 1231 12311292	2	03SEP2020	New or worsened joint pain	N	Sev	Mod	N	N	N	N	03SEP2020	2
Fatigue				N	Mod	Mild	Mod	Mild	N	Sev	12SEP2020	9	
	C4591001 1231 12311329	2	04SEP2020	New or worsened joint pain	N	N	N	N	N	N	Sev	12SEP2020	4
Headache				N	Mod	N	Sev	Sev	Sev	Mod			
	C4591001 1231 12311390	1	15AUG2020	Headache	Mild	Sev	Mild	N	N	Mild	Mild	22AUG2020	8

Abbreviations: Dur = duration; Mod = moderate; N = none; Sev = severe.

Note: † = Human immunodeficiency virus (HIV)-positive subject, ^ = Phase 1 subjects.

a. Relative day (Rel Day) = date of event - date of last vaccination + 1.

b. Stop date is the date the event was last reported.

c. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive. If the event continued beyond Day 7, the calculation includes all days from the last electronic diary (e-diary) day until the date of resolution collected on the case report form. If the event is ongoing at the time of the subsequent vaccination, the end date/day for the event is the date/day that the next vaccine was administered, which was used for the duration calculation.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adce\_l004\_sevse\_all

### 16.2.7.3.2 Listing of Severe and Grade 4 Systemic Events – Subjects Enrolled in Multiple Sites

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
No subject meets the reporting criteria.													
<p>Abbreviation: Dur = duration.</p> <p>a. Relative day (Rel Day) = date of event - date of last vaccination + 1.</p> <p>b. Stop date is the date the event was last reported.</p> <p>c. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive. If the event continued beyond Day 7, the calculation includes all days from the last electronic diary (e-diary) day until the date of resolution collected on the case report form. If the event is ongoing at the time of the subsequent vaccination, the end date/day for the event is the date/day that the next vaccine was administered, which was used for the duration calculation.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)            (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_1004_sevse_menrol_all</p>													

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
18-55/ C4591001 1001 10011004 <sup>^</sup>	GENRL	Malaise/ malaise	1	05MAY2020	2/1	1	No	O	NA	R (05MAY2020)	N/N
18-55/ C4591001 1001 10011005 <sup>^</sup>	INJ&P	Contusion/ deltoid bruise	2	26MAY2020	1/3	1	Yes		NA	R (28MAY2020)	N/N
18-55/ C4591001 1001 10011006 <sup>^</sup>	GENRL	Injection site pain/ soreness at injection site	1	07MAY2020	2/7	1	Yes		NA	R (13MAY2020)	N/N
	SKIN	Dermatitis/ dermatitis	1	09MAY2020	4/3	1	No	O	NA	R (11MAY2020)	N/N
	SKIN	Hand dermatitis/ dermatitis right hand	1	16MAY2020	11/20	1	No	O	NA	R (04JUN2020)	N/N
		Papule/ micropapules on skin of wrist	1	16MAY2020	11/20	1	No	O	NA	R (04JUN2020)	N/N
	SKIN	Dermatitis/ bilateral arm dermatitis	2	01JUN2020	6/4	1	No	O	NA	R (04JUN2020)	N/N
18-55/ C4591001 1001 10011007 <sup>^</sup>	GASTR	Diarrhoea/ diarrhea	1	19MAY2020	14/1	1	No	O	NA	R (19MAY2020)	N/N
	RESP	Nasal congestion/ Nasal congestion	1	20MAY2020	15/1	1	No	O	NA	R (20MAY2020)	N/N
18-55/ C4591001 1001 10011008 <sup>^</sup>	IMMUN	Seasonal allergy/ Worsening Seasonal allergies	2	31MAY2020	5/6	1	No	O	NA	R (05JUN2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
18-55/ C4591001 1001 10011009 <sup>^</sup>	GASTR	Abdominal pain lower/ LLQ abdominal pain	2	06JUN2020	11/8	1	No	O	NA	R (13JUN2020)	N/N	
	CARD	Tachycardia/ mild tachycardia	1	07MAY2020	2/2	1	Yes		NA	R (08MAY2020)	N/N	
18-55/ C4591001 1001 10011011 <sup>^</sup>	EYE	Blepharitis/ Blepharitis	2	08JUN2020	13/2	2	No	O	NA	R (09JUN2020)	N/N	
	GENRL	Injection site pain/ tenderness at left arm injection site	1	11MAY2020	1/3	1	Yes		NA	R (13MAY2020)	N/N	
18-55/ C4591001 1001 10011012 <sup>^</sup>	GENRL	Pyrexia/ fever	1	17MAY2020	7/2	1	Yes		NA	R (18MAY2020)	N/N	
	NERV	Migraine/ Migraine headache	2	30DEC2020	213/3	2	No	O	NA	R (01JAN2021)	N/N	
	NERV	Presyncope/ Vaso-vagal reaction with phlebotomy*		13MAY2020	1/1	2	No	O	NA	R (13MAY2020)	N/N	
18-55/ C4591001 1001 10011013 <sup>^</sup>	CARD	Tachycardia/ tachycardia	1	14MAY2020	2/6	1	Yes		NA	R (19MAY2020)	N/N	
	GENRL	Injection site pain/ Left deltoid injection site soreness#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N	
18-55/ C4591001 1001 10011015 <sup>^</sup>	CARD	Tachycardia/ tachycardia	1	12MAY2020	2/7	1	Yes		NA	R (18MAY2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	1	12MAY2020	2/1	1	Yes		NA	R (12MAY2020)	N/N
		Injection site swelling/ injection site swelling at injection site	1	12MAY2020	2/2	1	Yes		NA	R (13MAY2020)	N/N
	METAB	Decreased appetite/ anorexia	2	01JUN2020	1/15	1	Yes		NA	R (15JUN2020)	N/N
	GASTR	Diarrhoea/ diarrhea	2	02JUN2020	2/2	1	Yes		NA	R (03JUN2020)	N/N
	GENRL	Chills/ Chills	2	02JUN2020	2/2	2	Yes		NA	R (03JUN2020)	N/N
		Fatigue/ fatigue	2	02JUN2020	2/2	1	Yes		NA	R (03JUN2020)	N/N
		Pyrexia/ Fever (101.0F)	2	02JUN2020	2/4	3	Yes		NA/TC	R (05JUN2020)	N/N
	NERV	Headache/ Headache	2	02JUN2020	2/4	2	Yes		NA/TC	R (05JUN2020)	N/N
18-55/ C4591001 1001 10011017^	PSYCH	Insomnia/ insomnia	1	13MAY2020	1/2	2	Yes		NA	R (14MAY2020)	N/N
	MUSC	Arthralgia/ Joint pain	1	14MAY2020	2/2	1	Yes		NA	R (15MAY2020)	N/N
		Myalgia/ muscle soreness	1	14MAY2020	2/2	1	Yes		NA	R (15MAY2020)	N/N
18-55/ C4591001 1001 10011019^	GASTR	Nausea/ nausea	1	14MAY2020	2/1	1	Yes		NA	R (14MAY2020)	N/N
	PSYCH	Sleep disorder/ sleep disturbance	2	04JUN2020	2/1	1	Yes		NA	R (04JUN2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
18-55/ C4591001 1001 10011021 <sup>^</sup>	GASTR	Paraesthesia oral/ Tingling sensation of mouth	1	20MAY2020	1/1	1	Yes		NA	R (20MAY2020)	N/N	
	RESP	Pharyngeal paraesthesia/ Tingling sensation of throat	1	20MAY2020	1/1	1	Yes		NA	R (20MAY2020)	N/N	
18-55/ C4591001 1001 10011024 <sup>^</sup>	MUSC	Arthralgia/ shoulder pain	1	13MAY2020	1/2	2	Yes		NA	R (14MAY2020)	N/N	
		Back pain/ back pain	1	13MAY2020	1/2	2	Yes		NA	R (14MAY2020)	N/N	
18-55/ C4591001 1001 10011026 <sup>^</sup>	CARD	Tachycardia/ tachycardia	1	18MAY2020	1/2	1	Yes		NA	R (19MAY2020)	N/N	
18-55/ C4591001 1001 10011028 <sup>^</sup>	PSYCH	Sleep disorder/ Sleep disturbance	1	20MAY2020	1/4	2	Yes		NA	R (23MAY2020)	N/N	
	MUSC	Pain in extremity/ Left plantar heel pain	1	16JUL2020	58/13	2	No	O	NA/TCN	R (28JUL2020)	N/N	
	GASTR	Nausea/ nausea	2	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N	
18-55/ C4591001 1001 10011030 <sup>^</sup>	PSYCH	Sleep disorder/ Moderate sleep disturbance	1	20MAY2020	1/9	2	Yes		NA	R (28MAY2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	1	21MAY2020	2/4	1	Yes		NA	R (24MAY2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
18-55/ C4591001 1001 10011032 <sup>^</sup>	MUSC	Myalgia/ muscle pain	1	21MAY2020	2/2	1	Yes		NA	R (22MAY2020)	N/N	
	GENRL	Injection site erythema/ Injection site redness	1	24MAY2020	5/2	1	Yes		NA	R (25MAY2020)	N/N	
18-55/ C4591001 1001 10011034 <sup>^</sup>	NERV	Presyncope/ Vaso-vagal reaction with finger prick*		15MAY2020	-5/1	2	No	O	NA	R (15MAY2020)	N/N	
	GASTR	Nausea/ nausea	1	20MAY2020	1/6	2	Yes		NA	R (25MAY2020)	N/N	
	PSYCH	Sleep disorder/ sleep disturbance	1	20MAY2020	1/3	3	Yes		NA	R (22MAY2020)	N/N	
	METAB	Decreased appetite/ loss of appetite	1	21MAY2020	2/24	2	Yes		NA	R (13JUN2020)	N/N	
	NERV	Presyncope/ vasovagal reaction	1	09JUL2020	51/1	2	No	O	NA	R (09JUL2020)	N/N	
	GENRL	Fatigue/ fatigue	2	17AUG2020	1/9	1	Yes		NA	R (25AUG2020)	N/N	
	GASTR	Nausea/ nausea	2	24AUG2020	8/1	1	No	O	NA	R (24AUG2020)	N/N	
	GASTR	Dysphagia/ Dysphagia	2	15NOV2020	91/C	1	No	O	NA/TC	N	N/N	
	GASTR	Gastric polyps/ Gastric Polyps	2	01DEC2020	107/C	1	No	O	NA/TC	RG	N/N	
		Gastritis/ Gastritis	2	01DEC2020	107/C	1	No	O	NA/TC	N	N/N	
18-55/ C4591001	GASTR	Nausea/ Nausea	1	30JUN2020	2/1	1	Yes		NA/TC	R (30JUN2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1001 10011068 <sup>^</sup>	NERV	Paraesthesia/ Left lower extremity tingling	1	02JUL2020	4/3	1	No	O	NA	R (04JUL2020)	N/N	
	NERV	Neuropathy peripheral/ Bilateral lower extremity neuropathy	2	20JUL2020	1/18	1	No	O	NA	R (06AUG2020)	N/N	
	EYE	Retinal tear/ retinal eye tear	2	29JUL2020	10/2	2	No	O	NA	R (30JUL2020)	N/N	
	NERV	Neuropathy peripheral/ neuropathy in right arm	2	30JUL2020	11/8	1	No	O	NA	R (06AUG2020)	N/N	
18-55/ C4591001 1001 10011069 <sup>^</sup>	SKIN	Rash/ Rash	1	18JUL2020	18/4	1	No	O	NA	R (21JUL2020)	N/N	
18-55/ C4591001 1001 10011071 <sup>^</sup>	NERV	Disturbance in attention/ difficulty concentrating post vaccination	1	01JUL2020	1/2	1	Yes		NA	R (02JUL2020)	N/N	
		Paraesthesia/ Tingling LE BIL	1	01JUL2020	1/1	1	Yes		NA	R (01JUL2020)	N/Y	
	NERV	Dizziness/ lightheadedness	1	09JUL2020	9/1	1	No	O	NA	R (09JUL2020)	N/N	
18-55/ C4591001 1001 10011076 <sup>^</sup>	PSYCH	Sleep disorder/ sleep disturbance post vaccination	1	01JUL2020	1/2	1	No	O	NA	R (02JUL2020)	N/N	
	GENRL	Injection site pain/ injection site tenderness	1	02JUL2020	2/3	1	Yes		NA	R (04JUL2020)	N/N	
	SKIN	Rash/ Upper Extremity Rash	1	05JUL2020	5/11	1	No	O	NA	R (15JUL2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
18-55/ C4591001 1002 10021011 <sup>^</sup>	NERV	Headache/ headache	2	22JUL2020	2/2	1	Yes		NA	R (23JUL2020)	N/N
	GASTR	Abdominal discomfort/ upset stomach	2	25JUL2020	5/3	1	No	O	NA/TC	R (27JUL2020)	N/N
		Diarrhoea/ Loose stools	2	25JUL2020	5/2	1	Yes		NA/TC	R (26JUL2020)	N/N
	RESP	Cough/ Cough	1	08MAY2020	3/3	1	Yes		NA	R (10MAY2020)	N/N
	RESP	Dyspnoea/ Shortness of Breath	2	15JUN2020	21/13	1	No	O	NA	R (27JUN2020)	N/N
		Throat irritation/ Throat Irritation	2	15JUN2020	21/13	1	No	O	NA	R (27JUN2020)	N/N
	INFEC	Hordeolum/ Stye right lower eyelid	1	13AUG2020	88/8	1	No	O	NA/TC	R (20AUG2020)	N/N
	GASTR	Nausea/ Nausea	1	18MAY2020	1/3	2	Yes		NA	R (20MAY2020)	N/N
	INFEC	Urinary tract infection/ Urinary Tract Infection	1	21MAY2020	4/11	1	No	O	NA/TC	R (31MAY2020)	N/N
	INJ&P	Wound/ Shoulder Wound	1	25JUN2020	39/13	1	No	O	NA/TC	R (07JUL2020)	N/N
GASTR	Nausea/ Nausea	2	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N	
18-55/ C4591001	GENRL	Fatigue/ Fatigue	1	16JUN2020	27/13	1	No	O	NA/TC	R (28JUN2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1002 10021036 <sup>^</sup>	RESP	Sinus congestion/ Sinus Fullness	1	16JUN2020	27/11	1	No	O	NA	R (26JUN2020)	N/N	
	INFEC	Wound infection/ Multiple wound infection	2	23AUG2020	6/9	1	No	O	NA/TC	R (31AUG2020)	N/N	
	INJ&P	Fall/ Fall	2	23AUG2020	6/1	1	No	O	NA	R (23AUG2020)	N/N	
18-55/ C4591001 1002 10021080 <sup>^</sup>	INJ&P	Muscle strain/ Muscle Strain middle back	1	04JUL2020	4/11	1	No	O	NA	R (14JUL2020)	N/N	
	NERV	Paraesthesia/ Tingling in both hands	2	21JUL2020	1/1	1	Yes		NA	R (21JUL2020)	N/N	
18-55/ C4591001 1002 10021082 <sup>^</sup>	INJ&P	Muscle strain/ Neck Strain	2	24JUL2020	4/3	1	No	O	NA/TC	R (26JUL2020)	N/N	
18-55/ C4591001 1003 10031020 <sup>^</sup>	MUSC	Muscle spasms/ worsening leg cramps left calf	2	10JUL2020	9/5	2	No	O	NA	R (14JUL2020)	N/N	
18-55/ C4591001 1003 10031030 <sup>^</sup>	INJ&P	Ligament sprain/ Right sprained ankle	2	06AUG2020	30/75	1	No	O	NA	R (19OCT2020)	N/N	
18-55/ C4591001 1003 10031038 <sup>^</sup>	INFEC	Appendicitis/ appendicitis	2	19SEP2020	74/5	3	No	O	NA/TC/TCN	R (23SEP2020)	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
18-55/ C4591001 1003 10031065 <sup>^</sup>	MUSC	Pain in extremity/ right arm pain	2	29JUL2020	15/C	2	No	O	NA	N	N/N	
	NERV	Neuritis/ neuritis	2	29JUL2020	15/C	3	No	O	NA	N	Y/N	
18-55/ C4591001 1003 10031066 <sup>^</sup>	INJ&P	Fall/ fall while exercising	1	24JUN2020	3/1	2	No	O	NA/TCN	R (24JUN2020)	N/N	
		Tendon injury/ Achilles tendon injury	1	24JUN2020	3/7	2	No	O	NA/TCN	R (30JUN2020)	N/N	
18-55/ C4591001 1007 10071014 <sup>^</sup>	MUSC	Myalgia/ LEFT SHOULDER MUSCLE PAIN	1	18JUN2020	8/16	2	No	O	NA/TC	R (03JUL2020)	N/N	
		Myalgia/ Left Scapula area muscle pain	1	18JUN2020	8/16	2	No	O	NA/TC	R (03JUL2020)	N/N	
	INFEC	Urinary tract infection/ Urinary Tract Infection	1	27JUN2020	17/11	1	No	O	NA/TC	R (07JUL2020)	N/N	
	RENAL	Nephrolithiasis/ renal calculi	1	27JUN2020	17/23	2	No	O	NA/TC/TCN	R (19JUL2020)	N/N	
18-55/ C4591001 1007 10071017 <sup>^</sup>	GENRL	Injection site pain/ left injection site arm pain	1	15JUN2020	1/3	1	Yes		NA	R (17JUN2020)	N/N	
18-55/ C4591001 1007 10071019 <sup>^</sup>	GENRL	Injection site pain/ tenderness at injection site	1	08JUN2020	1/1	1	Yes		NA	R (08JUN2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	RESP	Rhinorrhoea/ nasal drainage	2	03JUL2020	5/8	1	No	O	NA/TC	R (10JUL2020)	N/N	
18-55/ C4591001 1007 10071020 <sup>^</sup>	GENRL	Injection site erythema/ redness at injection site	1	10JUN2020	1/1	1	Yes		NA	R (10JUN2020)	N/N	
18-55/ C4591001 1007 10071021 <sup>^</sup>	GENRL	Injection site erythema/ redness at injection site	1	10JUN2020	1/1	1	Yes		NA	R (10JUN2020)	N/Y	
18-55/ C4591001 1007 10071025 <sup>^</sup>	GASTR	Oral disorder/ oral lesion	1	29JUN2020	13/12	1	No	O	NA/TC	R (10JUL2020)	N/N	
	GENRL	Injection site pain/ Injection Site Soreness#	3	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N	
18-55/ C4591001 1007 10071026 <sup>^</sup>	SKIN	Rash papular/ erythematous papular rash chest, forehead, cheek	2	12JUL2020	7/7	1	Yes		NA/TC	R (18JUL2020)	N/N	
18-55/ C4591001 1007 10071027 <sup>^</sup>	PSYCH	Sleep disorder/ Sleep disturbance	1	17JUN2020	1/4	1	Yes		NA	R (20JUN2020)	N/N	
18-55/ C4591001 1007 10071029 <sup>^</sup>	NERV	Ageusia/ partial loss of taste	1	17JUN2020	1/1	1	Yes		NA	R (17JUN2020)	N/Y	
	NERV	Taste disorder/ change in sensation of taste	2	08JUL2020	1/2	1	Yes		NA	R (09JUL2020)	N/Y	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
18-55/ C4591001 1007 10071046^	NERV	Migraine/ Migraine Exacerbation	1	28JUN2020	7/2	3	No	O	NA	R (29JUN2020)	N/N	
18-55/ C4591001 1007 10071050^	BLOOD	Lymphadenopathy/ Right axillary lymph node enlargement	2	15JUL2020	3/13	1	Yes		NA	R (27JUL2020)	N/N	
18-55/ C4591001 1007 10071063^	GENRL	Injection site pain/ soreness at injection site	1	24JUN2020	1/1	1	Yes		NA	R (24JUN2020)	N/Y	
18-55/ C4591001 1007 10071066^	NERV	Dizziness/ Dizziness	2	16JUL2020	2/1	2	Yes		NA/TCN	R (16JUL2020)	N/N	
65-85/ C4591001 1001 10011037^	EYE	Eye paraesthesia/ intermittent paraesthesia in both eyes	1	11JUN2020	1/2	1	Yes		NA/TC	R (12JUN2020)	N/Y	
	NERV	Headache/ intermittent headache	2	01JUL2020	2/46	1	No	O	NA	RG (15AUG2020)	N/N	
65-85/ C4591001 1001 10011039^	MUSC	Muscle spasms/ worsening leg cramps	1	14JUN2020	6/2	2	No	O	NA	R (15JUN2020)	N/N	
	GENRL	Fatigue/ fatigue	2	29JUN2020	1/3	1	Yes		NA	R (01JUL2020)	N/N	
	GASTR	Aphthous ulcer/ aphthous ulcer	2	04JUL2020	6/4	1	Yes		NA	R (07JUL2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Back pain/ Low back pain	2	07AUG2020	40/C	2	No	CND	NA	N	N/N	
65-85/ C4591001 1001 10011040 <sup>^</sup>	GASTR	Gastroesophageal reflux disease/ gastroesophageal reflux	2	01AUG2020	31/26	1	No	O	NA/TC	R (26AUG2020)	N/N	
	RESP	Oropharyngeal pain/ sore throat	2	01AUG2020	31/26	1	No	O	NA	R (26AUG2020)	N/N	
65-85/ C4591001 1001 10011041 <sup>^</sup>	MUSC	Arthralgia/ generalized joint pain	2	27AUG2020	57/8	1	No	O	NA/TC	R (03SEP2020)	N/N	
		Myalgia/ Muscle pain	2	27AUG2020	57/8	1	No	O	NA/TC	R (03SEP2020)	N/N	
65-85/ C4591001 1001 10011042 <sup>^</sup>	MUSC	Myalgia/ muscle pain	1	12JUN2020	2/2	1	Yes		NA	R (13JUN2020)	N/N	
	SKIN	Dermatitis contact/ contact dermatitis	1	12JUN2020	2/2	1	No	O	NA	R (13JUN2020)	N/N	
65-85/ C4591001 1001 10011043 <sup>^</sup>	NERV	Dizziness/ Lightheadedness	2	14JUL2020	7/1	1	No	O	NA	R (14JUL2020)	N/N	
65-85/ C4591001 1001 10011045 <sup>^</sup>	SKIN	Ecchymosis/ ecchymosis to left deltoid	2	16JUL2020	15/9	1	No	O	NA	R (24JUL2020)	N/N	
65-85/ C4591001	INJ&P	Skin abrasion/ excoriation palms, BIL	2	13JUL2020	5/25	1	No	O	NA	R (06AUG2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1001 10011046 <sup>^</sup>		Skin abrasion/ excoriation right elbow	2	13JUL2020	5/25	1	No	O	NA	R (06AUG2020)	N/N	
	MUSC	Pain in extremity/ right thigh pain	2	13JUL2020	5/25	1	No	O	NA	R (06AUG2020)	N/N	
	INJ&P	Contusion/ right knee bruise	2	16JUL2020	8/22	1	No	O	NA/TCN	R (06AUG2020)	N/N	
		Fall/ fall	2	16JUL2020	8/1	1	No	O	NA	R (16JUL2020)	N/N	
		Road traffic accident/ bike accident	2	16JUL2020	8/1	1	No	O	NA	R (16JUL2020)	N/N	
	GENRL	Oedema peripheral/ right thigh edema	2	22JUL2020	14/16	1	No	O	NA	R (06AUG2020)	N/N	
65-85/ C4591001 1001 10011048 <sup>^</sup>	GENRL	Injection site bruising/ injection site bruising	1	16JUN2020	1/15	1	Yes		NA	R (30JUN2020)	N/N	
	SKIN	Dermatitis contact/ contact dermatitis	1	16JUN2020	1/4	1	No	O	NA	R (19JUN2020)	N/N	
	GENRL	Fatigue/ fatigue	2	08JUL2020	1/C	1	Yes		NA	RG	N/N	
	GASTR	Abdominal discomfort/ Abdominal Discomfort	2	09JUL2020	2/2	1	Yes		NA	R (10JUL2020)	N/N	
	METAB	Decreased appetite/ Anorexia	2	09JUL2020	2/3	1	Yes		NA	R (11JUL2020)	N/N	
	PSYCH	Irritability/ Irritability	2	09JUL2020	2/3	1	Yes		NA	R (11JUL2020)	N/N	
	MUSC	Myalgia/ myalgias	2	23JUL2020	16/41	1	Yes		NA/TC	RS (01SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
65-85/ C4591001 1001 10011049^	GENRL	Fatigue/ intermittent fatigue	2	13JUL2020	8/C	1	Yes		NA	RG	N/N
65-85/ C4591001 1001 10011052^	BLOOD	Anaemia/ Anemia	1	08JUL2020	22/C	2	No	O	NA	RG	N/N
65-85/ C4591001 1001 10011055^	PSYCH	Sleep disorder/ sleep disturbance	1	18JUN2020	2/1	1	Yes		NA	R (18JUN2020)	N/N
	METAB	Decreased appetite/ Anorexia	2	09JUL2020	2/4	1	Yes		NA	R (12JUL2020)	N/N
65-85/ C4591001 1001 10011057^	INJ&P	Venomous sting/ Jellyfish sting	2	19JUL2020	12/1	1	No	O	NA	R (19JUL2020)	N/N
65-85/ C4591001 1001 10011058^	SKIN	Ecchymosis/ ecchymosis left arm*		16JUN2020	-2/4	1	No	O	NA	R (19JUN2020)	N/N
65-85/ C4591001 1001 10011059^	GENRL	Injection site pain/ injection site tenderness	1	18JUN2020	2/3	1	Yes		NA	R (20JUN2020)	N/N
	INJ&P	Fall/ Fall	1	03JUL2020	17/1	1	No	O	NA	R (03JUL2020)	N/N
		Fibula fracture/ proximal non-displaced fracture of the right fibula	1	03JUL2020	17/5	2	No	O	NA	R (07JUL2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
65-85/ C4591001 1001 10011063 <sup>^</sup>	MUSC	Myalgia/ Left deltoid local site pain	1	18JUN2020	1/2	1	Yes		NA	R (19JUN2020)	N/N
	GENRL	Fatigue/ Fatigue	2	07JUL2020	1/2	3	Yes		NA/TC	R (08JUL2020)	N/N
		Peripheral swelling/ Swelling on left arm 4x2cm	2	07JUL2020	1/16	1	Yes		NA	R (22JUL2020)	N/N
65-85/ C4591001 1002 10021043 <sup>^</sup>	INJ&P	Skin laceration/ Laceration Right Thumb	1	10JUN2020	2/13	2	No	O	NA	R (22JUN2020)	N/N
	SURG	Suture insertion/ Right Thumb Suture Insertion	1	10JUN2020	2/13	2	No	O	NA	R (22JUN2020)	N/N
65-85/ C4591001 1002 10021044 <sup>^</sup>	SKIN	Hyperhidrosis/ Sweating	1	10JUN2020	2/1	1	Yes		NA	R (10JUN2020)	N/N
	RESP	Dyspnoea/ Shortness of Breath	1	12JUN2020	4/1	1	No	O	NA	R (12JUN2020)	N/N
65-85/ C4591001 1002 10021050 <sup>^</sup>	RESP	Oropharyngeal pain/ Sore Throat	1	16JUN2020	2/1	1	No	O	NA	R (16JUN2020)	N/N
65-85/ C4591001 1002 10021052 <sup>^</sup>	MUSC	Back pain/ Lower back pain	1	27JUN2020	17/3	1	No	O	NA/TC	R (29JUN2020)	N/N
65-85/ C4591001	INFEC	Herpes zoster/ Shingles	1	16JUN2020	2/3	3	No	O	NA/TC	R (18JUN2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1002 10021060^	GASTR	Toothache/ Tooth Pain	2	13JUL2020	7/2	1	No	O	NA/TC	R (14JUL2020)	N/N	
	SURG	Tooth extraction/ Tooth Extraction	2	13JUL2020	7/1	1	No	O	NA/TC	R (13JUL2020)	N/N	
65-85/ C4591001 1002 10021071^	GASTR	Nausea/ Nausea	2	09JUL2020	2/1	2	Yes		NA	R (09JUL2020)	N/N	
65-85/ C4591001 1003 10031035^	NERV	Presyncope/ near syncope	2	06AUG2020	32/1	1	No	O	NA	R (06AUG2020)	N/N	
65-85/ C4591001 1003 10031043^	GENRL	Chills/ chills#	4	29JAN2021	1/3	3	Yes		NA	R (31JAN2021)	N/N	
		Pain/ body ache#	4	29JAN2021	1/1	3	Yes		NA	R (29JAN2021)	N/N	
65-85/ C4591001 1003 10031046^	INJ&P	Vaccination complication/ reaction to vaccine#	4	27JAN2021	2/4	3	Yes		NA/TC	R (30JAN2021)	N/N	
65-85/ C4591001 1003 10031058^	MUSC	Muscle spasms/ Worsening leg cramping	2	10JUL2020	2/5	3	No	O	NA	R (14JUL2020)	N/N	
65-85/ C4591001	NERV	Radiculopathy/ worsening radiculitis	1	03JUL2020	3/6	3	No	O	NA	R (08JUL2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1003 10031083 <sup>^</sup> 65-85/ C4591001 1007 10071043 <sup>^</sup>	NERV	Sciatica/ exacerbation of sciatica	1	22JUN2020	5/26	1	No	O	NA/TC/TCN	R (17JUL2020)	N/N
65-85/ C4591001 1007 10071049 <sup>^</sup>	VASC	Hypertension/ Hypertension	2	13JUL2020	5/C	2	No	O	NA/TC	N	N/N
65-85/ C4591001 1007 10071052 <sup>^</sup>	GASTR	Nausea/ nausea	1	18JUN2020	2/2	2	Yes		NA	R (19JUN2020)	N/N
65-85/ C4591001 1007 10071071 <sup>^</sup>	GASTR	Nausea/ Nausea	1	22JUN2020	6/2	1	Yes		NA	R (23JUN2020)	N/N
65-85/ C4591001 1007 10071071 <sup>^</sup>	INJ&P	Contusion/ coccyx contusion	1	04JUL2020	6/18	1	No	O	NA	R (21JUL2020)	N/N
65-85/ C4591001 1007 10071075 <sup>^</sup>		Contusion/ right knee contusion	1	04JUL2020	6/42	1	No	O	NA	R (14AUG2020)	N/N
65-85/ C4591001 1007 10071075 <sup>^</sup>		Fall/ fall from side of bathtub	1	04JUL2020	6/1	1	No	O	NA	R (04JUL2020)	N/N
65-85/ C4591001 1007 10071075 <sup>^</sup>	SURG	Tooth extraction/ Tooth extraction	1	12JUL2020	13/1	2	No	O	NA/TC	R (12JUL2020)	N/N
65-85/ C4591001 1007 10071075 <sup>^</sup>	SURG	Tooth extraction/ tooth extraction	1	14JUL2020	15/1	2	No	O	NA/TCN	R (14JUL2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site tenderness#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	NEOPL	Squamous cell carcinoma of skin/ Squamous Cell Carcinoma to cheek#	4	15FEB2021	12/12	2	No	O	NA/TC/TCN	R (26FEB2021)	N/N
16-55/ C4591001 1001 10011083	INFEC	Urinary tract infection/ urinary tract infection	2	14SEP2020	27/7	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C4591001 1001 10011089	INJ&P	Fall/ Fall from mountainbike	2	04SEP2020	18/C	2	No	O	NA/TCN	N	N/N
		Ligament sprain/ Sprained shoulder	2	04SEP2020	18/C	2	No	O	NA	N	N/N
16-55/ C4591001 1001 10011092	GENRL	Chest discomfort/ intermittent chest discomfort	2	14SEP2020	27/15	1	No	O	NA	R (28SEP2020)	N/N
	INJ&P	Ligament rupture/ right ACL rupture#	2	15JAN2021	150/33	2	No	O	NA/TC	R (16FEB2021)	N/N
	GENRL	Feeling hot/ Feeling Warm#	4	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
	MUSC	Myalgia/ Muscle aches#	4	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1001 10011106	MUSC	Back pain/ Lower Back Pain	1	02AUG2020	3/2	2	Yes		NA	R (03AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1001 10011113	NERV	Migraine/ worsening migraine	1	07AUG2020	5/9	2	No	O	NA	R (15AUG2020)	N/N	
16-55/ C4591001 1001 10011125	NERV	Dizziness/ dizziness*		04AUG2020	1/1	1	Yes		NA	R (04AUG2020)	N/N	
	NERV	Migraine/ migraine headache	1	05AUG2020	2/5	3	Yes		NA	R (09AUG2020)	N/N	
	MUSC	Myalgia/ diffuse myalgias	1	06AUG2020	3/2	3	Yes		NA	R (07AUG2020)	N/N	
	PSYCH	Disorientation/ disorientation	1	08AUG2020	5/2	1	No	O	NA	R (09AUG2020)	N/N	
16-55/ C4591001 1001 10011130	INJ&P	Arthropod bite/ Insect bites, left ankle	1	07AUG2020	3/3	1	No	O	NA/TC	R (09AUG2020)	N/N	
16-55/ C4591001 1001 10011132	RESP	Allergic respiratory disease/ Allergy upper respiratory	2	01SEP2020	7/3	1	No	O	NA	R (03SEP2020)	N/N	
16-55/ C4591001 1001 10011135	BLOOD	Lymphadenopathy/ Left axilla lymphadenopathy#	3	15JAN2021	2/12	2	Yes		NA	R (26JAN2021)	N/N	
	GENRL	Injection site pain/ Left arm pain at injection site#	3	15JAN2021	2/33	2	Yes		NA/TC	R (16FEB2021)	N/N	
16-55/ C4591001	MUSC	Arthralgia/ exacerbation of history of left shoulder pain	2	15SEP2020	20/C	1	No	O	NA	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1001 10011138 16-55/ C4591001 1001 10011143	MUSC	Pain in extremity/ right arm pain	2	11SEP2020	16/3	1	No	O	NA	R (13SEP2020)	N/N	
16-55/ C4591001 1001 10011145	GASTR	Gastroesophageal reflux disease/ exacerbation of gastroesophageal reflux disease	2	03SEP2020	7/2	1	No	O	NA	R (04SEP2020)	N/N	
	INV	Body temperature increased/ elevated temperature	2	03SEP2020	7/1	1	Yes		NA	R (03SEP2020)	N/N	
16-55/ C4591001 1001 10011149	GENRL	Malaise/ Malaise	1	14AUG2020	8/5	1	No	O	NA	R (18AUG2020)	N/N	
	NERV	Sciatica/ Back pain, subjectively described as sciatica	1	18AUG2020	12/C	1	No	O	NA/TC	N	N/N	
	INJ&P	Muscle strain/ muscle strain	2	23SEP2020	27/3	1	No	O	NA	R (25SEP2020)	N/N	
16-55/ C4591001 1003 10031101	SKIN	Dermatitis contact/ Poison Ivy on both legs, both arms, and both wrists.	2	09SEP2020	23/15	2	No	O	NA/TC	R (23SEP2020)	N/N	
	VASC	Hypertension/ Hypertension	2	16SEP2020	30/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1003 10031111	MUSC	Psoriatic arthropathy/ psoriatic arthritis	2	26SEP2020	38/C	2	Yes		NA/TC	N	Y/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1003 10031125	METAB	Obesity/ obesity	2	03SEP2020	14/C	3	No	O	NA/TC/TCN	RG	N/N	
16-55/ C4591001 1003 10031147	VASC	Hypertension/ worsening hypertension	2	SEP2020	7/C	1	No	O	NA/TC	N	N/N	
	REPRO	Endometriosis/ endometriosis#	3	29JAN2021	19/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1003 10031155	GENRL	Fatigue/ Mild Fatigue	1	11AUG2020	6/2	1	No	O	NA	R (12AUG2020)	N/N	
16-55/ C4591001 1003 10031156	GENRL	Pyrexia/ fever 102#	3	30JAN2021	2/2	2	Yes		NA	R (31JAN2021)	N/N	
	SKIN	Rash/ rash on torso#	3	31JAN2021	3/3	2	Yes		NA	R (02FEB2021)	N/N	
16-55/ C4591001 1003 10031160	INJ&P	Contusion/ traumatic bruise left knee	1	10AUG2020	5/6	2	No	O	NA/TC	R (15AUG2020)	N/N	
		Fall/ fall from bicycle	1	10AUG2020	5/6	2	No	O	NA/TC	R (15AUG2020)	N/N	
	PSYCH	Anxiety/ Anxiety	2	NOV2020	67/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001	GASTR	Diverticulum/ R/O worsening of diverticular disease#	2	04FEB2021	161/21	2	No	O	NA	R (24FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1003 10031166	INJ&P	Exposure during pregnancy/ Exposure During partner Pregnancy	2	17SEP2020	15/C		No	O	NA	UNK	N/N
16-55/ C4591001 1003 10031186	CONG	Congenital ureteropelvic junction obstruction/ Congenital right ureteropelvic junction obstruction	2	01DEC2020	90/58	3	No	O	NA/TC/TCN	R (27JAN2021)	Y/N
16-55/ C4591001 1003 10031201	IMMUN	Hypersensitivity/ Allergy Attack	2	20SEP2020	18/1	1	No	O	NA/TC	R (20SEP2020)	N/N
1003 10031201	INFEC	Sinusitis/ Sinus Infection	2	22SEP2020	20/4	1	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1003 10031205	EYE	Uveitis/ bilateral Uveitis	2	DEC2020	89/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1003 10031206	INV	Biopsy breast normal/ Left breast lesion biopsy benign	2	11JAN2021	130/1	1	No	O	NA	R (11JAN2021)	N/N
16-55/ C4591001 1003 10031206	GASTR	Colitis ulcerative/ ulcerative colitis	2	24OCT2020	51/16	3	No	O	NA	R (08NOV2020)	N/N
16-55/ C4591001 1003 10031207	VASC	Deep vein thrombosis/ bilateral lower extremity DVT	2	27DEC2020	115/48	3	No	O	NA/TC	R (12FEB2021)	Y/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	CONG	Protein S deficiency/ S protein deficiency	2	28DEC2020	116/C	2	No	O	NA/TC	N	N/N	
	RESP	Pulmonary embolism/ pulmonary embolism	2	28DEC2020	116/15	3	No	O	NA/TC	R (11JAN2021)	Y/N	
16-55/ C4591001 1005 10051003	MUSC	Back pain/ BACK PAIN	2	30SEP2020	32/9	2	No	O	NA/TC	R (08OCT2020)	N/N	
16-55/ C4591001 1005 10051024	METAB	Decreased appetite/ DECREASED APPETITE	2	01SEP2020	2/1	2	Yes		NA	R (01SEP2020)	N/N	
16-55/ C4591001 1005 10051026	EAR	Vertigo positional/ INTERMITTENT POSITIONAL VERTIGO	1	13AUG2020	3/5	1	Yes		NA	R (17AUG2020)	N/N	
16-55/ C4591001 1005 10051028	MUSC	Myalgia/ generalized myalgia#	3	23FEB2021	1/C	2	Yes		NA/TC	N	N/N	
16-55/ C4591001 1005 10051054	GENRL	Non-cardiac chest pain/ INTERMITTENT NON CARDIAC CHEST PAIN	2	09SEP2020	6/9	2	No	O	NA	R (17SEP2020)	Y/N	
16-55/ C4591001 1005 10051055	GENRL	Fatigue/ FATIGUE	1	19AUG2020	7/2	1	Yes		NA	R (20AUG2020)	N/N	
	MUSC	Myalgia/ MUSCLE PAIN	1	19AUG2020	7/2	1	Yes		NA	R (20AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051066	GENRL	Chills/ CHILLS	2	03SEP2020	2/1	2	Yes		NA	R (03SEP2020)	N/N
16-55/ C4591001 1005 10051071	GENRL	Chills/ CHILLS#	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
		Fatigue/ FATIGUE#	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
	MUSC	Myalgia/ GENERALIZED MYALGIA#	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
	NERV	Headache/ HEADACHE#	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1005 10051075	GENRL	Fatigue/ FATIGUE	2	06SEP2020	3/9	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001 1005 10051076	GENRL	Chills/ CHILLS	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
		Malaise/ MALAISE	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ MYALGIA	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
	GENRL	Pyrexia/ FEVER 100.9	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051077	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
	MUSC	Myalgia/ MYALGIA	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
16-55/ C4591001 1005 10051081	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	19AUG2020	1/4	1	Yes		NA	R (22AUG2020)	N/Y
		Injection site warmth/ CALOR AT INJECTION SITE	1	19AUG2020	1/1	1	Yes		NA	R (19AUG2020)	N/Y
	GASTR	Diarrhoea/ DIARRHEA	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001 1005 10051082	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
	NERV	Depressed level of consciousness/ CLOUDING OF CONCIUSNESS	1	05SEP2020	18/8	1	No	O	NA	R (12SEP2020)	N/N
16-55/ C4591001 1005 10051084	EYE	Conjunctival oedema/ RIGHT EYE CONJUNCTIVA SWELLING	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		Eye irritation/ RIGHT EYE IRRITATION	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
		Ocular hyperaemia/ RIGHT EYE ERYTHEMA	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE#	4	13JAN2021	2/1	2	Yes		NA	R (13JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051093	MUSC	Pyrexia/ FEVER (101.9F)#	4	13JAN2021	2/1	2	Yes		NA/TC	R (13JAN2021)	N/N
		Myalgia/ GENERALIZED MYALGIA#	4	13JAN2021	2/1	2	Yes		NA	R (13JAN2021)	N/N
	NERV	Dizziness/ DIZZINESS	2	21SEP2020	12/4	1	No	O	NA	R (24SEP2020)	N/N
16-55/ C4591001 1005 10051094	GENRL	Dizziness/ LIGHT HEADED	2	21SEP2020	12/4	1	No	O	NA	R (24SEP2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE#	3	18DEC2020	2/1	1	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1005 10051100	GENRL	Injection site pain/ SORE INJECTION SITE ARM RADIATING TO NECK	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Chills/ CHILLS	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	MUSC	Pyrexia/ FEVER	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
Myalgia/ MYALGIA		2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N	
16-55/ C4591001 1005 10051105	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	22DEC2020	2/3	1	Yes		NA	R (24DEC2020)	N/N
16-55/ C4591001	GENRL	Malaise/ MALAISE	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1005 10051107	MUSC	Myalgia/ GENERALIZED MYALGIA	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N	
16-55/ C4591001 1005 10051119	GENRL	Injection site pain/ PAIN AT INJECTION SITE*		24AUG2020	1/4	1	Yes		NA	R (27AUG2020)	N/N	
16-55/ C4591001 1005 10051123	MUSC	Myalgia/ Muscle Aches	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N	
	INFEC	Urinary tract infection/ URINATRY TRACT INFECTION	2	14OCT2020	31/15	2	No	O	NA/TC	R (28OCT2020)	N/N	
16-55/ C4591001 1005 10051125	GENRL	Injection site pain/ INJECTION SITE PAIN	1	25AUG2020	2/5	1	Yes		NA	R (29AUG2020)	N/N	
	GENRL	Chills/ CHILLS	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	
		Fatigue/ FATIGUE	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	
	MUSC	Myalgia/ GENERALIZED MYALGIA	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001 1005 10051129	GENRL	Injection site pain/ INJECTION SITE PAIN	1	24AUG2020	1/5	1	Yes		NA	R (28AUG2020)	N/N	
	GENRL	Asthenia/ ASTHENIA	1	26AUG2020	3/1	1	Yes		NA/TC	R (26AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1005 10051134	MUSC	Arthralgia/ LEFT SHOULDER PAIN	1	05SEP2020	13/18	2	No	O	NA/TC	R (22SEP2020)	N/N	
16-55/ C4591001 1005 10051135	GENRL	Injection site pain/ INJECTION SITE PAIN	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N	
16-55/ C4591001 1005 10051145	GENRL	Injection site pain/ INJECTION SITE PAIN	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N	
	GASTR	Diarrhoea/ DIARRHEA	1	28AUG2020	4/1	1	Yes		NA	R (28AUG2020)	N/N	
	RESP	Oropharyngeal pain/ SORE THROAT	1	28AUG2020	4/1	1	Yes		NA	R (28AUG2020)	N/N	
	GASTR	Diarrhoea/ INTERMITTENT DIARRHEA	1	02SEP2020	9/13	1	Yes		NA	R (14SEP2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N	
	MUSC	Pain in extremity/ RIGHT LEG PAIN	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N	
	RESP	Oropharyngeal pain/ SORE THROAT	2	14SEP2020	1/1	1	Yes		NA	R (14SEP2020)	N/N	
	RESP	Oropharyngeal pain/ SORE THROAT	2	19SEP2020	6/1	1	No	O	NA	R (19SEP2020)	N/N	
	GASTR	Diarrhoea/ DIARRHEA	2	20SEP2020	7/1	1	No	O	NA	R (20SEP2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	25AUG2020	1/2	1	Yes		NA/TC	R (26AUG2020)	N/Y	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1005 10051146	MUSC	Myalgia/ GENERALIZED MYALGIA	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N	
	GASTR	Nausea/ NAUSEA	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N	
	GENRL	Asthenia/ WEAKNESS	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N	
		Pyrexia/ FEVER	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N	
	MUSC	Arthralgia/ GENERALIZED ARTHRALGIA	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N	
		Myalgia/ GENERALIZED MYALGIA	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N	
	GENRL	Chills/ CHILLS	2	16SEP2020	3/1	2	Yes		NA	R (16SEP2020)	N/N	
16-55/ C4591001 1005 10051150	NERV	Nerve compression/ PINCHED NERVE IN NECK	2	15SEP2020	2/72	2	Yes		NA/TC	R (25NOV2020)	N/N	
16-55/ C4591001 1005 10051151	GENRL	Injection site pain/ INJECTION SITE PAIN	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N	
	MUSC	Myalgia/ GENERALIZED MYALGIA	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N	
16-55/ C4591001 1005 10051161	GENRL	Chills/ CHILLS	2	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051165	GENRL	Fatigue/ FATIGUE	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ GENERALIZED MYALGIA	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	27AUG2020	2/1	1	Yes		NA	R (27AUG2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	1	14SEP2020	20/2	1	No	O	NA	R (15SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1005 10051166		Injection site pain/ INJECTION SITE PAIN	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ FEVER 100.5	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	INFEC	Helicobacter gastritis/ H Pylori gastroenteritis#	3	09JAN2021	19/11	1	No	O	NA/TC	R (19JAN2021)	N/N
	GENRL	Chills/ CHILLS#	4	12JAN2021	1/2	2	Yes		NA	R (13JAN2021)	N/N
		Pyrexia/ FEVER#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ GENERALIZED MYALGIA#	4	12JAN2021	1/2	2	Yes		NA	R (13JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N
GENRL	Chills/ CHILLS#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1005 10051168 16-55/ C4591001 1005 10051169 16-55/ C4591001 1005 10051170 16-55/ C4591001 1005 10051171	MUSC	Pyrexia/ FEVER 101.0#	4	13JAN2021	2/2	2	Yes		NA	R (14JAN2021)	N/N	
		Myalgia/ GENERALIZED MYALIGIA#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N	
	MUSC	Costochondritis/ LEFT CHOSTOCHONDRITIS	1	16SEP2020	21/4	1	No	O	NA/TC	R (19SEP2020)	N/N	
	METAB	Decreased appetite/ LACK OF APPETITE	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N	
	MUSC	Musculoskeletal stiffness/ LEFT SHOULDER STIFFNESS	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N	
	MUSC	Musculoskeletal stiffness/ STIFFNESS ON LEFT SIDE OF NECK	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N	
	NERV	Dizziness/ LIGHT HEADED	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N	
	NERV	Headache/ HEADACHE	1	27AUG2020	1/2	1	Yes		NA/TC	R (28AUG2020)	N/N	
	NERV	Lethargy/ LETHARGY	1	29AUG2020	3/3	2	Yes		NA	R (31AUG2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	4	05FEB2021	1/C	2	Yes		NA	N	N/N	
GASTR	Dyspepsia/ HEARTBURN	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N		

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1005 10051175	NERV	Nausea/ NAUSEA	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	
		Migraine/ WORSENING OF MIGRINES	2	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N	
	GENRL	Chills/ CHILLS#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N	
		Pyrexia/ FEVER (102.6)#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N	
16-55/ C4591001 1005 10051178	MUSC	Myalgia/ GENERALIZED MYALGIA#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N	
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N	
	IMMUN	Allergy to arthropod sting/ BEE STING REACTION	1	11SEP2020	15/5	1	No	O	NA/TC	R (15SEP2020)	N/N	
	GENRL	Chills/ CHILLS	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N	
		Fatigue/ FATIGUE	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N	
	MUSC	Injection site pain/ INJECTION SITE PAIN	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N	
		Pyrexia/ FEVER 100.4	2	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N	
		Arthralgia/ GENERALIZED ARTHRALGIA	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N	
Myalgia/ GENERALIZED MYALGIA		2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N		

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1005 10051179	GASTR	Vomiting/ EMESIS	2	01OCT2020	14/1	2	No	O	NA	R (01OCT2020)	N/N	
	EYE	Eye pain/ STINGING IN EYES	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/N	
	RESP	Cough/ COUGH	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/Y	
		Throat irritation/ TICKLE IN THROAT	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/Y	
16-55/ C4591001 1005 10051181		Upper-airway cough syndrome/ POST NASAL DRIP	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N	
16-55/ C4591001 1005 10051182	GENRL	Injection site pain/ INJECTION SITE PAIN	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N	
	GENRL	Fatigue/ EXTREME FATIGUE	1	29AUG2020	2/1	2	Yes		NA	R (29AUG2020)	N/N	
16-55/ C4591001 1005 10051183	GENRL	Injection site pain/ INJECTION SITE PAIN	1	31AUG2020	1/7	1	Yes		NA	R (06SEP2020)	N/N	
	GENRL	Pain/ BODY ACHES	1	01SEP2020	2/3	1	Yes		NA/TC	R (03SEP2020)	N/N	
	RESP	Cough/ COUGH	1	01SEP2020	2/3	1	Yes		NA/TC	R (03SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1005 10051187	GENRL	Nasal congestion/ NASAL CONGESTION	1	01SEP2020	2/3	1	Yes		NA/TC	R (03SEP2020)	N/N	
		Injection site pain/ INJECTION SITE PAIN	1	23SEP2020	24/6	1	Yes		NA	R (28SEP2020)	N/N	
	NERV	Headache/ HEADACHE	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N	
16-55/ C4591001 1005 10051188	GENRL	Fatigue/ FATIGUE	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N	
	GENRL	Fatigue/ FATIGUE	1	01SEP2020	1/3	2	Yes		NA	R (03SEP2020)	N/N	
	MUSC	Injection site pain/ INJECTION SITE PAIN	1	01SEP2020	1/8	1	Yes		NA	R (08SEP2020)	N/N	
Myalgia/ MUSCLE ACHES		1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N		
16-55/ C4591001 1005 10051189	GENRL	Fatigue/ FATIGUE	2	24SEP2020	1/3	2	Yes		NA	R (26SEP2020)	N/N	
	MUSC	Injection site pain/ INJECTION SITE PAIN	2	24SEP2020	1/8	2	Yes		NA	R (01OCT2020)	N/N	
		Myalgia/ MUSCLE ACHES	2	24SEP2020	1/3	1	Yes		NA/TC	R (26SEP2020)	N/N	
GENRL	Injection site pain/ injection site pain#	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N		
16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	2	23SEP2020	1/3	2	Yes		NA/TC	R (25SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1005 10051192	GENRL	Fatigue/ FATIGUE	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
		Pain/ BODY ACHES	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1005 10051198	GENRL	Chills/ chills#	4	12MAR2021	1/2	2	Yes		NA	R (13MAR2021)	N/N
		Pyrexia/ fever 102F#	4	12MAR2021	1/2	2	Yes		NA/TC	R (13MAR2021)	N/N
	MUSC	Myalgia/ generalized myalgia#	4	12MAR2021	1/2	2	Yes		NA/TC	R (13MAR2021)	N/N
16-55/ C4591001 1005 10051199	GENRL	Injection site pain/ INJECTION SITE PAIN	1	03SEP2020	1/3	2	Yes		NA/TC	R (05SEP2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	24SEP2020	1/3	2	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Chills/ BODY CHILLS	2	25SEP2020	2/2	2	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1005 10051200	GENRL	Injection site pain/ INJECTION SITE PAIN	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1005 10051203	GENRL	Injection site pain/ INJECTION SITE PAIN	1	03SEP2020	1/4	1	Yes		NA	R (06SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051210	GASTR	Diarrhoea/ LOOSE STOOL	1	04SEP2020	2/3	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Chills/ CHILLS	1	04SEP2020	2/3	1	Yes		NA	R (06SEP2020)	N/N
		Pyrexia/ FEVER	1	04SEP2020	2/3	1	Yes		NA	R (06SEP2020)	N/N
	MUSC	Myalgia/ GENERALIZED MYALGIA	1	04SEP2020	2/3	1	Yes		NA/TC	R (06SEP2020)	N/N
	INFEC	Gastroenteritis/ GASTROENTERITIS	1	19SEP2020	17/1	2	No	O	NA	R (19SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	23SEP2020	2/4	1	Yes		NA	R (26SEP2020)	N/N
		Pain/ BODY ACHES	2	23SEP2020	2/4	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Myalgia/ MYALGIA	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1005 10051216	GASTR	Diarrhoea/ DIARRHEA	2	27SEP2020	4/3	1	Yes		NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 1005 10051217	GENRL	Feeling hot/ overall body CALOR - no fever	1	04SEP2020	2/1	1	Yes		NA	R (04SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051219	RESP	Injection site pain/ PAIN AT INJECTION SITE	1	04SEP2020	2/3	2	Yes		NA	R (06SEP2020)	N/N
		Oropharyngeal pain/ SORE THROAT	1	05SEP2020	3/1	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1005 10051220	RENAL	Pollakiuria/ INCREASED FREQUENCY OF URINATION	1	04SEP2020	2/4	1	Yes		NA	R (07SEP2020)	N/N
	GENRL	Fatigue/ fatigue#	4	09FEB2021	2/1	2	Yes		NA	R (09FEB2021)	N/N
	MUSC	Myalgia/ generalized myalgia#	4	09FEB2021	2/1	2	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1005 10051221	GENRL	Chills/ chills#	4	17FEB2021	1/2	2	Yes		NA	R (18FEB2021)	N/N
	MUSC	Pyrexia/ fever#	4	17FEB2021	1/2	2	Yes		NA	R (18FEB2021)	N/N
	MUSC	Myalgia/ generalized myalgia#	4	17FEB2021	1/2	2	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1005 10051223	NERV	Headache/ headache#	4	17FEB2021	1/2	2	Yes		NA	R (18FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain	1	13OCT2020	2/4	2	Yes		NA/TC	R (16OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051224	MUSC	Myalgia/ GENERALIZED MYALGIAS#	4	29JAN2021	3/1	1	Yes		NA	R (29JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	29JAN2021	3/1	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1005 10051232	INFEC	Ear infection/ LEFT EAR INFECTION	1	23OCT2020	12/6	2	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C4591001 1005 10051236	GENRL	Chills/ CHILLS	2	04NOV2020	2/1	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C4591001 1005 10051241	GENRL	Fatigue/ FATIGUE	1	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE	1	14OCT2020	2/5	1	Yes		NA	R (18OCT2020)	N/N
	MUSC	Myalgia/ MYALGIA	1	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	03NOV2020	1/3	2	Yes		NA	R (05NOV2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	03NOV2020	1/4	2	Yes		NA/TC	R (06NOV2020)	N/N
	MUSC	Myalgia/ MYALGIA	2	03NOV2020	1/3	2	Yes		NA	R (05NOV2020)	N/N
	NERV	Headache/ HEADACHE	2	03NOV2020	1/3	2	Yes		NA	R (05NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1005 10051244 16-55/ C4591001 1005 10051246 16-55/ C4591001 1005 10051259 16-55/ C4591001 1005 10051264 16-55/ C4591001 1005	GENRL	Pyrexia/ FEVER	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N	
	MUSC	Arthralgia/ GENERALIZED ARTHRALGIA	2	05NOV2020	3/8	1	Yes		NA	R (12NOV2020)	N/N	
	NERV	Migraine/ WORSENING OF MIGRAINES	2	07NOV2020	6/1	2	No	O	NA/TC	R (07NOV2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N	
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N	
	MUSC	Malaise/ MALAISE	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N	
	MUSC	Arthralgia/ SHOULDER ACHING NOT INJECTION ARM	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N	
	GENRL	Myalgia/ MYALGIA	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N	
	GENRL	Chills/ CHILLS#	3	16DEC2020	1/2	2	Yes		NA	R (17DEC2020)	N/N	
	MUSC	Myalgia/ GENERALIZED MYALGIA#	3	16DEC2020	1/4	2	Yes		NA/TC	R (19DEC2020)	N/N	
GENRL	Fatigue/ FATIGUE	1	15OCT2020	1/1	2	Yes		NA	R (15OCT2020)	N/N		

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1005 10051270	GENRL	Injection site pain/ INJECTION SITE ARM PAIN	1	17OCT2020	2/4	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 1005 10051283	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	16OCT2020	1/5	2	Yes		NA	R (20OCT2020)	N/Y
1005 10051285	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/Y
	MUSC	Myalgia/ GENERALIZED MYALGIA	2	06NOV2020	2/1	1	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1005 10051288	INFEC	Tooth abscess/ RIGHT TOOTH ABSCESS	1	20OCT2020	5/17	2	No	O	NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1005 10051290	GENRL	Injection site pain/ INJECTION SITE PAIN	2	05NOV2020	2/31	1	Yes		NA	R (05DEC2020)	N/N
16-55/ C4591001 1005 10051301	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1005 10051302	GENRL	Injection site pain/ MILD ARM PAIN AT INJECTION SITE	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
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16-55/ C4591001 1005 10051318	GENRL	Pain/ BODY ACHES	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1005 10051332	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	20OCT2020	1/4	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Chills/ CHILLS	2	11NOV2020	2/1	1	Yes		NA	R (11NOV2020)	N/N
		Pyrexia/ FEVER (101.5)	2	11NOV2020	2/1	2	Yes		NA	R (11NOV2020)	N/N
	MUSC	Myalgia/ MYALGIA	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N
	NERV	Headache/ HEADACHE	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1005 10051335	GENRL	Injection site pain/ TENDERNESS AT INJECTION SITE	1	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1005 10051340	GASTR	Nausea/ NAUSEA	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ TENDERNESS AT INJECTION SITE	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001	INFEC	Groin abscess/ LEFT GROIN ABSCESS	1	12DEC2020	53/20	2	No	O	NA/TC	R (31DEC2020)	N/N

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1005 10051341												
16-55/ C4591001 1005 10051346	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	21OCT2020	1/4	1	Yes		NA	R (24OCT2020)	N/N	
16-55/ C4591001 1005 10051349	GENRL	Fatigue/ FATIGUE	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N	
		Injection site pain/ PAIN AT INJECTION SITE	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/Y	
	GENRL	Fatigue/ FATIGUE#	4	09FEB2021	2/2	2	Yes		NA	R (10FEB2021)	N/N	
		Pyrexia/ FEVER (102.0)#	4	09FEB2021	2/2	2	Yes		NA	R (10FEB2021)	N/N	
	MUSC	Myalgia/ GENERALIZED MYALGIA#	4	09FEB2021	2/2	2	Yes		NA	R (10FEB2021)	N/N	
	NERV	Headache/ HEADACHE#	4	09FEB2021	2/2	2	Yes		NA	R (10FEB2021)	N/N	
16-55/ C4591001 1005 10051350	GENRL	Injection site pain/ INJECTION SITE PAIN	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N	
16-55/ C4591001 1005 10051358	GENRL	Injection site pain/ INJECTION SITE PAIN#	3	08FEB2021	1/C	1	Yes		NA	N	N/N	
	MUSC	Myalgia/ GENERALIZED MYALGIA#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	

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16-55/ C4591001 1005 10051361	GENRL	Chills/ CHILLS	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N	
		Fatigue/ FATIGUE	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N	
	NERV	Headache/ HEADACHE	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N	
16-55/ C4591001 1005 10051363	GASTR	Nausea/ NAUSEA	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N	
	MUSC	Myalgia/ MYALGIA	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N	
	VASC	Hot flush/ HOT FLASHES	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N	
	MUSC	Arthralgia/ GENERALIZED JOINT ACHES	2	01DEC2020	19/9	1	No	O	NA	R (09DEC2020)	N/N	
16-55/ C4591001 1005 10051365	GENRL	Injection site pain/ BURNING SENSATION AT INJECTION SITE	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N	
16-55/ C4591001 1005 10051366	GENRL	Fatigue/ FATIGUE	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N	
		Malaise/ MALAISE	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N	

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16-55/ C4591001 1005 10051368	MUSC	Myalgia/ MUSCLE ACHES	2	13NOV2020	1/2	1	Yes		NA/TC	R (14NOV2020)	N/N	
	NERV	Headache/ HEADACHES	2	13NOV2020	1/2	1	Yes		NA/TC	R (14NOV2020)	N/N	
16-55/ C4591001 1005 10051369	MUSC	Back pain/ WORSENING OF LOWER BACK PAIN	1	04NOV2020	13/22	2	No	O	NA/TC	R (25NOV2020)	N/N	
	NERV	Dizziness/ LIGHTHEADED	1	09NOV2020	18/2	2	No	O	NA	R (10NOV2020)	N/N	
16-55/ C4591001 1005 10051378	GENRL	Injection site pain/ INJECTION SITE PAIN	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N	
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	18NOV2020	1/2	1	Yes		NA	R (19NOV2020)	N/N	
16-55/ C4591001 1005 10051378	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N	
	NERV	Dizziness/ LIGHT HEADED	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N	
16-55/ C4591001 1005 10051380	NERV	Headache/ HEADACHE	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	06JAN2021	1/3	2	Yes		NA	R (08JAN2021)	N/N	
	NERV	Headache/ HEADACHE#	4	06JAN2021	1/5	2	Yes		NA	R (10JAN2021)	N/N	



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16-55/ C4591001 1005 10051385	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	28OCT2020	1/3	1	Yes		NA	R (30OCT2020)	N/N
	GENRL	Pyrexia/ FEVER 101.4	2	17NOV2020	2/2	2	Yes		NA	R (18NOV2020)	N/N
	MUSC	Myalgia/ MYALGIA	2	17NOV2020	2/2	2	Yes		NA	R (18NOV2020)	N/N
	NERV	Headache/ WORSENING OF HEADACHE	2	17NOV2020	2/2	2	Yes		NA	R (18NOV2020)	N/N
16-55/ C4591001 1005 10051386	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	29OCT2020	2/3	1	Yes		NA	R (31OCT2020)	N/N
	GENRL	Malaise/ MALIASE	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N
	NERV	Headache/ HEADACHE	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N
16-55/ C4591001 1005 10051390	GENRL	Fatigue/ FATIGUE	1	31OCT2020	2/7	1	Yes		NA	R (06NOV2020)	N/N
	MUSC	Myalgia/ MYALGIA	1	31OCT2020	2/7	1	Yes		NA	R (06NOV2020)	N/N
	NERV	Headache/ HEADACHE	1	31OCT2020	2/7	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1005 10051393	GENRL	Injection site pain/ INJECTION SITE PAIN	1	30OCT2020	1/4	1	Yes		NA	R (02NOV2020)	N/N

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16-55/ C4591001 1005 10051396	GENRL	Injection site pain/ INJECTION SITE PAIN	2	23NOV2020	1/34	1	Yes		NA	R (26DEC2020)	N/N
	MUSC	Myalgia/ MYALGIA	2	24NOV2020	2/1	2	Yes		NA/TC	R (24NOV2020)	N/N
16-55/ C4591001 1005 10051398	GENRL	Pyrexia/ fever post injection#	3	18FEB2021	1/1	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Injection site pain/ injection site reaction - arm pain#	3	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Pyrexia/ fever 101F#	4	12MAR2021	2/1	2	Yes		NA/TC	R (12MAR2021)	N/N
	NERV	Headache/ headache#	4	12MAR2021	2/1	2	Yes		NA/TC	R (12MAR2021)	N/N
16-55/ C4591001 1005 10051400	GENRL	Injection site swelling/ INJECTION SITE SWELLING	2	23NOV2020	1/2	1	Yes		NA	R (24NOV2020)	N/N
16-55/ C4591001 1005 10051411	GASTR	Abdominal pain/ ABDOMINAL PAIN	2	29JAN2021	2/4	3	No	O	NA/TC	R (01FEB2021)	Y/N
16-55/ C4591001 1005 10051442	GENRL	Fatigue/ FATIGUE	2	14JAN2021	2/3	2	Yes		NA	R (16JAN2021)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	14JAN2021	2/4	1	Yes		NA	R (17JAN2021)	N/N

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16-55/ C4591001 1006 10061023	MUSC	Injection site swelling/ INJECTION SITE SWELLING (1 INCH)	2	14JAN2021	2/4	1	Yes		NA	R (17JAN2021)	N/N
		Arthralgia/ GENERALIZED ARTHRALGIA	2	14JAN2021	2/3	1	Yes		NA	R (16JAN2021)	N/N
		Myalgia/ GENERALIZED MYALGIA	2	14JAN2021	2/3	2	Yes		NA	R (16JAN2021)	N/N
16-55/ C4591001 1006 10061023	NERV	Headache/ WORSENING OF HEADACHE	2	14JAN2021	2/3	2	Yes		NA/TC	R (16JAN2021)	N/N
	INJ&P	Bone contusion/ RIGHT HIP BONE CONTUSION	1	28AUG2020	17/8	2	No	O	NA/TC	R (04SEP2020)	N/N
16-55/ C4591001 1006 10061031	GENRL	Fatigue/ Fatigue#	4	05FEB2021	2/1	2	Yes		NA	R (05FEB2021)	N/N
	INFEC	Oral fungal infection/ ORAL YEAST INFECTION	1	16AUG2020	4/11	2	No	O	NA/TC	R (26AUG2020)	N/N
16-55/ C4591001 1006 10061032	GENRL	Chills/ generalized chills	2	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	2	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1006 10061040	INFEC	Pharyngitis streptococcal/ Strep throat	2	08SEP2020	5/11	2	No	O	NA/TC	R (18SEP2020)	N/N
	INFEC	Clostridium difficile infection/ Clostridium Difficile Infection	2	30SEP2020	27/152	2	No	O	NA/TC	R (28FEB2021)	N/N

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	GENRL	Injection site pain/ Injection Site Pain#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
	INJ&P	Procedural pain/ Post Surgical Pain#	3	28DEC2020	11/16	3	No	O	NA/TC	R (12JAN2021)	N/N
	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy#	4	08FEB2021	32/C		No	O	NA	UNK	N/N
16-55/ C4591001 1006 10061052	INJ&P	Exposure during pregnancy/ Exposure During Partner Pregnancy	2	01JAN2021	116/C		No	O	NA	UNK	N/N
16-55/ C4591001 1006 10061053	NERV	Dizziness/ Lightheadedness	1	18AUG2020	1/9	2	Yes		NA	R (26AUG2020)	N/N
16-55/ C4591001 1006 10061056	GASTR	Nausea/ Intermittent Nausea#	4	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Aches#	4	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1006 10061067	GENRL	Injection site pain/ Injection site tenderness#	3	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
	IMMUN	Seasonal allergy/ Worsening of seasonal allergies#	3	01MAR2021	7/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1006 10061070	NERV	Migraine/ Migraines - Intermittent	1	31AUG2020	13/C	3	No	O	NA	N	N/N

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16-55/ C4591001 1006 10061074	INJ&P	Skin laceration/ Left Index Finger Laceration#	2	02MAR2021	174/C	3	No	O	NA/TC/TCN	N	N/N	
16-55/ C4591001 1006 10061079	GENRL	Chills/ CHILLS	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
		Pyrexia/ FEVER	2	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N	
	GENRL	Pain/ BODY ACHES-GENERALIZED	2	17SEP2020	2/3	2	Yes		NA	R (19SEP2020)	N/N	
16-55/ C4591001 1006 10061088	MUSC	Myalgia/ Generalized Muscle Aches#	3	05FEB2021	1/2	3	Yes		NA/TC	R (06FEB2021)	N/N	
	NERV	Headache/ Headache#	3	05FEB2021	1/2	3	Yes		NA/TC	R (06FEB2021)	N/N	
16-55/ C4591001 1006 10061089	CARD	Tachycardia/ Tachycardia	2	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N	
16-55/ C4591001 1006 10061090	MUSC	Back pain/ BACK ACHE	2	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N	
16-55/ C4591001 1006 10061093	NERV	Paraesthesia/ FACIAL TINGLING	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N	

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16-55/ C4591001 1006 10061094	SKIN	Rash/ CHEST RASH (8 cm)	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Pain/ GENERALIZED ACHES	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Pyrexia/ FEVER	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Pain/ GENERALIZED ACHES	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Pyrexia/ FEVER	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	15NOV2020	59/C		No	O	NA	UNK	N/N
	GASTR	Vomiting/ Vomiting#	3	21JAN2021	2/1	2	Yes		NA/TC	R (21JAN2021)	N/N
	16-55/ C4591001 1006 10061099	INFEC	Urinary tract infection/ Urinary Tract Infection#	3	23FEB2021	8/8	1	No	O	NA/TC	R (02MAR2021)
16-55/ C4591001 1006 10061112	GENRL	Chills/ Chills	2	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N

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16-55/ C4591001 1006 10061134	MUSC	Myalgia/ mUSCLE aCHES	2	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N
	SKIN	Dermatitis/ DERMATITIS-FACIAL	2	01OCT2020	10/62	2	No	O	NA/TC	R (01DEC2020)	N/N
16-55/ C4591001 1006 10061137	GASTR	Nausea/ Nausea	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001 1006 10061144	GENRL	Pain/ Body aches	1	02SEP2020	2/1	3	Yes		NA/TC	R (02SEP2020)	N/N
	NERV	Headache/ Headache	1	22SEP2020	20/2	1	No	O	NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1006 10061151	NERV	Headache/ Headache	2	05NOV2020	23/1	2	No	O	NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1006 10061153	PSYCH	Attention deficit hyperactivity disorder/ Attention Deficit Hyperactive Disorder	2	02NOV2020	22/C	2	No	O	NA	N	N/N
16-55/ C4591001 1006 10061160	GASTR	Diarrhoea/ DIARRHEA	1	27SEP2020	3/3	2	Yes		NA/TC	R (29SEP2020)	N/N
		Vomiting/ VOMITING	1	27SEP2020	3/3	2	Yes		NA/TC	R (29SEP2020)	N/N

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	NERV	Headache/ HEADACHE	1	27SEP2020	3/3	2	Yes		NA	R (29SEP2020)	N/N	
16-55/ C4591001 1006 10061161	INJ&P	Maternal exposure before pregnancy/ Maternal Exposure before Pregnancy	2	28DEC2020	73/C		No	O	NA	UNK	N/N	
16-55/ C4591001 1006 10061163	SKIN	Urticaria/ hives left forearm	2	15NOV2020	32/6	1	No	O	NA	R (20NOV2020)	N/N	
	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	26JAN2021	104/4	2	No	O	NA/TC	R (29JAN2021)	N/N	
16-55/ C4591001 1006 10061165	GENRL	Pain/ Generalized Body Aches	2	16OCT2020	2/2	2	Yes		NA	R (17OCT2020)	N/N	
		Pyrexia/ Fever	2	16OCT2020	2/2	2	Yes		NA	R (17OCT2020)	N/N	
16-55/ C4591001 1006 10061166	GENRL	Chills/ CHILLS	1	27SEP2020	3/2	2	Yes		NA	R (28SEP2020)	N/N	
	GENRL	Pain/ Body Aches	2	16OCT2020	2/3	2	Yes		NA	R (18OCT2020)	N/N	
16-55/ C4591001 1006 10061170	MUSC	Arthralgia/ Bilateral Ankle Joint Pain	2	28OCT2020	1/5	2	Yes		NA/TC	R (01NOV2020)	N/N	
		Neck pain/ Pain at base of neck	2	28OCT2020	1/5	2	Yes		NA/TC	R (01NOV2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1006 10061176	RESP	Asthma/ Acute Asthma Exacerbation#	2	03FEB2021	77/8	3	No	O	NA/TC	R (10FEB2021)	Y/N	
16-55/ C4591001 1006 10061194	INFEC	Otitis externa/ Otitis Externa Left	2	15JAN2021	24/13	3	No	O	NA/TC/TCN	R (27JAN2021)	N/N	
	INJ&P	Mouth injury/ Oral laceration#	2	15FEB2021	55/10	1	No	O	NA/TC/TCN	R (24FEB2021)	N/N	
16-55/ C4591001 1006 10061202	NERV	Headache/ Headache	2	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N	
16-55/ C4591001 1006 10061204	GENRL	Injection site bruising/ 1 MM BRUISING AT INJECTION SITE LEFT DELTOID	2	22DEC2020	1/25	1	Yes		NA	R (15JAN2021)	N/Y	
16-55/ C4591001 1006 10061205	INJ&P	Foot fracture/ Left Great Toe Fracture	2	29JAN2021	37/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1006 10061208	GENRL	Pain/ Body Aches	2	24DEC2020	2/1	1	Yes		NA/TC	R (24DEC2020)	N/N	
	NERV	Headache/ Headache	2	24DEC2020	2/1	1	Yes		NA/TC	R (24DEC2020)	N/N	
	RESP	Oropharyngeal pain/ Sore Throat	2	24DEC2020	2/1	1	Yes		NA/TC	R (24DEC2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1006 10061215	INJ&P	Ligament sprain/ Knee sprain Right	1	10DEC2020	7/3	1	No	O	NA/TC	R (12DEC2020)	N/N	
	MUSC	Arthralgia/ right shoulder pain	2	23JAN2021	2/C	3	No	O	NA/TC/TCN	RG	N/N	
16-55/ C4591001 1006 10061216	GENRL	Chills/ Chills#	3	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N	
16-55/ C4591001 1006 10061240	GENRL	Injection site pain/ Injection site pain	2	05JAN2021	1/1	1	Yes		NA/TC	R (05JAN2021)	N/N	
		Pyrexia/ Fever	2	05JAN2021	1/1	1	Yes		NA/TC	R (05JAN2021)	N/N	
16-55/ C4591001 1006 10061246	GENRL	Chills/ Chills#	3	18FEB2021	2/3	2	Yes		NA/TC	R (20FEB2021)	N/N	
	NERV	Headache/ Headache#	3	18FEB2021	2/3	2	Yes		NA/TC	R (20FEB2021)	N/N	
16-55/ C4591001 1007 10071083	RESP	Oropharyngeal pain/ sore throat	1	05AUG2020	9/2	1	No	O	NA	R (06AUG2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	4	27JAN2021	2/2	2	Yes		NA/TC	R (28JAN2021)	N/N	
	MUSC	Myalgia/ myalgias#	4	27JAN2021	2/2	2	Yes		NA/TC	R (28JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1007 10071087	NERV	Headache/ headache#	4	27JAN2021	2/2	2	Yes		NA/TC	R (28JAN2021)	N/N	
	REPRO	Menorrhagia/ exacerbation of menorrhagia	2	06SEP2020	19/14	2	No	O	NA	R (19SEP2020)	N/N	
16-55/ C4591001 1007 10071089	MUSC	Pain in extremity/ Arm Pain#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N	
	GENRL	Chills/ Chills#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N	
16-55/ C4591001 1007 10071097		Pyrexia/ fever#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N	
	MUSC	Arthralgia/ pain in elbow#	3	06JAN2021	2/C	1	Yes		NA/TC	N	N/N	
	INJ&P	Hand fracture/ Fractured left 4th finger#	4	13FEB2021	19/C	2	No	O	NA	RG	N/N	
	MUSC	Myalgia/ Right Scapular Muscle Pain	2	21AUG2020	2/12	3	No	O	NA/TC/TCN	R (01SEP2020)	N/N	
16-55/ C4591001 1007 10071108	BLOOD	Lymphadenopathy/ Bilateral Swollen Cervical Lymph Nodes	2	23AUG2020	4/12	1	No	O	NA/TC	R (03SEP2020)	N/N	
	MUSC	Tendonitis/ Exacerbation of tendonitis	2	23SEP2020	28/C	2	No	O	NA/TCN	RG	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	24FEB2021	1/3	2	Yes		NA/TC	R (26FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1007 10071110	PSYCH	Anxiety/ exacerbation of anxiety	2	07SEP2020	15/120	2	No	O	NA/TC	R (04JAN2021)	N/N	
16-55/ C4591001 1007 10071117	BLOOD	Lymphadenopathy/ right supraclavicular swollen lymph node#	4	09MAR2021	2/C	1	Yes		NA	RG	N/N	
	GENRL	Chills/ chills#	4	09MAR2021	2/1	1	Yes		NA	R (09MAR2021)	N/N	
	MUSC	Myalgia/ myalgias#	4	09MAR2021	2/1	1	Yes		NA	R (09MAR2021)	N/N	
16-55/ C4591001 1007 10071119	GENRL	Fatigue/ fatigue#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N	
		Pyrexia/ fever#	4	25JAN2021	1/2	2	Yes		NA/TC	R (26JAN2021)	N/N	
	MUSC	Myalgia/ myalgia#	4	25JAN2021	1/2	2	Yes		NA/TC	R (26JAN2021)	N/N	
16-55/ C4591001 1007 10071130	NERV	Syncope/ fainting episode	1	11AUG2020	7/1	2	No	O	NA	R (11AUG2020)	N/N	
16-55/ C4591001 1007 10071143	GENRL	Fatigue/ Fatigue#	3	18FEB2021	1/1	1	Yes		NA	R (18FEB2021)	N/N	
		Injection site pain/ Pain at injection site#	3	18FEB2021	1/1	1	Yes		NA	R (18FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1007 10071145	GENRL	Chills/ Chills#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
		Injection site pain/ Injection Site Muscle Soreness#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
16-55/ C4591001 1007 10071148	GENRL	Injection site nodule/ nodule at injection site	2	27AUG2020	1/8	1	Yes		NA	R (03SEP2020)	N/N	
16-55/ C4591001 1007 10071151	METAB	Type 2 diabetes mellitus/ Type 2 Diabetes	2	11JAN2021	134/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1007 10071154	GENRL	Injection site pain/ Injection Site Arm Soreness#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N	
	GENRL	Chills/ chills#	4	02FEB2021	1/2	2	Yes		NA	R (03FEB2021)	N/N	
		Pyrexia/ fever#	4	02FEB2021	1/2	2	Yes		NA/TC	R (03FEB2021)	N/N	
16-55/ C4591001 1007 10071157	GENRL	Injection site pain/ burning sensaion at injection site	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y	
16-55/ C4591001 1007 10071158	GENRL	Injection site pain/ tenderness at injection site	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INFEC	Folliculitis/ Folliculitis#	3	02MAR2021	13/5	1	No	O	NA/TCN	R (06MAR2021)	N/N
16-55/ C4591001 1007 10071159	BLOOD	Lymphadenopathy/ Left axilla enlarged lymph node	1	11AUG2020	2/2	1	Yes		NA/TC	R (12AUG2020)	N/N
16-55/ C4591001 1007 10071162	GENRL	Injection site pain/ Muscle soreness at injection site#	3	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1007 10071171	GENRL	Injection site pain/ injection site pain#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1007 10071172	EAR	Ear discomfort/ Right ear pressure	2	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Malaise/ Malaise	2	03SEP2020	2/2	2	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1007 10071175	GENRL	Injection site pain/ Injection site soreness#	3	14JAN2021	1/3	2	Yes		NA	R (16JAN2021)	N/N
	GENRL	Chills/ chills#	3	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
16-55/ C4591001 1007 10071181	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	1	17AUG2020	6/8	1	No	O	NA	R (24AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1007 10071185	SKIN	Rash/ generalized Rash	2	05SEP2020	4/7	2	No	O	NA/TC	R (11SEP2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	05JAN2021	1/3	2	Yes		NA/TCN	R (07JAN2021)	N/N	
16-55/ C4591001 1007 10071186	INFEC	Dermatitis infected/ Infected Atopic Dermatitis of the cheek	2	28SEP2020	26/11	2	No	O	NA/TC	R (08OCT2020)	N/N	
16-55/ C4591001 1007 10071194	SKIN	Ecchymosis/ right foot ecchymosis	1	25AUG2020	13/64	2	No	O	NA/TC/TCN	R (27OCT2020)	N/N	
16-55/ C4591001 1007 10071203	GENRL	Fatigue/ Fatigue#	3	12JAN2021	2/3	1	Yes		NA	R (14JAN2021)	N/N	
		Injection site pain/ Injection site arm pain#	3	12JAN2021	2/1	1	Yes		NA/TC	R (12JAN2021)	N/N	
	NERV	Headache/ Headache#	3	12JAN2021	2/1	1	Yes		NA/TC	R (12JAN2021)	N/N	
16-55/ C4591001 1007 10071207	GENRL	Fatigue/ fatigue	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N	
16-55/ C4591001 1007 10071207		Injection site pain/ injection site soreness	1	17AUG2020	1/2	1	Yes		NA/TC	R (18AUG2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1007 10071208	MUSC	Pyrexia/ Fever	2	09SEP2020	2/2	1	Yes		NA/TC	R (10SEP2020)	N/N	
		Myalgia/ Myalgia	2	09SEP2020	2/2	1	Yes		NA/TC	R (10SEP2020)	N/N	
	RENAL	Dysuria/ intermittent dysuria	2	09SEP2020	2/26	2	No	O	NA/TC	R (04OCT2020)	N/N	
		Pollakiuria/ intermittent urinary frequency	2	09SEP2020	2/26	1	No	O	NA/TC	R (04OCT2020)	N/N	
	INFEC	Viral infection/ viral illness	2	08SEP2020	1/84	1	No	O	NA	R (30NOV2020)	N/N	
16-55/ C4591001 1007 10071217	CARD	Palpitations/ heart palpitations	2	23SEP2020	16/69	1	No	O	NA/TC	R (30NOV2020)	N/N	
	GENRL	Chest pain/ Chest Pain	2	23SEP2020	16/69	1	No	O	NA/TC	R (30NOV2020)	N/N	
	NERV	Headache/ Headache	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N	
16-55/ C4591001 1007 10071218	GENRL	Injection site pain/ Injection site pain#	3	07JAN2021	1/2	2	Yes		NA/TC	R (08JAN2021)	N/Y	
	MUSC	Myalgia/ myalgia to neck and shoulder	1	21AUG2020	3/3	1	Yes		NA/TC	R (23AUG2020)	N/N	
16-55/ C4591001 1007 10071219	INJ&P	Joint injury/ Left Knee Injury	1	09SEP2020	22/104	2	No	O	NA/TCN	R (21DEC2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071228	GENRL	Fatigue/ Fatigue#	3	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1007 10071229	GENRL	Injection site pain/ Injection site pain#	3	11JAN2021	1/2	2	Yes		NA/TC	R (12JAN2021)	N/N
16-55/ C4591001 1007 10071233	GENRL	Fatigue/ Fatigue#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
		Injection site pain/ injection site pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1007 10071235	GENRL	Injection site pain/ Injection site arm pain#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ Headache#	3	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1007 10071236	MUSC	Myalgia/ left arm muscle pain*		20AUG2020	1/1	2	Yes		NA/TC	R (20AUG2020)	N/N
16-55/ C4591001 1007 10071238	SKIN	Rash/ rash	2	12SEP2020	3/17	1	No	O	NA	R (28SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1007 10071246 16-55/ C4591001 1007 10071253	GENRL	Injection site erythema/ redness at injection site	1	24AUG2020	1/2	2	Yes		NA	R (25AUG2020)	N/Y
		Injection site induration/ induration at injection site	1	24AUG2020	1/2	1	Yes		NA	R (25AUG2020)	N/Y
	GENRL	Injection site erythema/ redness at injection site	2	14SEP2020	1/1	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	13JAN2021	1/2	2	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1007 10071256	GENRL	Injection site pain/ Injection site pain#	3	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1007 10071276	BLOOD	Leukocytosis/ leukocytosis	2	24SEP2020	8/26	3	No	O	NA	R (19OCT2020)	N/N
		Thrombocytosis/ thrombocytosis	2	24SEP2020	8/33	3	No	O	NA	R (26OCT2020)	N/N
	NEOPL	Chronic myeloid leukaemia/ chronic myelogenous leukemia	2	24SEP2020	8/C	4	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1007 10071280	GENRL	Injection site pain/ Muscle Soreness in arm of injection#	3	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N
	BLOOD	Lymphadenopathy/ bilateral deep cervical swollen lymph nodes#	4	18FEB2021	2/8	1	Yes		NA	R (25FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071284	GENRL	Injection site pain/ Right Arm Injection Site Pain	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	28AUG2020	2/2	2	Yes		NA	R (29AUG2020)	N/N
	SKIN	Rash/ rash on chest	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	RESP	Reflux laryngitis/ laryngopharyngeal reflux	2	02OCT2020	16/1	1	No	O	NA	R (02OCT2020)	N/N
16-55/ C4591001 1007 10071289	GENRL	Injection site erythema/ redness at injection	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/Y
	GENRL	Chills/ Chills	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		Pain/ Bodyaches	2	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N
		Pyrexia/ fever	2	17SEP2020	1/2	2	Yes		NA/TC	R (18SEP2020)	N/N
	MUSC	Pain in extremity/ Left arm soreness	2	17SEP2020	1/7	1	Yes		NA	R (23SEP2020)	N/Y
	NERV	Headache/ Headache	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1007 10071295	INJ&P	Fall/ Fall	2	03OCT2020	18/1	1	No	O	NA	R (03OCT2020)	N/N
		Skin laceration/ Laceration to left leg	2	03OCT2020	18/60	2	No	O	NA/TCN	R (01DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071296	GENRL	Injection site pain/ Injection site pain#	3	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1007 10071307	GENRL	Injection site pain/ pain at injection site	1	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1007 10071334	GENRL	Chills/ chills	2	04NOV2020	1/2	1	Yes		NA/TC	R (05NOV2020)	N/N
		Pyrexia/ fever	2	04NOV2020	1/3	2	Yes		NA/TC	R (06NOV2020)	N/N
	MUSC	Pain in extremity/ pain right arm	2	04NOV2020	1/3	2	Yes		NA	R (06NOV2020)	N/N
	RESP	Dry throat/ dry throat	2	04NOV2020	1/1	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C4591001 1007 10071337	GENRL	Injection site pain/ burning at injection site#	4	01FEB2021	1/1	1	Yes		NA	R (01FEB2021)	N/Y
16-55/ C4591001 1007 10071339	EAR	Vertigo/ Vertigo	2	05NOV2020	3/9	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1007 10071341	GENRL	Injection site pain/ Injection site pain#	3	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071342	GENRL	Injection site pain/ Muscle Soreness in Arm of Injection site#	3	14JAN2021	1/3	1	Yes		NA	R (16JAN2021)	N/N
16-55/ C4591001 1007 10071350	MUSC	Pain in extremity/ Sore Arm	1	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	06NOV2020	2/3	1	Yes		NA/TC	R (08NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	06NOV2020	2/2	2	Yes		NA/TC	R (07NOV2020)	N/N
16-55/ C4591001 1007 10071352	GENRL	Injection site pain/ Injection site pain	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1007 10071353	METAB	Decreased appetite/ loss of appetite	2	06NOV2020	2/13	1	Yes		NA	R (18NOV2020)	N/N
16-55/ C4591001 1007 10071358	MUSC	Myalgia/ bilateral quadriceps myalgia	2	13NOV2020	4/4	1	Yes		NA	R (16NOV2020)	N/N
16-55/ C4591001 1007 10071362	GENRL	Injection site pain/ Tenderness at injection site	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1007 10071365	GENRL	Chills/ Chills	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N	
		Malaise/ Malaise	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N	
	NERV	Headache/ Headache	2	10NOV2020	2/1	1	Yes		NA/TC	R (10NOV2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	20OCT2020	2/4	1	Yes		NA	R (23OCT2020)	N/N	
	NERV	Headache/ Headache	1	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue#	3	03MAR2021	1/4	1	Yes		NA	R (06MAR2021)	N/N	
	NERV	Headache/ Headache#	3	03MAR2021	1/2	1	Yes		NA	R (04MAR2021)	N/N	
	GASTR	Gingival discomfort/ Gum irritation	1	03NOV2020	16/8	2	No	O	NA/TC	R (10NOV2020)	N/N	
	GENRL	Injection site pain/ Tenderness at injection site	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N	
	GENRL	Injection site pain/ Injection Site pain	1	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/Y	
16-55/ C4591001	CARD	Palpitations/ heart palpitations	1	09NOV2020	21/3	1	Yes		NA/TC	R (11NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1007 10071374	INFEC	Vaginal infection/ Vaginitis	1	09NOV2020	21/10	2	No	O	NA/TC	R (18NOV2020)	N/N
	GASTR	Nausea/ nausea	2	12NOV2020	3/2	1	Yes		NA	R (13NOV2020)	N/N
	NERV	Headache/ headache	2	12NOV2020	3/2	2	Yes		NA/TC	R (13NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1007 10071376	MUSC	Myalgia/ Muscle Aches	2	11NOV2020	2/1	1	Yes		NA	R (11NOV2020)	N/N
	SKIN	Alopecia/ Increased Hair Loss	2	23NOV2020	14/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1007 10071377	NERV	Headache/ Headache#	3	12JAN2021	1/2	3	Yes		NA/TC	R (13JAN2021)	N/N
16-55/ C4591001 1007 10071381	MUSC	Pain in extremity/ Generalized soreness left upper arm#	3	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1007 10071382	GENRL	Pyrexia/ Fever	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
	NERV	Headache/ Headache	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071385	GENRL	Pyrexia/ fever	1	21OCT2020	2/1	1	Yes		NA/TC	R (21OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	11NOV2020	2/1	1	Yes		NA/TCN	R (11NOV2020)	N/N
16-55/ C4591001 1007 10071388	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	1/5	2	Yes		NA	R (25OCT2020)	N/N
	NERV	Headache/ Headache	1	21OCT2020	1/2	2	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1007 10071390	MUSC	Pain in extremity/ sore arm	1	21OCT2020	1/4	1	Yes		NA	R (24OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Chills/ Chills	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
		Fatigue/ Fatigue	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1007 10071392	GENRL	Injection site pain/ Pain at injection site	1	21OCT2020	1/3	2	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain in injection arm	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1007 10071397	GENRL	Injection site pain/ Injection Site Pain#	3	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N	
	PSYCH	Anxiety/ Anxiety#	3	11JAN2021	1/1	1	Yes		NA	R (11JAN2021)	N/Y	
16-55/ C4591001 1007 10071398	GENRL	Chills/ Chills#	3	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N	
		Injection site pain/ Injection site pain#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N	
		Pyrexia/ Fever#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N	
16-55/ C4591001 1007 10071399	GENRL	Injection site pain/ Injection site pain#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
16-55/ C4591001 1007 10071400	GENRL	Pyrexia/ fever	1	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N	
16-55/ C4591001 1007 10071401	GENRL	Injection site pain/ injection site pain	1	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N	
		Malaise/ Malaise	1	22OCT2020	2/3	1	Yes		NA	R (24OCT2020)	N/N	
	GENRL	Chills/ Chills	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071404	MUSC	Pyrexia/ Fever	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N
		Myalgia/ Myalgia	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N
		Nausea/ nausea	1	23OCT2020	3/1	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1007 10071406	GENRL	Vomiting/ vomiting	1	23OCT2020	3/1	1	Yes		NA	R (23OCT2020)	N/N
		Injection site pain/ Pain at injection site	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/Y
16-55/ C4591001 1007 10071407	RESP	Epistaxis/ epistaxis	1	16NOV2020	26/1	1	No	O	NA	R (16NOV2020)	N/N
16-55/ C4591001 1007 10071408	GENRL	Fatigue/ Fatigue#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
		Injection site pain/ injection site tenderness#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
		NERV	Headache/ headache#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)
16-55/ C4591001 1007 10071408	GASTR	Diarrhoea/ Diarrhea	2	04DEC2020	2/4	1	Yes		NA	R (07DEC2020)	N/N
		Vomiting/ Vomiting	2	04DEC2020	2/3	1	Yes		NA	R (06DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071410	GENRL	Chills/ Chills	2	04DEC2020	2/3	1	Yes		NA/TC	R (06DEC2020)	N/N
		Pyrexia/ fever	2	04DEC2020	2/3	2	Yes		NA/TC	R (06DEC2020)	N/N
	MUSC	Myalgia/ Myalgia	2	04DEC2020	2/3	2	Yes		NA/TC	R (06DEC2020)	N/N
	GENRL	Injection site pain/ Injection site arm pain#	3	12JAN2021	1/2	2	Yes		NA/TC	R (13JAN2021)	N/N
	NERV	Headache/ Headache#	3	13JAN2021	2/2	2	Yes		NA/TC	R (14JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Chills/ chills#	4	11MAR2021	1/3	1	Yes		NA	R (13MAR2021)	N/N
	MUSC	Myalgia/ myalgias#	4	11MAR2021	1/3	2	Yes		NA/TC	R (13MAR2021)	N/N
	NERV	Headache/ headache#	4	11MAR2021	1/3	2	Yes		NA/TC	R (13MAR2021)	N/N
16-55/ C4591001 1007 10071416	GENRL	Pyrexia/ Fever	2	13NOV2020	2/1	1	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1007 10071421	GENRL	Injection site pain/ injection site pain	2	13NOV2020	2/4	2	Yes		NA/TC	R (16NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071422	NERV	Injection site pain/ injection site tenderness	2	13NOV2020	2/5	2	Yes		NA/TC	R (17NOV2020)	N/N
		Headache/ headache	2	13NOV2020	2/4	2	Yes		NA/TC	R (16NOV2020)	N/N
16-55/ C4591001 1007 10071422	GENRL	Vessel puncture site pain/ Pain at blood draw site*		22OCT2020	1/1	1	No	O	NA	R (22OCT2020)	N/N
16-55/ C4591001 1007 10071423	GENRL	Fatigue/ fatigue	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
		Vessel puncture site pain/ pain at blood draw site*		22OCT2020	1/2	1	No	O	NA	R (23OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N
	NERV	Headache/ Headache	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Chills/ chills	1	27OCT2020	6/2	1	Yes		NA	R (28OCT2020)	N/N
		Fatigue/ fatigue	1	27OCT2020	6/2	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	13NOV2020	2/2	2	Yes		NA/TC	R (14NOV2020)	N/N
		Pyrexia/ Fever	2	13NOV2020	2/2	1	Yes		NA/TC	R (14NOV2020)	N/N
	NERV	Headache/ Headache	2	13NOV2020	2/2	2	Yes		NA/TC	R (14NOV2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ sorness at injection site	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1007 10071424	GENRL	Injection site pain/ Injection Site Pain*		22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N	
16-55/ C4591001 1007 10071426	MUSC	Myalgia/ Myalgia (Generalized)	1	24OCT2020	3/2	2	Yes		NA	R (25OCT2020)	N/N	
	GENRL	Injection site pain/ injection site tenderness	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N	
	MUSC	Arthralgia/ generalized arthralgia	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N	
16-55/ C4591001 1007 10071427	GENRL	Chills/ Chills#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N	
		Pain/ Body Aches#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N	
	NERV	Headache/ Headache#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
16-55/ C4591001 1007 10071433	NERV	Headache/ headache	1	30OCT2020	4/7	2	Yes		NA/TC	R (05NOV2020)	N/N	
	GASTR	Nausea/ Nausea	1	31OCT2020	5/3	2	Yes		NA	R (02NOV2020)	N/N	
	GENRL	Pyrexia/ fever	1	31OCT2020	5/2	1	Yes		NA/TC	R (01NOV2020)	N/N	
	GASTR	Vomiting/ Vomiting	1	01NOV2020	6/1	1	Yes		NA	R (01NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071439	NERV	Headache/ Headache	2	20NOV2020	4/C	1	Yes		NA	RG	N/N
	GENRL	Chills/ Chills	2	20NOV2020	2/2	1	Yes		NA/TC	R (21NOV2020)	N/N
		Pyrexia/ Fever	2	20NOV2020	2/2	2	Yes		NA/TC	R (21NOV2020)	N/N
16-55/ C4591001 1007 10071440	NERV	Headache/ Headache	2	20NOV2020	2/2	1	Yes		NA/TC	R (21NOV2020)	N/N
	GENRL	Chills/ chills	2	19NOV2020	1/2	2	Yes		NA/TC	R (20NOV2020)	N/N
		Pyrexia/ fever	2	19NOV2020	1/2	2	Yes		NA/TC	R (20NOV2020)	N/N
16-55/ C4591001 1007 10071441	NERV	Headache/ headache	2	20NOV2020	2/1	2	Yes		NA/TC	R (20NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	19FEB2021	2/4	1	Yes		NA	R (22FEB2021)	N/N
16-55/ C4591001 1007 10071442	NERV	Facial paralysis/ Bell's Palsy#	4	13MAR2021	3/C	3	Yes		NA/TC	RG	N/N
	GENRL	Injection site pain/ Injection site pain#	3	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001	NERV	Generalised tonic-clonic seizure/ Grand Mal Seizure	2	29NOV2020	5/1	3	No	O	NA	R (29NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1007 10071443	GENRL	Injection site pain/ muscle pain at injection site#	3	23FEB2021	1/4	1	Yes		NA	R (26FEB2021)	N/N	
16-55/ C4591001 1007 10071449	GENRL	Chills/ chills#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N	
16-55/ C4591001 1007 10071455	EYE	Lacrimation increased/ Watery Eyes#	3	03MAR2021	3/3	1	No	O	NA	R (05MAR2021)	N/N	
16-55/ C4591001 1007 10071463	GASTR	Nausea/ nausea	1	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N	
16-55/ C4591001 1007 10071464	GENRL	Injection site pain/ Injection site pain#	3	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N	
16-55/ C4591001 1007 10071470	NERV	Headache/ Headache#	3	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N	
16-55/ C4591001 1007 10071493	GENRL	Injection site pain/ Injection site pain#	2	22FEB2021	63/3	1	Yes		NA	R (24FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	3	23FEB2021	2/8	1	No	O	NA	R (02MAR2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1007 10071502	NERV	Headache/ Headache#	3	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N	
	GENRL	Injection site discomfort/ Weighted feeling in injection site arm	1	03DEC2020	1/3	1	Yes		NA	R (05DEC2020)	N/N	
	INFEC	Cellulitis/ Right axillary cellulitis	2	01JAN2021	11/8	2	No	O	NA/TC	R (08JAN2021)	N/N	
16-55/ C4591001 1007 10071510		Folliculitis/ Right axillary folliculitis	2	01JAN2021	11/8	2	No	O	NA	R (08JAN2021)	N/N	
	GENRL	Injection site pain/ Injection Site Pain#	3	22FEB2021	1/2	1	Yes		NA/TC/TCN	R (23FEB2021)	N/N	
16-55/ C4591001 1007 10071538	GENRL	Fatigue/ Fatigue#	3	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N	
16-55/ C4591001 1007 10071548	NERV	Presyncope/ Vasovagal response with venipuncture#	2	11MAR2021	72/1	2	No	O	NA	R (11MAR2021)	N/N	
16-55/ C4591001 1007 10071553	GENRL	Injection site pain/ injection site pain	1	10DEC2020	1/3	1	Yes		NA	R (12DEC2020)	N/Y	
	NERV	Dizziness/ Lightheaded*		10DEC2020	1/1	1	No	O	NA	R (10DEC2020)	N/N	
	GENRL	Chills/ Chills#	3	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081029	NERV	Injection site pain/ Injection site pain#	3	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N
		Pain/ Body aches#	3	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
		Headache/ Headache#	3	18FEB2021	2/2	2	Yes		NA/TC	R (19FEB2021)	N/N
		Nausea/ nausea#	4	05JAN2021	1/2	2	Yes		NA	R (06JAN2021)	N/N
		Chills/ chills#	4	05JAN2021	1/2	2	Yes		NA	R (06JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	05JAN2021	1/2	2	Yes		NA	R (06JAN2021)	N/N
		Pain/ bodyaches#	4	05JAN2021	1/2	2	Yes		NA	R (06JAN2021)	N/N
		Headache/ headache#	4	05JAN2021	1/2	2	Yes		NA	R (06JAN2021)	N/N
		Otitis media/ Right otitis media	2	24OCT2020	51/15	1	No	O	NA/TC	R (07NOV2020)	N/N
		Synovitis/ Synovitis, right wrist(etiology unknown)	2	06OCT2020	23/57	1	No	O	NA/TC	R (01DEC2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
		Headache/ headache#	4	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1008 10081046 16-55/ C4591001 1008 10081064	GENRL	Chills/ chills	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N	
		Fatigue/ fatigue	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N	
		Pyrexia/ fever	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N	
16-55/ C4591001 1008 10081089	GENRL	Chills/ Chills	2	17SEP2020	3/1	2	Yes		NA	R (17SEP2020)	N/N	
		Pain/ Body aches	2	17SEP2020	3/1	2	Yes		NA/TC	R (17SEP2020)	N/N	
16-55/ C4591001 1008 10081095	GENRL	Chills/ chills	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N	
		Fatigue/ fatigue	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001 1008 10081099	INFEC	Gastroenteritis/ gastroenteritis	2	03OCT2020	19/5	2	No	O	NA	R (07OCT2020)	N/N	
	NERV	Nerve compression/ pinched nerve right shoulder#	4	02MAR2021	21/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001	GENRL	Chills/ chills#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1008 10081101		Fatigue/ fatigue#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N	
		Injection site pain/ injection site pain#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N	
	NERV	Headache/ headache#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N	
16-55/ C4591001 1008 10081103	GENRL	Chills/ chills#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N	
		Injection site pain/ injection site pain#	3	20JAN2021	1/2	2	Yes		NA	R (21JAN2021)	N/N	
	GASTR	Vomiting/ vomiting#	3	21JAN2021	2/1	1	Yes		NA	R (21JAN2021)	N/N	
	GENRL	Pain/ body aches#	3	21JAN2021	2/1	1	Yes		NA	R (21JAN2021)	N/N	
16-55/ C4591001 1008 10081138	INJ&P	Skin laceration/ Finger laceration	1	06SEP2020	10/32	2	No	O	NA/TC	R (07OCT2020)	N/N	
16-55/ C4591001 1008 10081142	GENRL	Pain/ Body aches	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	
		Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N	
	NERV	Headache/ Headache	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1008 10081143	GENRL	Pain/ body aches#	4	09JAN2021	2/2	1	Yes		NA/TC	R (10JAN2021)	N/N	
	NERV	Headache/ headache#	4	09JAN2021	2/2	1	Yes		NA/TC	R (10JAN2021)	N/N	
16-55/ C4591001 1008 10081149	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
		Injection site pain/ Injection site pain left arm	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
		Pain/ Body aches	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 1008 10081150	GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
		Pain/ Body aches	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 1008 10081151	GENRL	Pain/ body aches#	4	19JAN2021	2/1	1	Yes		NA	R (19JAN2021)	N/N	
		Pyrexia/ low grade fever#	4	19JAN2021	2/1	1	Yes		NA	R (19JAN2021)	N/N	
16-55/ C4591001 1008 10081152	NERV	Optic neuritis/ Optic neuritis left eye	2	09DEC2020	80/14	3	No	O	NA/TC	R (22DEC2020)	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081155	MUSC	Myalgia/ Generalized muscle aches	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	NERV	Headache/ Headache	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain Left deltoid	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
		Pain/ Body aches	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1008 10081159	GENRL	Injection site pain/ Injection site pain left arm	2	22SEP2020	1/5	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1008 10081160	GASTR	Diarrhoea/ Diarrhea	1	02SEP2020	2/6	1	Yes		NA	R (07SEP2020)	N/N
		Nausea/ Nausea	1	02SEP2020	2/6	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1008 10081166	GASTR	Diarrhoea/ Diarrhea	1	12SEP2020	11/4	1	Yes		NA	R (15SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	30SEP2020	8/4	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1008 10081183												
16-55/ C4591001 1008 10081193	GENRL	Pain/ body aches	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N	
	GENRL	Chills/ chills	2	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1008 10081194	GENRL	Chills/ chills#	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N	
		Pain/ bodyaches#	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N	
16-55/ C4591001 1008 10081197	GASTR	Vomiting/ VOMITING#	4	08JAN2021	1/1	1	Yes		NA	R (08JAN2021)	N/N	
	GENRL	Chills/ CHILLS#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N	
16-55/ C4591001 1008 10081198	GENRL	Fatigue/ Fatigue	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N	
16-55/ C4591001 1008 10081215	GENRL	Pyrexia/ Fever	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N	
	MUSC	Myalgia/ Muscle aches	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081217	CARD	Tachycardia/ Tachycardia	1	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/Y
16-55/ C4591001 1008 10081225	GENRL	Fatigue/ Fatigue	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Pain/ Body aches	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1008 10081232	GENRL	Injection site pain/ injection site pain#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
	NERV	Headache/ Headache#	3	29JAN2021	4/2	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1008 10081235	VASC	Hypertension/ Hypertension#	2	17DEC2020	81/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1008 10081240	GENRL	Pain/ Body aches#	3	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1008 10081244	GENRL	Injection site pain/ intermittent injection site pain#	3	18JAN2021	1/C	1	Yes		NA	RG	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1008 10081256		Pain/ Body aches	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N	
16-55/ C4591001 1008 10081257	GENRL	Fatigue/ fatigue#	4	22JAN2021	2/1	1	Yes		NA	R (22JAN2021)	N/N	
16-55/ C4591001 1008 10081258	GENRL	Fatigue/ Fatigue	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
	GENRL	Pain/ Body aches	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	01OCT2020	1/4	1	Yes		NA	R (04OCT2020)	N/N	
	MUSC	Arthralgia/ Joint pain	2	01OCT2020	1/4	1	Yes		NA/TC	R (04OCT2020)	N/N	
16-55/ C4591001 1008 10081260	SKIN	Alopecia areata/ Alopecia areata	1	23SEP2020	15/C	1	Yes		NA	RG	N/N	
16-55/ C4591001 1008 10081261	GENRL	Pain/ Body aches	1	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N	
	NERV	Headache/ Headaches	1	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Chills/ Chills	2	01OCT2020	1/2	2	Yes		NA	R (02OCT2020)	N/N	
		Pain/ Body aches	2	01OCT2020	1/2	2	Yes		NA/TC	R (02OCT2020)	N/N	
		Pyrexia/ Fever	2	01OCT2020	1/2	2	Yes		NA/TC	R (02OCT2020)	N/N	
	NERV	Headache/ Headache	2	01OCT2020	1/2	2	Yes		NA/TC	R (02OCT2020)	N/N	
16-55/ C4591001 1008 10081271	GENRL	Injection site pain/ injection site pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N	
	GENRL	Injection site pain/ injection site pain	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N	
	GENRL	Pain/ bodyaches	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N	
16-55/ C4591001 1008 10081281	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N	
		Pain/ Body aches#	3	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N	
16-55/ C4591001 1008 10081289	GENRL	Injection site pain/ Injection site pain	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N	
		Pain/ Body aches	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N	
16-55/ C4591001	GENRL	Chills/ Chills	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1008 10081293		Injection site pain/ Injection site pain	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N	
		Pain/ Body aches	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001 1008 10081300	GASTR	Eosinophilic oesophagitis/ Eosinophilic esophagitis#	2	08JAN2021	99/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1008 10081313	GENRL	Injection site pain/ injection site pain#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N	
16-55/ C4591001 1008 10081314	INFEC	Urinary tract infection/ Urinary tract infection	1	30SEP2020	17/11	1	No	O	NA/TC	R (10OCT2020)	N/N	
	GENRL	Pyrexia/ fever(102.5)#	4	10FEB2021	1/2	3	Yes		NA/TC	R (11FEB2021)	N/N	
	NERV	Headache/ headache#	4	10FEB2021	1/2	2	Yes		NA/TC	R (11FEB2021)	N/N	
16-55/ C4591001 1008 10081316	GENRL	Fatigue/ Fatigue	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N	
		Pain/ Body aches	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N	
16-55/ C4591001	GENRL	Pain/ Body aches	2	06OCT2020	2/5	1	Yes		NA	R (10OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1008 10081321	GENRL	Chills/ Chills	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N	
16-55/ C4591001 1008 10081327		Pain/ Body aches	2	06OCT2020	2/3	1	Yes		NA	R (08OCT2020)	N/N	
		Pyrexia/ Fever	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N	
	NERV	Headache/ Headache	2	06OCT2020	2/3	1	Yes		NA	R (08OCT2020)	N/N	
16-55/ C4591001 1008 10081333	GENRL	Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N	
		Pyrexia/ Fever	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N	
16-55/ C4591001 1008 10081337	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N	
		Pain/ Body aches	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N	
	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	2	23DEC2020	79/C		No	O	NA	UNK	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/4	1	Yes		NA/TC	R (31JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1008 10081338	GENRL	Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N	
16-55/ C4591001 1008 10081341	NERV	Fatigue/ Fatigue Headache/ Headache	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N	
16-55/ C4591001 1008 10081343	VASC	Hypertension/ Hypertension	2	NOV2020	27/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1008 10081344	GENRL	Injection site bruising/ Injection site bruising#	3	01JAN2021	2/15	1	Yes		NA	R (15JAN2021)	N/N	
16-55/ C4591001 1008 10081346	GENRL	Injection site pain/ Injection site pain# Chills/ Chills	3	01JAN2021	2/2	2	Yes		NA	R (02JAN2021)	N/N	
	GENRL	Chills/ Chills	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site soreness	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N	
	GENRL	Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site soreness	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1008 10081347	GENRL	Pyrexia/ Fever	1	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N	
	GENRL	Chills/ Chills	2	09OCT2020	2/2	2	Yes		NA	R (10OCT2020)	N/N	
		Pyrexia/ Fever	2	09OCT2020	2/2	2	Yes		NA	R (10OCT2020)	N/N	
16-55/ C4591001 1008 10081348	GENRL	Chills/ Chills	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N	
		Pain/ Body aches	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N	
	NERV	Headache/ Headache	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N	
16-55/ C4591001 1008 10081350	INFEC	Gastroenteritis viral/ viral gastroenteritis	2	22OCT2020	15/3	2	No	O	NA	R (24OCT2020)	N/N	
	NERV	Headache/ headache#	4	09JAN2021	2/1	1	Yes		NA/TC	R (09JAN2021)	N/N	
16-55/ C4591001 1008 10081361	GASTR	Diarrhoea/ diarrhea	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001 1008 10081364	GASTR	Diarrhoea/ Diarrhea	1	20SEP2020	5/1	1	Yes		NA	R (20SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Pain/ Bodyaches#	4	07JAN2021	1/3	2	Yes		NA	R (09JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Chills/ Chills#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
		Pyrexia/ Fever#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ Headache#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1008 10081365	GENRL	Injection site pain/ injection site pain#	3	28JAN2021	1/3	2	Yes		NA	R (30JAN2021)	N/N
	NERV	Headache/ headache#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1008 10081366	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	07OCT2020	1/3	2	Yes		NA/TC	R (09OCT2020)	N/N
	GENRL	Chills/ Chills	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
		Pyrexia/ Fever	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Migraine/ Migraine	2	08OCT2020	2/2	2	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1008 10081367	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/4	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	2/5	1	Yes		NA	R (12OCT2020)	N/N
16-55/ C4591001 1008 10081382	GENRL	Injection site pain/ injection site pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1008 10081384	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1008 10081388	METAB	Decreased appetite/ Loss of appetite	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1008 10081391	GASTR	Diarrhoea/ Diarrhea	1	30SEP2020	14/1	1	No	O	NA	R (30SEP2020)	N/N
		Nausea/ Nausea	1	30SEP2020	14/1	1	No	O	NA	R (30SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1008 10081393	INFEC	Vomiting/ Vomiting	1	30SEP2020	14/1	1	No	O	NA	R (30SEP2020)	N/N	
		Ear infection/ Left ear infection	2	31OCT2020	24/10	1	No	O	NA	R (09NOV2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N	
16-55/ C4591001 1008 10081402	GENRL	Injection site pain/ Injection site pain	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N	
16-55/ C4591001 1008 10081404	GENRL	Chills/ Chills	2	10OCT2020	2/2	3	Yes		NA	R (11OCT2020)	N/N	
		Fatigue/ Fatigue	2	10OCT2020	2/1	3	Yes		NA	R (10OCT2020)	N/N	
		Injection site erythema/ Injection site redness	2	10OCT2020	2/3	2	Yes		NA	R (12OCT2020)	N/N	
		Injection site pain/ Injection site pain	2	10OCT2020	2/2	2	Yes		NA/TC	R (11OCT2020)	N/N	
		Injection site swelling/ Injection site swelling	2	10OCT2020	2/3	2	Yes		NA	R (12OCT2020)	N/N	
		METAB	Decreased appetite/ Loss of appetite	2	10OCT2020	2/2	2	Yes		NA	R (11OCT2020)	N/N
	PSYCH	Anxiety/ Anxiety episode	1	18SEP2020	1/1	2	Yes		NA/TCN	R (18SEP2020)	N/Y	
16-55/ C4591001	GENRL	Chills/ Chills	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1008 10081408	GENRL	Injection site pain/ Injection site pain	1	19SEP2020	2/1	1	Yes	NA	NA	R (19SEP2020)	N/N
1008 10081410	GENRL	Injection site pain/ Injection site pain	2	10OCT2020	2/1	1	Yes	NA	NA	R (10OCT2020)	N/N
16-55/ C4591001 1008 10081425	GENRL	Fatigue/ Fatigue#	3	23JAN2021	2/2	1	Yes	NA	NA	R (24JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	23JAN2021	2/2	2	Yes	NA	NA	R (24JAN2021)	N/N
		Pyrexia/ Fever#	3	23JAN2021	2/2	1	Yes	NA	NA	R (24JAN2021)	N/N
	NERV	Headache/ Headache#	3	23JAN2021	2/2	2	Yes	NA	NA	R (24JAN2021)	N/N
16-55/ C4591001 1008 10081427	GENRL	Fatigue/ Fatigue	1	21SEP2020	1/2	1	Yes	NA	NA	R (22SEP2020)	N/N
		Injection site pain/ Injection site pain	1	21SEP2020	1/2	1	Yes	NA/TC	NA/TC	R (22SEP2020)	N/N
	NERV	Headache/ Headache	1	21SEP2020	1/3	1	Yes	NA/TC	NA/TC	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12OCT2020	1/3	1	Yes	NA	NA	R (14OCT2020)	N/N
		Injection site pain/ Injection site pain	2	12OCT2020	1/3	1	Yes	NA/TC	NA/TC	R (14OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081430	NERV	Headache/ Headache	2	12OCT2020	1/3	1	Yes		NA/TC	R (14OCT2020)	N/N
	NERV	Headache/ Headache#	3	29DEC2020	2/2	1	Yes		NA	R (30DEC2020)	N/N
	GENRL	Chills/ chills#	4	19JAN2021	2/2	2	Yes		NA	R (20JAN2021)	N/N
	GENRL	Pain/ bodyaches#	4	19JAN2021	2/2	2	Yes		NA/TC	R (20JAN2021)	N/N
16-55/ C4591001 1008 10081435	IN FEC	Pyrexia/ fever#	4	19JAN2021	2/2	1	Yes		NA/TC	R (20JAN2021)	N/N
16-55/ C4591001 1008 10081435	IN FEC	Tooth infection/ Tooth infection	2	07NOV2020	27/6	1	No	O	NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1008 10081453	GENRL	Chills/ Chills	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1008 10081462	GENRL	Pyrexia/ Fever	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
	GENRL	Pain/ body aches#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1008 10081463	IN FEC	Sinusitis/ Sinus infection	2	01NOV2020	20/13	2	No	O	NA/TC	R (13NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081468	GENRL	Injection site pain/ Injection site pain	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Chills/ Chills	2	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1008 10081471	GENRL	Injection site pain/ injection site pain#	4	09JAN2021	2/3	2	Yes		NA	R (11JAN2021)	N/N
		Pain/ Body aches#	4	09JAN2021	2/2	2	Yes		NA/TC	R (10JAN2021)	N/N
		Pyrexia/ Fever#	4	09JAN2021	2/2	2	Yes		NA/TC	R (10JAN2021)	N/N
	NERV	Headache/ headache#	4	09JAN2021	2/2	2	Yes		NA/TC	R (10JAN2021)	N/N
16-55/ C4591001 1008 10081474	GENRL	Injection site pain/ injection site pain#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1008 10081477	GENRL	Pyrexia/ Fever(101.3 degrees fahrenheit)	2	14OCT2020	1/3	2	Yes		NA	R (16OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	14OCT2020	1/3	2	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1008 10081485	GASTR	Nausea/ Nausea	2	14OCT2020	1/5	1	Yes		NA	R (18OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081492	GENRL	Fatigue/ Fatigue	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N
		Injection site pain/ Injection site pain	2	14OCT2020	1/4	2	Yes		NA/TC	R (17OCT2020)	N/N
	NERV	Headache/ Headache	2	14OCT2020	1/2	2	Yes		NA/TC	R (15OCT2020)	N/N
	GASTR	Toothache/ Toothache	1	03OCT2020	11/5	1	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1008 10081496	GENRL	Fatigue/ Fatigue	2	10NOV2020	2/4	1	Yes		NA	R (13NOV2020)	N/N
		Injection site erythema/ Injection site redness	2	10NOV2020	2/4	1	Yes		NA	R (13NOV2020)	N/N
		Injection site pain/ Injection site arm soreness	2	10NOV2020	2/4	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1008 10081496	GASTR	Tooth impacted/ Impacted wisdom tooth	1	08OCT2020	16/1	2	No	O	NA/TC/TCN	R (08OCT2020)	N/N
16-55/ C4591001 1008 10081497	GASTR	Abdominal pain upper/ Upper abdominal pain	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Pain/ Body aches	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Pain/ Body aches	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001	GENRL	Pain/ Body aches	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1008 10081500	NERV	Headache/ Headache	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N	
	GENRL	Pyrexia/ Fever	2	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001 1008 10081513	GENRL	Injection site pain/ Injection site pain	1	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N	
	GENRL	Chills/ Chills	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N	
		Pain/ Body aches	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N	
16-55/ C4591001 1008 10081518	GENRL	Injection site pain/ injection site pain#	3	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N	
16-55/ C4591001 1008 10081524	GENRL	Injection site pain/ Injection site pain	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
16-55/ C4591001 1008 10081525	GENRL	Injection site pain/ Injection site pain	1	24SEP2020	1/2	2	Yes		NA/TC	R (25SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001	NERV	Headache/ headache#	3	27JAN2021	1/3	1	Yes		NA/TC	R (29JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1008 10081532	GENRL	Injection site pain/ injection site pain#	3	28JAN2021	2/3	1	Yes		NA/TC	R (30JAN2021)	N/N	
		Pyrexia/ Low grade temperature#	3	28JAN2021	2/3	1	Yes		NA/TC	R (30JAN2021)	N/N	
16-55/ C4591001 1008 10081533	GENRL	Injection site pain/ Injection site pain	1	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N	
16-55/ C4591001 1008 10081541	GENRL	Pain/ Body aches	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N	
16-55/ C4591001 1008 10081548	GENRL	Injection site pain/ Injection site pain	1	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N	
	GASTR	Nausea/ nausea	1	03OCT2020	6/1	1	Yes		NA	R (03OCT2020)	N/N	
	NERV	Dizziness/ Dizziness	1	03OCT2020	6/1	1	Yes		NA	R (03OCT2020)	N/N	
	GENRL	Injection site pain/ injection site pain	2	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N	
	GASTR	Nausea/ nausea	2	24OCT2020	6/1	1	Yes		NA	R (24OCT2020)	N/N	
	NERV	Dizziness/ Dizziness	2	24OCT2020	6/1	1	Yes		NA	R (24OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081549	GENRL	Fatigue/ Fatigue	1	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ Injection site pain	1	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Chills/ Chills	2	20OCT2020	2/3	2	Yes		NA	R (22OCT2020)	N/N
		Pain/ Body aches	2	20OCT2020	2/3	2	Yes		NA/TC	R (22OCT2020)	N/N
		Pyrexia/ Fever	2	20OCT2020	2/3	2	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1008 10081551	GENRL	Fatigue/ Fatigue#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
		Injection site pain/ injection site pain#	3	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
	NERV	Headache/ headache#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1008 10081554	GENRL	Injection site pain/ injection site pain	2	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
		Pain/ body aches	2	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
		Pyrexia/ fever	2	22OCT2020	2/1	2	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001	MUSC	Myalgia/ generalized muscle pain#	4	07JAN2021	1/1	2	Yes		NA	R (07JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1008 10081555	GENRL	Injection site pain/ injection site pain	2	23OCT2020	2/8	2	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1008 10081557	GENRL	Fatigue/ fatigue	2	24OCT2020	3/7	2	Yes		NA	R (30OCT2020)	N/N
		Pain/ bodyaches	2	24OCT2020	3/7	2	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1008 10081567	GENRL	Injection site pain/ Injection site pain	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Chills/ Chills	2	27OCT2020	1/3	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1008 10081568	GENRL	Injection site pain/ injection site pain#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1008 10081572	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/3	1	Yes		NA/TC	R (09OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	28OCT2020	1/3	1	Yes		NA	R (30OCT2020)	N/N
	GENRL	Chills/ Chills	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N
		Fatigue/ Fatigue	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081574	GENRL	Pain/ Body aches	2	29OCT2020	2/2	1	Yes		NA/TC	R (30OCT2020)	N/N
		Injection site pain/ Injection site pain	2	31OCT2020	2/3	1	Yes		NA	R (02NOV2020)	N/N
16-55/ C4591001 1008 10081576	GENRL	Pain/ Body aches	2	31OCT2020	2/3	1	Yes		NA	R (02NOV2020)	N/N
		Injection site pain/ Injection site pain#	3	27JAN2021	1/1	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1008 10081577	GENRL	Injection site pain/ Injection site pain	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1008 10081578	GENRL	Chills/ Chills	1	13OCT2020	5/3	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1008 10081579	GENRL	Fatigue/ Fatigue	1	13OCT2020	5/3	1	Yes		NA	R (15OCT2020)	N/N
		Injection site pain/ Injection site pain	1	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1008 10081580	GENRL	Fatigue/ Fatigue	1	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081581	MUSC	Myalgia/ Muscle aches	1	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	10OCT2020	2/5	1	Yes		NA	R (14OCT2020)	N/N
		Injection site pruritus/ Injection site itching	1	10OCT2020	2/8	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1008 10081595	GENRL	Fatigue/ Fatigue	1	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
		Injection site pain/ Injection site pain	1	14OCT2020	2/4	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Chills/ Chills	2	03NOV2020	2/2	2	Yes		NA	R (04NOV2020)	N/N
		Fatigue/ Fatigue	2	03NOV2020	2/2	2	Yes		NA	R (04NOV2020)	N/N
		Injection site pain/ Injection site pain	2	03NOV2020	2/2	2	Yes		NA/TC	R (04NOV2020)	N/N
	NERV	Pain/ Body aches	2	03NOV2020	2/2	2	Yes		NA/TC	R (04NOV2020)	N/N
		Headache/ Headache	2	03NOV2020	2/2	2	Yes		NA/TC	R (04NOV2020)	N/N
		Fatigue/ fatigue#	3	10FEB2021	3/1	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1008 10081598	NERV	Headache/ headache#	3	10FEB2021	3/1	1	Yes		NA	R (10FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081600	GENRL	Chills/ Chills	2	04NOV2020	1/4	1	Yes		NA	R (07NOV2020)	N/N
		Pyrexia/ Fever	2	04NOV2020	1/4	3	Yes		NA/TC	R (07NOV2020)	N/N
	GENRL	Pain/ Body aches	2	05NOV2020	2/5	1	Yes		NA	R (09NOV2020)	N/N
16-55/ C4591001 1008 10081605	GENRL	Chills/ Chills	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
		Fatigue/ Fatigue	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
		Pain/ Body aches	1	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
	GENRL	Chills/ chills	2	03NOV2020	1/3	1	Yes		NA	R (05NOV2020)	N/N
	GASTR	Vomiting/ vomiting	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
	GENRL	Pain/ body aches	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
	NERV	Headache/ headache	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
16-55/ C4591001 1008 10081620	GENRL	Injection site pain/ injection site pain#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	NERV	Headache/ headache#	3	01FEB2021	1/1	1	Yes		NA	R (01FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081628	BLOOD	Lymphadenopathy/ swollen lymph nodes left armpit#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	13FEB2021	2/2	2	Yes		NA/TC	R (14FEB2021)	N/N
		Injection site erythema/ injection site redness#	4	13FEB2021	2/6	1	Yes		NA	R (18FEB2021)	N/N
		Injection site pain/ injection site pain#	4	13FEB2021	2/4	2	Yes		NA/TC	R (16FEB2021)	N/N
		Pain/ body aches#	4	13FEB2021	2/2	2	Yes		NA	R (14FEB2021)	N/N
	NERV	Headache/ headache#	4	13FEB2021	2/2	2	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1008 10081629	INJ&P	Ligament rupture/ Torn ligament left knee(no further information)	1	31OCT2020	16/C	2	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1008 10081643	GENRL	Fatigue/ fatigue#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
		Pyrexia/ fever#	3	02FEB2021	2/2	2	Yes		NA/TC	R (03FEB2021)	N/N
16-55/ C4591001 1008 10081647	GENRL	Chills/ Chills	2	10NOV2020	1/3	2	Yes		NA	R (12NOV2020)	N/N
		Pain/ Body aches	2	10NOV2020	1/3	2	Yes		NA/TC	R (12NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081648	NERV	Pyrexia/ Fever	2	10NOV2020	1/3	2	Yes		NA/TC	R (12NOV2020)	N/N
		Headache/ Headache	2	10NOV2020	1/3	2	Yes		NA/TC	R (12NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	NERV	Headache/ Headache#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1008 10081653	GENRL	Chills/ Chills	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1008 10081654	GENRL	Pain/ Body aches	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	11NOV2020	1/2	2	Yes		NA/TC	R (12NOV2020)	N/N
		Chills/ Chills	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
	MUSC	Fatigue/ Fatigue	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
		Injection site pain/ Injection site pain	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001	GENRL	Myalgia/ Generalized muscle aches	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1008 10081655	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	
16-55/ C4591001 1008 10081659	INFEC	Urinary tract infection/ Urinary tract infection	1	05NOV2020	16/6	1	No	O	NA/TC	R (10NOV2020)	N/N	
16-55/ C4591001 1008 10081663	METAB	Hypercholesterolaemia/ hypercholesterolemia	2	28DEC2020	47/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1008 10081669	VASC	Hypertension/ hypertension	2	28DEC2020	47/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1008 10081673	GENRL	Fatigue/ Fatigue	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N	
16-55/ C4591001 1008 10081673	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N	
16-55/ C4591001 1008 10081680	GENRL	Chills/ Chills	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N	
		Fatigue/ Fatigue	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N	
		Injection site pain/ Injection site pain	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1008 10081695	GENRL	Injection site pain/ Injection site pain	1	27OCT2020	2/4	1	Yes		NA	R (30OCT2020)	N/N	
	RENAL	Nephrolithiasis/ Kidney stone	1	02NOV2020	8/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1008 10081696	GENRL	Injection site pain/ Injection site pain	1	26OCT2020	1/8	1	Yes		NA	R (02NOV2020)	N/N	
	NERV	Headache/ Headache	1	31OCT2020	6/1	1	Yes		NA	R (31OCT2020)	N/N	
16-55/ C4591001 1008 10081703	GENRL	Injection site pain/ Injection site pain	1	28OCT2020	2/3	1	Yes		NA	R (30OCT2020)	N/N	
16-55/ C4591001 1008 10081710	GENRL	Chills/ Chills	2	18NOV2020	1/2	1	Yes		NA	R (19NOV2020)	N/N	
		Fatigue/ Fatigue	2	18NOV2020	1/4	2	Yes		NA	R (21NOV2020)	N/N	
		Injection site pain/ Left arm pain(injection site pain)	2	18NOV2020	1/7	2	Yes		NA	R (24NOV2020)	N/N	
16-55/ C4591001 1008 10081712	GENRL	Injection site pain/ injection site pain#	3	02FEB2021	1/2	1	Yes		NA	RS (03FEB2021)	N/N	
	NERV	Headache/ headache#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081715	GENRL	Injection site pain/ Injection site pain	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1008 10081719	GENRL	Fatigue/ Fatigue	1	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N
		Injection site pain/ Injection site pain	1	29OCT2020	2/4	1	Yes		NA	R (01NOV2020)	N/N
16-55/ C4591001 1008 10081720	GENRL	Fatigue/ fatigue#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1008 10081727	GENRL	Injection site pain/ Injection site pain	1	29OCT2020	1/3	1	Yes		NA	R (31OCT2020)	N/N
16-55/ C4591001 1008 10081737	GENRL	Pyrexia/ fever (101.0 F)	1	31OCT2020	2/12	2	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1008 10081738	GENRL	Injection site pain/ injection site pain#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1008 10081776	GENRL	Pain/ body aches#	3	27FEB2021	2/3	2	Yes		NA/TC	R (01MAR2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1009 10091012	NERV	Pyrexia/ Fever#	3	27FEB2021	2/3	2	Yes		NA/TC	R (01MAR2021)	N/N	
		Headache/ Headache#	3	27FEB2021	2/C	2	Yes		NA/TC	RG	N/N	
	GENRL	Fatigue/ fatigue#	3	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N	
16-55/ C4591001 1009 10091045	MUSC	Pain/ body aches#	3	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N	
		Muscle spasms/ back muscle spasm#	3	17JAN2021	18/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1009 10091061	VASC	Hypertension/ worsening hypertension#	3	21JAN2021	22/C	2	No	O	NA/TC	N	N/N	
		PSYCH	Anxiety/ anxiety	2	20DEC2020	104/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1009 10091079	SKIN	Dermal cyst/ CYST ON FOREHEAD	1	28AUG2020	9/15	1	No	O	NA/TC	R (11SEP2020)	N/N	
16-55/ C4591001 1009 10091080	INFEC	Nasopharyngitis/ HEAD COLD	2	03OCT2020	24/8	1	No	O	NA/TC	R (10OCT2020)	N/N	
16-55/ C4591001	MUSC	Pain in extremity/ Worsening Pain in left foot arch#	2	18FEB2021	162/C	3	No	O	NA/TC/TCN	RG	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1009 10091081	PSYCH	Attention deficit hyperactivity disorder/ Attention Deficit Disorder	2	16DEC2020	97/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1009 10091084	GENRL	Chills/ CHILLS	2	12SEP2020	2/1	2	Yes		NA	R (12SEP2020)	N/N	
16-55/ C4591001 1009 10091088	GENRL	Injection site pain/ pain at injection site	2	15SEP2020	1/4	1	Yes		NA/TC	R (18SEP2020)	N/N	
10091108	GENRL	Chills/ CHILLS	2	16SEP2020	2/C	1	Yes		NA	RG	N/N	
	MUSC	Myalgia/ GENERALIZED MUSCLE ACHES	2	16SEP2020	2/C	1	Yes		NA	RG	N/N	
16-55/ C4591001 1009 10091109	NERV	Dysgeusia/ Metallic Taste In Mouth Following Vaccination	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/Y	
16-55/ C4591001 1009 10091110	GASTR	Aphthous ulcer/ CANKER SORES	2	07OCT2020	24/17	2	No	O	NA/TC	R (23OCT2020)	N/N	
	INFEC	Gingivitis/ RIGHT UPPER MOUTH GUM INFECTION	2	07OCT2020	24/17	2	No	O	NA	R (23OCT2020)	N/N	
16-55/ C4591001	MUSC	Myalgia/ generalized muscle aches	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1009 10091112												
16-55/ C4591001 1009 10091113	INFEC	Herpes zoster/ Shingles#	4	05FEB2021	8/14	2	No	O	NA/TC	R (18FEB2021)	N/N	
16-55/ C4591001 1009 10091116	MUSC	Myalgia/ generalized muscle soreness	2	18SEP2020	2/1	2	Yes		NA	R (18SEP2020)	N/N	
	INJ&P	Concussion/ CONCUSSION	2	23OCT2020	37/C	2	No	O	NA/TC	RG	N/N	
		Fall/ FALL	2	23OCT2020	37/1	2	No	O	NA	R (23OCT2020)	N/N	
		Muscle strain/ NECK MUSCLE STRAIN	2	23OCT2020	37/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1009 10091117	GENRL	Chills/ chills	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N	
	MUSC	Myalgia/ generalized muscle soreness	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001 1009 10091129	GENRL	Axillary pain/ LEFT AXILLA TENDERNESS	2	17SEP2020	2/19	1	Yes		NA/TC	R (05OCT2020)	N/N	
		Chills/ CHILLS	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N	
		Fatigue/ FATIGUE	2	17SEP2020	2/6	1	Yes		NA	R (22SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1009 10091138		Injection site pain/ INJECTION SITE PAIN	2	17SEP2020	2/8	1	Yes		NA/TC	R (24SEP2020)	N/N	
	MUSC	Myalgia/ MUSCLE PAIN, GENERALIZED	2	17SEP2020	2/2	3	Yes		NA/TC	R (18SEP2020)	N/N	
	NERV	Headache/ HEADACHE	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N	
	GENRL	Chills/ CHILLS	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N	
	GENRL	Chills/ chills	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
		Fatigue/ fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
	INFEC	Bacterial rhinitis/ BILATERAL NOSTRIL STAPHYLOCOCCUS INFECTION	2	01DEC2020	72/C	2	No	O	NA/TC	RG	N/N	
	GASTR	Gastroesophageal reflux disease/ WORSENING GERD#	2	01FEB2021	134/C	2	No	O	NA/TC	RG	N/N	
	GASTR	Constipation/ constipation#	3	03FEB2021	1/2	1	No	O	NA	R (04FEB2021)	N/N	
16-55/ C4591001 1009 10091142	INJ&P	Limb traumatic amputation/ ACCIDENTAL LEFT THUMB FINGER TIP AMPUTATION	1	07SEP2020	7/C	2	No	O	NA/TC/TCN	RG	N/N	
	RESP	Oropharyngeal pain/ SORE THROAT	1	11SEP2020	11/2	1	No	O	NA	R (12SEP2020)	N/N	
	GENRL	Chills/ chills	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1009 10091158	MUSC	Fatigue/ fatigue	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
		Myalgia/ generalized muscle aches	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
	GASTR	Diarrhoea/ diarrhea#	3	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1009 10091159	INJ&P	Ear injury/ RIGHT EAR TRAUMA	2	05DEC2020	67/15	2	No	O	NA/TC	R (19DEC2020)	N/N
16-55/ C4591001 1009 10091166	REPRO	Skin laceration/ RIGHT EAR LACERATION	2	05DEC2020	67/15	2	No	O	NA/TC	R (19DEC2020)	N/N
		Breast cyst/ Left Breast Cysts	1	17SEP2020	8/C	1	No	O	NA	N	N/N
16-55/ C4591001 1009 10091171	MUSC	Back pain/ WORSENING LOWER BACK PAIN	1	15SEP2020	5/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1009 10091175	GENRL	Pain in extremity/ BILATERAL LEG PAIN	1	15SEP2020	5/C	1	No	O	NA/TC	N	N/N
		Chills/ chills	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		Injection site pain/ soreness at injection site	1	15SEP2020	2/6	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1009 10091188	GENRL	Chills/ chills	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N	
		Pyrexia/ fever	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N	
	MUSC	Myalgia/ generalized muscle pain	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N	
	METAB	Hyperlipidaemia/ hyperlipidemia	2	31DEC2020	80/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1009 10091194	GENRL	Chills/ chills#	4	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N	
	INFEC	Bacterial vulvovaginitis/ Vaginal Bacterial Infection	1	30SEP2020	7/19	2	No	O	NA/TC	R (18OCT2020)	N/N	
16-55/ C4591001 1009 10091201	GENRL	Fatigue/ fatigue	2	16OCT2020	2/3	2	Yes		NA/TC	R (18OCT2020)	N/N	
		Injection site pain/ muscle pain at injection site	2	16OCT2020	2/3	2	Yes		NA/TC	R (18OCT2020)	N/N	
	NERV	Headache/ headache	2	16OCT2020	2/3	2	Yes		NA	R (18OCT2020)	N/N	
	INFEC	Urinary tract infection/ Urinary Tract Infection	2	01DEC2020	30/C	2	No	O	NA/TC	RG	N/N	
	NEOPL	Haemangioma of skin/ NEOPLASM OF UNCERTAIN BEHAVIOR OF SKIN, LEFT EAR 2mm dark freckle or hemangioma	2	04DEC2020	33/15	1	No	O	NA	R (18DEC2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1009 10091206	SKIN	Dermatitis allergic/ ALLERGIC DERMATITIS, FACIAL	2	04DEC2020	33/3	1	No	O	NA/TC	R (06DEC2020)	N/N	
	GASTR	Abdominal pain upper/ LEFT UPPER QUADRANT PAIN	2	08NOV2020	3/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1009 10091210	SKIN	Acne/ acne	2	07DEC2020	32/C	1	No	O	NA/TC	N	N/N	
	MUSC	Musculoskeletal chest pain/ left side rib pain	2	01DEC2020	16/3	1	No	O	NA/TC	R (03DEC2020)	N/N	
16-55/ C4591001 1009 10091242	VASC	Hypertension/ hypertension	1	22OCT2020	1/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1009 10091244	MUSC	Myalgia/ generalized muscle soreness	1	23OCT2020	2/3	1	Yes		NA	R (25OCT2020)	N/N	
	GENRL	Chills/ chills	2	19NOV2020	2/1	1	Yes		NA	R (19NOV2020)	N/N	
		Pain/ body aches	2	19NOV2020	2/1	1	Yes		NA	R (19NOV2020)	N/N	
16-55/ C4591001 1009 10091253	GASTR	Pyrexia/ fever	2	19NOV2020	2/1	2	Yes		NA/TC	R (19NOV2020)	N/N	
		Dyspepsia/ heartburn	2	08FEB2021	85/2	1	No	O	NA	R (09FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1009 10091254	GENRL	Chills/ chills	1	29OCT2020	4/1	1	Yes		NA	R (29OCT2020)	N/N	
		Pain/ body aches	1	29OCT2020	4/1	1	Yes		NA	R (29OCT2020)	N/N	
16-55/ C4591001 1009 10091256	GENRL	Chills/ chills	2	19NOV2020	1/2	1	Yes		NA	R (20NOV2020)	N/N	
16-55/ C4591001 1009 10091261	INJ&P	Skin laceration/ left index finger laceration	2	10FEB2021	71/C	2	No	O	NA/TC/TCN	RG	N/N	
16-55/ C4591001 1009 10091278	EAR	Ear pain/ ear ache	2	21JAN2021	31/8	1	No	O	NA	R (28JAN2021)	N/N	
16-55/ C4591001 1009 10091285	GENRL	Injection site pain/ pain at injection site	2	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N	
	INFEC	Impetigo/ impetigo on face	2	12JAN2021	22/9	1	No	O	NA/TC	R (20JAN2021)	N/N	
16-55/ C4591001 1009 10091286	GENRL	Chills/ chills#	3	06JAN2021	2/4	1	Yes		NA	R (09JAN2021)	N/N	
		Pain/ body aches#	3	06JAN2021	2/4	1	Yes		NA	R (09JAN2021)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1011 10111006	NERV	Headache/ Headache#	3	06JAN2021	2/4	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1011 10111021	NERV	Headache/ Headache#	4	19JAN2021	1/2	1	Yes		NA/TC	R (20JAN2021)	N/N
	GENRL	Chills/ Chills#	4	02MAR2021	2/2	1	Yes		NA	R (03MAR2021)	N/N
16-55/ C4591001 1011 10111035		Pyrexia/ Fever 100.6#	4	02MAR2021	2/2	1	Yes		NA	R (03MAR2021)	N/N
	MUSC	Myalgia/ Generalized Muscles Aches#	4	02MAR2021	2/2	1	Yes		NA/TC	R (03MAR2021)	N/N
16-55/ C4591001 1011 10111035	GENRL	Fatigue/ Fatigue	1	19AUG2020	6/4	1	Yes		NA	R (22AUG2020)	N/N
16-55/ C4591001 1011 10111039	GENRL	Injection site erythema/ Injection site redness	1	14AUG2020	1/9	1	Yes		NA	R (22AUG2020)	N/N
16-55/ C4591001 1011 10111042	GENRL	Fatigue/ Fatigue#	3	04FEB2021	24/2	1	Yes		NA	R (05FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	4	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1011 10111043	MUSC	Myalgia/ Generalized Muscle Aches#	3	04FEB2021	24/2	1	Yes		NA	R (05FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N	
16-55/ C4591001 1011 10111046	NERV	Headache/ Headache#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N	
	GENRL	Injection site bruising/ Bruise on left arm around the injection site	1	18AUG2020	2/5	1	Yes		NA	R (22AUG2020)	N/N	
	GENRL	Pyrexia/ Fever 101.4	2	08SEP2020	1/3	1	Yes		NA/TC	R (10SEP2020)	N/N	
16-55/ C4591001 1011 10111052	MUSC	Myalgia/ Generalized Muscle Aches	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N	
	GENRL	Chills/ Chills	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	
	GENRL	Pyrexia/ Fever - 101.0#	4	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N	
16-55/ C4591001 1011 10111070	EYE	Eye pruritus/ Itchy Eyes	1	15SEP2020	28/10	1	No	O	NA	R (24SEP2020)	N/N	
	RESP	Nasal congestion/ Nasal Congestion	1	15SEP2020	28/10	1	No	O	NA	R (24SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1011 10111071	RESP	Respiratory tract congestion/ Chest Congestion	1	25SEP2020	38/4	1	No	O	NA	R (28SEP2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N	
16-55/ C4591001 1011 10111079	GENRL	Chills/ Chills	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	
		Pyrexia/ Fever 100.6	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	
	MUSC	Myalgia/ Generalized myalgia	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	
	GENRL	Chills/ Chills	2	10SEP2020	1/6	1	Yes		NA	R (15SEP2020)	N/N	
		Fatigue/ Fatigue	2	10SEP2020	1/6	1	Yes		NA	R (15SEP2020)	N/N	
		Pyrexia/ Fever 101.9	2	10SEP2020	1/6	1	Yes		NA	R (15SEP2020)	N/N	
	NERV	Headache/ Headache	2	10SEP2020	1/6	1	Yes		NA/TC	R (15SEP2020)	N/N	
16-55/ C4591001 1011 10111088	INFEC	Oral candidiasis/ Oral Thrush	1	03SEP2020	11/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1011 10111107	GENRL	Chills/ Chills	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1011 10111116	MUSC	Pyrexia/ Fever 101.5	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Myalgia/ Generalized myalgia	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	INFEC	Labyrinthitis/ Inner Ear Infection	1	17SEP2020	22/9	1	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1011 10111117	GENRL	Chills/ Chills	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
		Fatigue/ Fatigue	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1011 10111118	MUSC	Pyrexia/ Fever 101.0	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
		Myalgia/ Left shoulder muscle pain	2	28SEP2020	11/12	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1011 10111123	GENRL	Myalgia/ Muscle pain left side of neck	2	28SEP2020	11/12	1	Yes		NA/TC	R (09OCT2020)	N/N
		Chills/ Chills	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ Fever 100.7	2	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1011 10111124	MUSC	Myalgia/ Generalized myalgia	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N	
	GENRL	Pyrexia/ Fever - 101.5#	4	09JAN2021	2/1	2	Yes		NA/TC	R (09JAN2021)	N/N	
16-55/ C4591001 1011 10111125	GENRL	Chills/ Chills	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N	
	MUSC	Pyrexia/ Fever	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001 1011 10111129	MUSC	Myalgia/ Generalized myalgia	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	
	NERV	Headache/ Headache	2	21SEP2020	1/1	2	Yes		NA	R (21SEP2020)	N/N	
16-55/ C4591001 1011 10111141	GENRL	Injection site pain/ Injection Site Pain#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N	
16-55/ C4591001 1011 10111154	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1011 10111168	MUSC	Pyrexia/ Fever 100.4	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		Myalgia/ Generalized Muscle Aches	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	13JAN2021	21/2	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1011 10111169	GENRL	Pyrexia/ Fever	1	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
	GENRL	Axillary pain/ Soreness in left auxiliary area	2	28OCT2020	2/3	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1011 10111170	GENRL	Chills/ Chills	2	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
	NERV	Pyrexia/ Fever 100.00	2	29OCT2020	1/2	1	Yes		NA/TC	R (30OCT2020)	N/N
16-55/ C4591001 1011 10111186	GENRL	Headache/ Headache	2	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
	GENRL	Chills/ Chills#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1011 10111190	MUSC	Pyrexia/ Fever - 100.4#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N	
		Myalgia/ Generalized Muscle Aches#	4	14JAN2021	3/3	1	Yes		NA	R (16JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	06FEB2021	9/2	1	Yes		NA	R (07FEB2021)	N/N	
	NERV	Injection site pain/ Injection Site Pain#	4	06FEB2021	9/3	1	Yes		NA	RS (08FEB2021)	N/N	
Headache/ Headache#		4	06FEB2021	9/1	1	Yes		NA/TC	R (06FEB2021)	N/N		
16-55/ C4591001 1011 10111199	GASTR	Nausea/ Nausea#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N	
16-55/ C4591001 1011 10111203	MUSC	Pyrexia/ Fever - 100.6#	4	14JAN2021	1/2	2	Yes		NA/TC	R (15JAN2021)	N/N	
		Myalgia/ Generalized Muscle Aches#	3	14JAN2021	24/1	1	Yes		NA	R (14JAN2021)	N/N	
	NERV	Headache/ Headache#	3	14JAN2021	24/1	1	Yes		NA/TC	R (14JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N	
NERV	Headache/ Headache#	3	18DEC2020	1/1	1	Yes		NA	R (18DEC2020)	N/N		

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1011 10111212	GENRL	Fatigue/ Fatigue#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
	NERV	Headache/ Headache#	4	08JAN2021	2/1	1	Yes		NA/TC	R (08JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	19JAN2021	2/5	1	Yes		NA	R (23JAN2021)	N/N
	INV	Body temperature increased/ Elevated Body Temp - 99.9#	4	19JAN2021	2/1	1	Yes		NA/TC	R (19JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Aches#	4	19JAN2021	2/3	1	Yes		NA	R (21JAN2021)	N/N
	VASC	Hot flush/ Hot Flashes	1	19OCT2020	1/1	1	Yes		NA	R (19OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	30JAN2021	2/3	1	Yes		NA	R (01FEB2021)	N/N
	NERV	Headache/ Headache#	4	30JAN2021	2/1	2	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Chills/ Chills	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
INV	Body temperature increased/ Increased Body temperature (99.7)	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1011 10111235	MUSC	Myalgia/ Generalized Muscle Aches	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N	
	MUSC	Arthralgia/ Hip/Pelvic Joint Pain	1	31OCT2020	2/7	2	Yes		NA	R (06NOV2020)	N/N	
	NERV	Headache/ Headache	1	31OCT2020	2/1	1	Yes		NA	R (31OCT2020)	N/N	
	SKIN	Rash/ Rash on left arm	1	04NOV2020	6/6	2	No	O	NA	R (09NOV2020)	N/N	
	GENRL	Chills/ Chills	2	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N	
16-55/ C4591001 1011 10111236	INV	Body temperature increased/ Increased Body Temperature 99.0	2	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N	
	GENRL	Chills/ Chills	2	21NOV2020	2/1	1	Yes		NA	R (21NOV2020)	N/N	
		Pyrexia/ Fever	2	21NOV2020	2/1	1	Yes		NA/TC	R (21NOV2020)	N/N	
	MUSC	Myalgia/ Generalized Muscle Aches	2	21NOV2020	2/1	1	Yes		NA/TC	R (21NOV2020)	N/N	
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N	
16-55/ C4591001 1012 10121006	MUSC	Back pain/ Back pain#	3	11FEB2021	1/2	1	No	CND	NA	R (12FEB2021)	N/N	
	NERV	Headache/ Headache#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1012 10121024	GENRL	Pyrexia/ Fever#	4	10MAR2021	2/1	1	Yes		NA	R (10MAR2021)	N/N	
16-55/ C4591001 1012 10121055	GENRL	Fatigue/ FATIGUE#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
		Injection site pain/ INJECTION SITE PAIN LEFT ARM#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
	MUSC	Arthralgia/ GENERALIZED JOINT PAIN#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
	NERV	Headache/ HEADACHE#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
16-55/ C4591001 1012 10121058	GENRL	Fatigue/ Fatigue	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N	
16-55/ C4591001 1012 10121065	INJ&P	Ligament sprain/ Left Ankle Sprain	1	30SEP2020	38/C	1	No	CND	NA/TC	RG	N/N	
16-55/ C4591001 1012 10121073	GENRL	Chills/ CHILLS	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N	
		Injection site pain/ RIGHT ARM INJECTION SITE PAIN	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N	
	PSYCH	Insomnia/ INSOMNIA	2	14SEP2020	1/1	2	Yes		NA	R (14SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	HEPAT	Cholelithiasis/ Cholelithiasis	2	28SEP2020	15/C	2	No	CND	NA/TC	N	N/N	
16-55/ C4591001 1012 10121074	GENRL	Chills/ BODY CHILLS#	3	18JAN2021	1/2	2	Yes		NA	R (19JAN2021)	N/N	
		Injection site pain/ LEFT ARM INJECTION SITE SORENESS#	3	18JAN2021	1/2	2	Yes		NA	R (19JAN2021)	N/N	
		Pyrexia/ LOW GRADE FEVER#	3	18JAN2021	1/2	2	Yes		NA	R (19JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	3	18JAN2021	1/2	2	Yes		NA	R (19JAN2021)	N/N	
	GENRL	Chills/ Body Chills#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N	
		Pyrexia/ Fever#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N	
	MUSC	Myalgia/ Muscle pain#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N	
16-55/ C4591001 1012 10121076	GENRL	Injection site erythema/ Redness at injection site#	4	20FEB2021	2/6	1	Yes		NA	R (25FEB2021)	N/N	
16-55/ C4591001 1012 10121079	NERV	Headache/ Intermittent Headaches	2	23SEP2020	9/C	1	No	CND	NA	RG	N/N	
	NERV	Amnesia/ Short-Term Memory Loss#	3	13FEB2021	6/C	2	No	O	NA	RG	N/N	
16-55/ C4591001	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1012 10121085	GENRL	Fatigue/ Fatigue	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/N	
		Injection site pain/ Left Arm Injection Site Pain	2	25SEP2020	1/4	2	Yes		NA	R (28SEP2020)	N/N	
		Pyrexia/ Fever	2	25SEP2020	1/34	2	Yes		NA	R (28OCT2020)	N/N	
16-55/ C4591001 1012 10121087	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	16SEP2020	1/4	1	Yes		NA	R (19SEP2020)	N/N	
	GENRL	Fatigue/ FATIGUE	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
		Pain/ BODY ACHES	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N	
		Pyrexia/ FEVER	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N	
	MUSC	Arthralgia/ JOINT PAIN	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001 1012 10121095	GENRL	Fatigue/ Fatigue	1	07SEP2020	8/8	1	Yes		NA	R (14SEP2020)	N/N	
	NERV	Dizziness/ Lightheadedness	1	07SEP2020	8/3	1	Yes		NA	R (09SEP2020)	N/N	
16-55/ C4591001	INFEC	Ear infection/ Bilateral Ear Infection	1	01SEP2020	2/10	2	No	O	NA/TC	R (10SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1012 10121096 16-55/ C4591001	GENRL	Injection site pain/ RIGHT ARM INJECTION SITE PAIN	1	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
1012 10121101	GENRL	Injection site pain/ Right Arm Injection Site Pain	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001	PSYCH	Anxiety/ ANXIETY	2	22SEP2020	1/C	1	No	O	NA	N	N/Y
1012 10121103		Post-traumatic stress disorder/ POST TRAUMATIC STRESS DISORDER	2	22SEP2020	1/C	1	No	O	NA	N	N/Y
16-55/ C4591001	GENRL	Injection site swelling/ Right arm localized swelling at injection site	1	02SEP2020	2/3	1	Yes		NA	R (04SEP2020)	N/N
1012 10121105	NERV	Headache/ Headache	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site discolouration/ Right arm hyperpigmentation at injection site	1	05SEP2020	5/C	1	Yes		NA	RG	N/N
	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Injection site discolouration/ Hyperpigmentation at Injection Site	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1012 10121108	GASTR	Injection site swelling/ Swelling at Injection Site	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Diarrhoea/ Diarrheal Episode	1	15SEP2020	15/1	1	No	O	NA	R (15SEP2020)	N/N
16-55/ C4591001 1012 10121111	GASTR	Nausea/ NAUSEA	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Chills/ CHILLS	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
		Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
		Pyrexia/ FEVER	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GASTR	Nausea/ NAUSEA	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ FEVER	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1012 10121118	SURG	Dental implantation/ Dental Implant Right Upper Molar	2	15OCT2020	25/1	1	No	CND	NA/TC	R (15OCT2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ FEVER	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1012 10121121	BLOOD	Anaemia/ ANEMIA	2	01OCT2020	7/C	1	No	CND	NA/TC	N	N/N
16-55/ C4591001 1012 10121124	GENRL	Injection site pain/ LEFT ARM PAIN AT INJECTION SITE#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
16-55/ C4591001 1012 10121130	GASTR	Nausea/ NAUSEA	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
10121131	GENRL	Chills/ CHILLS	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
		Fatigue/ FATIGUE	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ FEVER	2	29SEP2020	1/3	2	Yes		NA	R (01OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1012 10121132	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Chills/ Body Chills	2	23SEP2020	1/2	3	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	2/C	2	Yes		NA/TC	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1012 10121137	GENRL	Injection site pain/ Left Arm Injection Site Pain	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N
	EYE	Diplopia/ Double Vision	2	26SEP2020	2/2	1	No	CND	NA	R (27SEP2020)	N/N
	GENRL	Injection site pain/ Left Arm Injection Site Pain	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
		Pyrexia/ Fever	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1012 10121144	GENRL	Fatigue/ FATIGUE#	3	23JAN2021	1/4	1	Yes		NA	R (26JAN2021)	N/N
		Injection site pain/ LEFT INJECTION SITE ARM PAIN#	3	23JAN2021	1/3	1	Yes		NA	R (25JAN2021)	N/N
16-55/ C4591001 1012 10121145	GASTR	Nausea/ Nausea	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
		Vomiting/ Vomiting	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
	GENRL	Pain/ Body Aches	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
		Pyrexia/ Fever	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ Headache	2	25SEP2020	1/C	2	Yes		NA	RG	N/N
16-55/ C4591001	MUSC	Myalgia/ MUSCLE ACHES	1	05SEP2020	1/4	2	Yes		NA/TC	R (08SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1012 10121146	MUSC	Myalgia/ MUSCLE ACHES	2	28SEP2020	1/3	2	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1012 10121154	GENRL	Injection site pain/ Arm Pain at Injection Site	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1012 10121162	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N
	GASTR	Nausea/ NAUSEA	2	02OCT2020	2/1	2	Yes		NA	R (02OCT2020)	N/N
	GENRL	Pyrexia/ FEVER	2	02OCT2020	2/32	1	Yes		NA	R (02NOV2020)	N/N
	NERV	Headache/ HEADACHE	2	02OCT2020	2/32	2	Yes		NA/TC	R (02NOV2020)	N/N
16-55/ C4591001 1012 10121163	GENRL	Injection site dermatitis/ LEFT UPPER ARM DERMATITIS AT INJECTION SITE	1	11SEP2020	3/C	2	Yes		P/W	RG	N/N
	PSYCH	Insomnia/ INSOMNIA	1	12SEP2020	4/C	2	Yes		NA/TC	N	N/N
	INV	Weight decreased/ WEIGHT LOSS	1	14SEP2020	6/21	3	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1012 10121172	EAR	Vertigo/ Vertigo	2	21OCT2020	20/4	1	No	O	NA	R (24OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	NERV	Dizziness/ LIGHTHEADEDNESS#	3	23JAN2021	1/1	1	No	O	NA	R (23JAN2021)	N/N	
	INJ&P	Skin laceration/ Forehead laceration#	3	12FEB2021	21/7	1	No	O	NA/TCN	R (18FEB2021)	N/N	
	NERV	Syncope/ Syncope#	3	12FEB2021	21/1	1	No	O	NA	R (12FEB2021)	N/N	
	GENRL	Chills/ Body chills#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N	
		Pain/ Body aches#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N	
		Pyrexia/ Fever#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N	
	EAR	Vertigo/ Vertigo#	4	14FEB2021	3/1	1	No	O	NA	R (14FEB2021)	N/N	
16-55/ C4591001 1012 10121173	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N	
	GENRL	Chills/ CHILLS	2	02OCT2020	2/2	2	Yes		NA	R (03OCT2020)	N/N	
16-55/ C4591001 1012 10121174	GENRL	Injection site pain/ LOCALIZED LEFT ARM PAIN AT INJECTION SITE	1	11SEP2020	2/4	2	Yes		NA	R (14SEP2020)	N/N	
	GENRL	Chills/ CHILLS	2	01OCT2020	2/1	2	Yes		NA	R (01OCT2020)	N/N	
		Fatigue/ FATIGUE	2	01OCT2020	2/1	2	Yes		NA	R (01OCT2020)	N/N	
		Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1012 10121178	NERV  GENRL	Pain/ BODY ACHES	2	01OCT2020	2/1	2	Yes		NA	R (01OCT2020)	N/N	
		Pyrexia/ FEVER	2	01OCT2020	2/1	2	Yes		NA/TC	R (01OCT2020)	N/N	
		Headache/ HEADACHE	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N	
		Chills/ CHILLS	2	08OCT2020	1/2	2	Yes		NA	R (09OCT2020)	N/N	
16-55/ C4591001 1012 10121181	NERV  GENRL	Fatigue/ FATIGUE	2	08OCT2020	1/C	1	Yes		NA	RG	N/N	
		Pain/ BODY ACHES	2	08OCT2020	1/2	2	Yes		NA	R (09OCT2020)	N/N	
		Headache/ HEADACHE	2	08OCT2020	1/2	2	Yes		NA	R (09OCT2020)	N/N	
		Fatigue/ FATIGUE#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/Y	
16-55/ C4591001 1012 10121182	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N	
16-55/ C4591001 1012 10121182	GENRL	Chills/ CHILLS	2	02OCT2020	1/2	2	Yes		NA	R (03OCT2020)	N/N	
		Fatigue/ FATIGUE	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N	
		Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	02OCT2020	1/4	1	Yes		NA	R (05OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1012 10121183	GENRL	Pain/ BODY ACHES	2	02OCT2020	1/2	2	Yes		NA	R (03OCT2020)	N/N	
		Pyrexia/ FEVER	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N	
		Chills/ CHILLS	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N	
	GENRL	Chills/ CHILLS	2	03OCT2020	2/1	2	Yes		NA	R (03OCT2020)	N/N	
	MUSC	Arthralgia/ JOINT PAIN	2	03OCT2020	2/1	2	Yes		NA	R (03OCT2020)	N/N	
16-55/ C4591001 1012 10121187	NERV	Paraesthesia/ Left Shoulder Tingling	2	23OCT2020	22/3	1	No	O	NA	R (25OCT2020)	N/N	
16-55/ C4591001 1012 10121188	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/1	2	Yes		NA	R (03OCT2020)	N/N	
16-55/ C4591001 1013 10131003	GENRL	Pyrexia/ Fever	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N	
		Injection site pain/ PAIN AT INJECTION SITE	1	28JUL2020	1/11	1	Yes		NA	R (07AUG2020)	N/N	
	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	09AUG2020	13/4	1	Yes		NA	R (12AUG2020)	N/N	
16-55/ C4591001	MUSC	Arthropathy/ CYST, WRIST, LEFT	2	SEP2020	14/	1	No	O	NA/TCN	R	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1013 10131005	MUSC	Myalgia/ MUSCLE PAIN	1	04AUG2020	8/1	2	Yes		NA	R (04AUG2020)	N/N	
16-55/ C4591001 1013 10131006	GENRL	Fatigue/ FATIGUE	1	31JUL2020	3/6	1	Yes		NA	R (05AUG2020)	N/N	
1013 10131014	INFEC	Tonsillitis/ TONSILLITIS	2	17NOV2020	89/13	1	No	O	NA/TC	R (29NOV2020)	N/N	
	GENRL	Chills/ CHILLS#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N	
	MUSC	Pain in extremity/ SORE ARM#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N	
16-55/ C4591001 1013 10131015	GASTR	Diarrhoea/ DIARRHEA	1	29JUL2020	1/8	1	Yes		NA	R (05AUG2020)	N/N	
	GENRL	Fatigue/ FATIGUE	1	29JUL2020	1/8	2	Yes		NA	R (05AUG2020)	N/N	
16-55/ C4591001 1013 10131021	GASTR	Diarrhoea/ DIARRHEA	1	13AUG2020	15/9	2	No	O	NA	R (21AUG2020)	N/N	
16-55/ C4591001 1013 10131030	MUSC	Pain in extremity/ PAIN IN ARMS AND HANDS	2	22AUG2020	5/C	3	Yes		NA/TC	RG	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Pain in extremity/ PAIN IN LEGS AND FEET	2	22AUG2020	5/C	3	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1013 10131032	NERV	Headache/ HEADACHE	1	05AUG2020	7/2	1	Yes		NA	R (06AUG2020)	N/N	
16-55/ C4591001 1013 10131044	REPRO	Benign prostatic hyperplasia/ BENIGN PROSTATIC HYPERPLASIA	2	25NOV2020	99/C	1	No	O	NA/TC	RG	N/N	
	INFEC	Gonorrhoea/ GONORRHEA#	2	25FEB2021	191/C	1	No	O	NA/TC	RG	N/N	
	METAB	Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA#	2	01MAR2021	195/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1013 10131051	INJ&P	Skin laceration/ LACERATION TO LEFT EYEBROW	2	01OCT2020	38/7	1	No	O	NA/TCN	R (07OCT2020)	N/N	
16-55/ C4591001 1013 10131055	MUSC	Arthralgia/ PAIN RIGHT SHOULDER	2	25AUG2020	2/3	2	Yes		NA/TC	R (27AUG2020)	N/N	
	INFEC	Tooth abscess/ TOOTH ABSCESS	2	20OCT2020	58/16	1	No	O	NA/TC	R (04NOV2020)	N/N	
	MUSC	Back pain/ BACK PAIN	2	15DEC2020	114/22	2	No	O	NA/TC	R (05JAN2021)	N/N	
16-55/ C4591001 1013 10131059	GENRL	Fatigue/ FATIGUE	2	26AUG2020	2/1	3	Yes		NA	R (26AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Myalgia/ MUSCLE PAIN	2	26AUG2020	2/1	2	Yes		NA	R (26AUG2020)	N/N	
16-55/ C4591001 1013 10131066	INJ&P	Arthropod bite/ ERYTHEMA FROM BUG BITES#	4	29JAN2021	25/6	1	No	O	NA/TC	R (03FEB2021)	N/N	
16-55/ C4591001 1013 10131067	NERV	Headache/ HEADACHE	1	08AUG2020	5/4	1	Yes		NA	R (11AUG2020)	N/N	
	SKIN	Rash/ UNDERARM SKIN RASH	2	08NOV2020	75/16	1	No	O	NA/TC	R (23NOV2020)	N/N	
16-55/ C4591001 1013 10131068	INFEC	Otitis media/ left middle ear infection	1	15AUG2020	12/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1013 10131072	MUSC	Myalgia/ muscle pain left hip	1	05AUG2020	2/C	1	Yes		NA	RG	N/N	
16-55/ C4591001 1013 10131084	GENRL	Vascular stent occlusion/ OBSTRUCTED RENAL STENT (ARTERY)	2	01SEP2020	7/C	2	No	O	NA	RG	Y/N	
16-55/ C4591001 1013 10131089	VASC	Deep vein thrombosis/ LEFT ARM DEEP VEIN THROMBOSIS	2	20DEC2020	116/C	3	No	O	NA/TC	RG	Y/N	
16-55/ C4591001	GENRL	Chills/ CHILLS	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1013 10131112		Pain/ BODY ACHES	2	22SEP2020	1/4	2	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1013 10131113	PSYCH	Depression/ Recurrence of depression.	2	15SEP2020	15/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1013 10131124	VASC	Hypertension/ HYPERTENSION	1	20AUG2020	10/C	1	No	O	NA/TC	RG	N/N	
	MUSC	Bursitis/ BURSITIS LEFT SHOULDER	1	28AUG2020	18/1	1	No	O	NA/TC	R (28AUG2020)	N/N	
16-55/ C4591001 1013 10131125	EAR	Ear discomfort/ ear discomfort	1	26AUG2020	16/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1013 10131165	RESP	Pulmonary embolism/ Pulmonary Embolism Bilateral	2	14DEC2020	104/C	3	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1013 10131169	ENDO	Hypothyroidism/ HYPOTHYROIDISM	2	12OCT2020	41/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1013 10131190	RENAL	Nephrolithiasis/ kidney stones	2	04JAN2021	119/2	3	No	O	NA/TCN	R (05JAN2021)	Y/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131204	GENRL	Injection site pain/ INJECTION SITE PAIN	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N
16-55/ C4591001 1013 10131207	GENRL	Chills/ CHILLS	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
		Fatigue/ FATIGUE	2	10SEP2020	2/3	2	Yes		NA	R (12SEP2020)	N/N
		Pain/ BODY ACHES	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
		Pyrexia/ FEVER	2	10SEP2020	2/8	2	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Pain/ body aches	2	14SEP2020	6/2	3	Yes		NA	R (15SEP2020)	N/N
	VASC	Deep vein thrombosis/ DEEP VEIN THROMBOSIS RIGHT POPTIAL VEIN	2	23SEP2020	15/6	3	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C4591001 1013 10131209	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	2	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1013 10131215	GENRL	Injection site bruising/ 1/2 CM BY 1/2 CM BRUISE AT INJECTION SITE	1	18AUG2020	1/13	1	Yes		NA	R (30AUG2020)	N/Y
16-55/ C4591001 1013 10131218	GENRL	Injection site pain/ INJECTION SITE PAIN	2	10SEP2020	2/3	2	Yes		NA/TC	R (12SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1013 10131219	NERV	Pyrexia/ LOW GRADE FEVER	2	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N	
		Headache/ HEADACHE	1	19AUG2020	2/3	2	Yes		NA/TC	R (21AUG2020)	N/N	
16-55/ C4591001 1013 10131221	NERV	Headache/ FRONTAL HEADACHES	2	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N	
16-55/ C4591001 1013 10131225	GENRL	Chills/ CHILLIS	2	11SEP2020	3/2	1	Yes		NA	R (12SEP2020)	N/N	
16-55/ C4591001 1013 10131229	INJ&P	Pain/ BODY ACHES	2	11SEP2020	3/2	1	Yes		NA/TC	R (12SEP2020)	N/N	
		Pyrexia/ LOW GRADE FEVER	2	11SEP2020	3/2	2	Yes		NA/TC	R (12SEP2020)	N/N	
		Exposure during pregnancy/ Exposure During Pregnancy	2	10DEC2020	92/C		No	O	NA	RG	N/N	
16-55/ C4591001 1013 10131231	GENRL	Fatigue/ FATIGUE	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N	
		Injection site pain/ INJECTION SITE PAIN	1	20AUG2020	2/1	2	Yes		NA/TC	R (20AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1013 10131239	GENRL	Fatigue/ FATIGUE	2	09OCT2020	30/2	1	No	O	NA	R (10OCT2020)	N/N	
16-55/ C4591001 1013 10131245	NERV	Headache/ HEADACHE	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N	
	GENRL	Fatigue/ FATIGUE	2	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	14SEP2020	5/3	1	Yes		NA	R (16SEP2020)	N/N	
		Pyrexia/ FEVER	2	14SEP2020	5/2	2	Yes		NA/TC	R (15SEP2020)	N/N	
16-55/ C4591001 1013 10131251	GENRL	Chills/ CHILLS	2	09SEP2020	2/4	2	Yes		NA/TC	R (12SEP2020)	N/N	
	MUSC	Arthralgia/ JOINT PAIN	2	09SEP2020	2/4	2	Yes		NA/TC	R (12SEP2020)	N/N	
16-55/ C4591001 1013 10131255	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	2	SEP2020	1/		No	O	NA	R	N/N	
	PREG	Abortion spontaneous/ MISCARRIAGE	2	OCT2020	22/	3	No	O	NA	R	Y/N	
16-55/ C4591001 1013 10131258	GENRL	Injection site pain/ INJECTION SITE PAIN	1	21AUG2020	2/5	1	Yes		NA	R (25AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ CHILLS	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		Fatigue/ FATIGUE	2	11SEP2020	2/3	2	Yes		NA	R (13SEP2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N
		Pyrexia/ LOW GRADE FEVER	2	11SEP2020	2/2	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1013 10131259	GENRL	Injection site pain/ INJECTION SITE PAIN	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1013 10131264	INV	Blood pressure increased/ ELEVATED BLOOD PRESSURE	2	11SEP2020	2/4	1	No	O	NA	R (14SEP2020)	N/N
16-55/ C4591001 1013 10131268	GENRL	Injection site pain/ INJECTION SITE PAIN	1	22AUG2020	3/3	2	Yes		NA	R (24AUG2020)	N/N
16-55/ C4591001 1013 10131271	NERV	Headache/ HEADACHE	2	17SEP2020	1/8	2	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site swelling/ SWELLING AT INJECTION SITE	2	24SEP2020	8/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1013 10131276	GENRL	Injection site pain/ INJECTION SITE PAIN	2	15SEP2020	2/3	2	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1013 10131280	GENRL	Pain/ BODY ACHES	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N	
		Injection site pain/ INJECTION SITE PAIN	1	24AUG2020	1/2	1	Yes		NA	R (25AUG2020)	N/N	
		Chills/ INTERMITTENT CHILLS	2	16SEP2020	1/4	2	Yes		NA	R (19SEP2020)	N/N	
16-55/ C4591001 1013 10131283	GENRL	Pyrexia/ INTERMITTENT LOW GRADE FEVER	2	16SEP2020	1/4	1	Yes		NA/TC	R (19SEP2020)	N/N	
		Pain/ BODY ACHES	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N	
		Gastroesophageal reflux disease/ ACID REFLUX	2	01DEC2020	79/10	1	No	O	NA/TC	R (10DEC2020)	N/N	
16-55/ C4591001 1013 10131285	GASTR	Abdominal pain/ ABDOMINAL PAIN	1	26AUG2020	3/2	3	No	O	NA/TC	R (27AUG2020)	N/N	
		Chills/ CHILLS	1	26AUG2020	3/2	1	Yes		NA/TC	R (27AUG2020)	N/N	
16-55/ C4591001 1013 10131287	GENRL	Pyrexia/ FEVER	2	15SEP2020	2/2	2	Yes		NA/TC	R (16SEP2020)	N/N	
16-55/ C4591001 1013 10131293	GENRL	Chills/ CHILLS	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1013 10131299	GENRL	Pain/ BODY ACHES	2	15SEP2020	2/2	2	Yes		NA/TC	R (16SEP2020)	N/N	
		Pyrexia/ LOW GRADE FEVER	2	15SEP2020	2/2	2	Yes		NA/TC	R (16SEP2020)	N/N	
		Chills/ CHILLS	2	18SEP2020	4/2	2	Yes		NA	R (19SEP2020)	N/N	
16-55/ C4591001 1013 10131303	GENRL	Injection site haematoma/ INJECTION SITE HEMATOMA	2	18SEP2020	2/19	2	Yes		NA	R (06OCT2020)	N/N	
16-55/ C4591001 1013 10131304	GENRL	Chills/ CHILLS	2	19OCT2020	33/2	1	Yes		NA	R (20OCT2020)	N/N	
	GENRL	Fatigue/ FATIGUE	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001 1013 10131305	GENRL	Pain/ BODY ACHES	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
		Injection site pain/ INJECTION SITE PAIN	2	20SEP2020	4/4	2	Yes		NA/TC	R (23SEP2020)	N/N	
16-55/ C4591001 1013 10131318	SKIN	Pyrexia/ LOW GRADE FEVER	2	20SEP2020	4/2	2	Yes		NA/TC	R (21SEP2020)	N/N	
		Ingrowing nail/ RIGHT BIG TOE INGROWN TOE TAIL	1	04SEP2020	10/8	1	No	O	NA	R (11SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131338	GENRL	Chills/ CHILLS	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	GASTR	Vomiting/ VOMITING	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Pyrexia/ LOW GRADE FEVER	2	18SEP2020	2/2	2	Yes		NA/TC	R (19SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	18SEP2020	2/3	2	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1013 10131348	GENRL	Chills/ CHILLS	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ FEVER	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1013 10131349	INJ&P	Procedural pain/ RIGHT ARM SORENESS SECONDARY TO INJECTION	2	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1013 10131351	GENRL	Chills/ CHILLS#	4	18FEB2021	1/3	2	Yes		NA	R (20FEB2021)	N/N
		Injection site pain/ LEFT ARM INJECTION SITE PAIN#	4	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N
	INFEC	Diverticulitis/ DIVERTICULITIS#	4	19FEB2021	2/14	2	No	O	NA/TC	R (04MAR2021)	N/N
16-55/ C4591001	SURG	Tonsillectomy/ TONSILLECTOMY	2	10NOV2020	55/1	2	No	O	NA/TCN	R (10NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1013 10131352 16-55/ C4591001 1013 10131355	GENRL	Chills/ CHILLS	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N	
		Pain/ BODY ACHES	2	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N	
16-55/ C4591001 1013 10131357	GENRL	Chills/ CHILLS	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N	
		Fatigue/ FATIGUE	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N	
		Injection site pain/ INJECTION SITE PAIN	2	21SEP2020	1/4	2	Yes		NA/TC	R (24SEP2020)	N/N	
		Pyrexia/ LOW GRADE FEVER	2	21SEP2020	1/3	2	Yes		NA/TC	R (23SEP2020)	N/N	
	MUSC	Arthralgia/ JOINT PAIN	2	21SEP2020	1/3	2	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 1013 10131361	GENRL	Chills/ CHILLS	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
16-55/ C4591001 1013 10131365	INFEC	Sinusitis/ SINUS INFECTION	1	16SEP2020	17/14	1	No	O	NA/TC	R (29SEP2020)	N/N	
	MUSC	Myalgia/ MILD MUSCLE ACHES	2	25SEP2020	5/3	1	Yes		NA	R (27SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ HEADACHE	2	25SEP2020	5/3	1	Yes		NA	R (27SEP2020)	N/N
	INFEC	Sinusitis/ SINUS INFECTION	2	03NOV2020	44/11	2	No	O	NA/TC	R (13NOV2020)	N/N
	INFEC	Staphylococcal infection/ BILATERAL STAPH INFECTION TO THE ELBOWS AND HANDS	2	20NOV2020	61/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1013 10131371	GASTR	Nausea/ NAUSEA	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Pain/ BODY ACHES	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1013 10131377	GENRL	Chills/ CHILLS	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
		Fatigue/ FATIGUE	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
		Pain/ LEFT UPPER BODY PAIN	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1013 10131385	SKIN	Rash/ RASH TO UPPER EXTREMITIES	2	26SEP2020	4/2	2	Yes		NA/TC	R (27SEP2020)	N/N
		Rash/ RASH TO UPPER TORSO	2	26SEP2020	4/2	2	Yes		NA/TC	R (27SEP2020)	N/N
	SKIN	Rash/ RASH TO LOWER EXTREMITIES	2	27SEP2020	5/1	2	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001	NERV	Tension headache/ TENSION HEADACHE	1	10SEP2020	10/2	2	No	O	NA/TC	R (11SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1013 10131388 16-55/ C4591001 1013 10131391	MUSC	Muscle tightness/ MUSCLE TIGHTNESS	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N	
	NERV	Headache/ HEADACHE	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 1013 10131395	GENRL	Injection site pain/ INJECTION SITE PAIN	1	09SEP2020	9/2	1	Yes		NA	R (10SEP2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	22SEP2020	2/3	2	Yes		NA	R (24SEP2020)	N/N	
		Pyrexia/ LOW GRADE FEVER	2	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N	
16-55/ C4591001 1013 10131405	GENRL	Injection site pain/ INJECTION SITE PAIN	1	04SEP2020	3/2	1	Yes		NA	R (05SEP2020)	N/N	
	GENRL	Pyrexia/ LOW GRADE FEVER	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 1013 10131406	MUSC	Intervertebral disc degeneration/ MILD L5-S1 DISC DEGENERATION	1	13SEP2020	12/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1013 10131409	NERV	Dizziness/ LIGHTHEADEDNESS	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Investigational Vaccine Dose/ Subject	Action: Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131416	NERV	Headache/ HEADACHE	1	02SEP2020	1/1	1	Yes	NA/TC	R (02SEP2020)	N/N
		Lethargy/ LETHARGIC	1	02SEP2020	1/1	1	Yes	NA	R (02SEP2020)	N/N
		Dizziness/ LIGHTHEADEDNESS	2	23SEP2020	1/1	1	Yes	NA	R (23SEP2020)	N/N
		Headache/ HEADACHE	2	23SEP2020	1/3	2	Yes	NA/TC	R (25SEP2020)	N/Y
		Lethargy/ LETHARGIC	2	23SEP2020	1/3	1	Yes	NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	02SEP2020	1/2	1	Yes	NA	R (03SEP2020)	N/N
	GENRL	Chills/ CHILLS	1	03SEP2020	2/1	1	Yes	NA	R (03SEP2020)	N/N
		Pain/ BODY ACHES	1	03SEP2020	2/1	1	Yes	NA	R (03SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	03SEP2020	2/1	2	Yes	NA/TC	R (03SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	23SEP2020	1/3	2	Yes	NA/TC	R (25SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	24SEP2020	2/1	1	Yes	NA/TC	R (24SEP2020)	N/N
		Pain/ BODY ACHES	2	24SEP2020	2/1	1	Yes	NA/TC	R (24SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	24SEP2020	2/1	2	Yes	NA/TC	R (24SEP2020)	N/N
	16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	02SEP2020	1/2	1	Yes	NA	R (03SEP2020)

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1013 10131419	NERV	Headache/ HEADACHE	1	03SEP2020	2/1	2	Yes		NA	R (03SEP2020)	N/N	
	GENRL	Malaise/ MALAISE	1	07SEP2020	6/10	1	Yes		NA	R (16SEP2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N	
	GENRL	Chills/ CHILLS	2	24SEP2020	2/1	2	Yes		NA	R (24SEP2020)	N/N	
	NERV	Headache/ HEADACHE	2	24SEP2020	2/1	2	Yes		NA/TC	R (24SEP2020)	N/N	
16-55/ C4591001 1013 10131423	GENRL	Injection site pain/ INJECTION SITE PAIN	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 1013 10131424	GENRL	Injection site pain/ INJECTION SITE PAIN	1	04SEP2020	2/3	2	Yes		NA/TC	R (06SEP2020)	N/N	
		Pain/ BODY ACHES	1	04SEP2020	2/3	2	Yes		NA/TC	R (06SEP2020)	N/N	
16-55/ C4591001 1013 10131427	SKIN	Pruritus/ ITCHING ON ARMS AND LEGS	1	08SEP2020	6/26	1	Yes		NA	R (03OCT2020)	N/N	
16-55/ C4591001 1013 10131438	GENRL	Chills/ CHILLS	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1013 10131445	NERV	Injection site pain/ INJECTION SITE PAIN	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N	
		Headache/ HEADACHE	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	02OCT2020	2/3	2	Yes		NA/TC	R (04OCT2020)	N/N	
16-55/ C4591001 1013 10131448	NERV	Headache/ HEADACHE	2	02OCT2020	2/2	2	Yes		NA/TC	R (03OCT2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	28SEP2020	1/4	2	Yes		NA/TC	R (01OCT2020)	N/N	
	GASTR	Pyrexia/ FEVER	2	28SEP2020	1/2	2	Yes		NA/TC	R (29SEP2020)	N/N	
		Nausea/ NAUSEA	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N	
16-55/ C4591001 1013 10131451	GENRL	Chills/ CHILLS	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N	
	GENRL	Fatigue/ FATIGUE	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	09SEP2020	2/1	1	Yes		NA/TC	R (09SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131463	GENRL	Injection site pain/ INJECTION SITE PAIN	1	28SEP2020	21/1	1	Yes		NA/TC	R (28SEP2020)	N/N
16-55/ C4591001 1013 10131469	GENRL	Injection site pain/ INJECTION SITE PAIN	1	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1013 10131470	GASTR	Nausea/ NAUSEA	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	09SEP2020	2/3	2	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1013 10131472	GENRL	Injection site pain/ INJECTION SITE PAIN	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Chills/ CHILLS	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Pain/ BODY ACHES	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/N
		Pain/ BODY ACHES	1	30SEP2020	22/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1013 10131476	GENRL	Injection site pain/ INJECTION SITE PAIN	2	28SEP2020	1/4	2	Yes		NA/TC	R (01OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Chills/ CHILLS	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N	
		Pain/ BODY ACHES	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N	
16-55/ C4591001 1013 10131486	GENRL	Injection site pain/ INJECTION PAIN	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N	
	GENRL	Injection site pain/ INJECTION PAIN	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/Y	
16-55/ C4591001 1013 10131492	GENRL	Injection site pain/ INJECTION PAIN	1	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N	
	GENRL	Fatigue/ FATIGUE	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N	
16-55/ C4591001 1013 10131493	GENRL	Injection site pain/ INJECTION SITE PAIN	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	29SEP2020	2/3	1	Yes		NA/TC	R (01OCT2020)	N/N	
	MUSC	Arthralgia/ LEFT SHOULDER PAIN	2	29SEP2020	2/2	2	Yes		NA/TC	R (30SEP2020)	N/N	
	GASTR	Diarrhoea/ DIARRHEA	2	30SEP2020	3/2	1	Yes		NA	R (01OCT2020)	N/N	
16-55/ C4591001 1013 10131499	GENRL	Injection site pain/ INJECTION SITE PAIN	1	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/Y	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/Y
16-55/ C4591001 1013 10131500	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1013 10131507	GENRL	Injection site pain/ INJECTION SITE PAIN	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1013 10131513	NERV	Headache/ HEADACHE	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
	MUSC	Arthralgia/ RIGHT SHOULDER PAIN#	4	24FEB2021	15/C	1	No	O	NA	N	N/N
16-55/ C4591001 1013 10131514	GENRL	Chills/ CHILLS	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	11SEP2020	2/3	2	Yes		NA	R (13SEP2020)	N/N
	GENRL	Pyrexia/ LOW GRADE FEVER	1	12SEP2020	3/1	1	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION PAIN	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	02OCT2020	3/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131515	SKIN	Rash erythematous/ 2 RASH ON CHEST (PRURITIS AND REDDENED)	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1013 10131518	NERV	Headache/ HEADACHE	1	15SEP2020	2/15	1	No	O	NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 1013 10131529	GENRL	Injection site pain/ INJECTION SITE PAIN	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1013 10131533	GENRL	Pyrexia/ FEVER	1	16SEP2020	2/3	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1013 10131534	GENRL	Injection site pain/ INJECTION SITE PAIN	2	06OCT2020	2/3	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1013 10131534	GENRL	Chills/ Chills	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1013 10131534	GENRL	Injection site pain/ INJECTION SITE PAIN	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1013 10131534	GENRL	Pain/ BODY ACHES	1	16SEP2020	2/4	2	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1013 10131546	GENRL	Chills/ CHILLS	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	NERV	Headache/ HEADACHE	2	07OCT2020	2/C	1	Yes		NA	RG	N/N	
16-55/ C4591001 1013 10131553	METAB	Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2	20OCT2020	15/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1013 10131556	GENRL	Injection site pain/ INJECTION SITE PAIN	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	2/4	1	Yes		NA/TC	R (09OCT2020)	N/N	
		Pyrexia/ Fever	2	06OCT2020	2/3	1	Yes		NA/TC	R (08OCT2020)	N/N	
	NERV	Headache/ Headache	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N	
16-55/ C4591001 1013 10131557	INJ&P	Ligament sprain/ ANKLE SPRAIN RIGHT	1	26SEP2020	11/17	2	No	O	NA/TC	R (12OCT2020)	N/N	
16-55/ C4591001 1013 10131563	GENRL	Injection site pain/ INJECTION SITE PAIN	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001 1013 10131567	GENRL	Fatigue/ FATIGUE	1	17SEP2020	1/5	2	Yes		NA	R (21SEP2020)	N/N	
	MUSC	Myalgia/ MUSCLE ACHES	2	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131568	GENRL	Fatigue/ FATIGUE	1	18SEP2020	2/3	2	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ ACHING UPPER BODY MUSCLES BILATERAL ARMS	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
		Myalgia/ ACHING UPPER BODY MUSCLES BILATERAL SHOULDERS	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1013 10131569	GENRL	Injection site pain/ MUSCLE SORENESS AT INJECTION SITE	1	18SEP2020	2/4	2	Yes		NA	R (21SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
	NERV	Dizziness/ DIZZINESS	2	28OCT2020	21/C	2	No	O	NA/TC	RG	N/N
	METAB	Diabetes mellitus/ NEW ONSET DIABETES	2	31DEC2020	85/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1013 10131571†	GENRL	Injection site pain/ PAIN INJECTION SITE	2	07OCT2020	1/3	2	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1013 10131580	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1013 10131581	NERV	Headache/ Headache	1	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N	
		Pain/ BODY ACHES	2	07OCT2020	2/4	1	Yes		NA	R (10OCT2020)	N/N	
	NERV	Headache/ HEADACHE	2	07OCT2020	2/4	1	Yes		NA	R (10OCT2020)	N/N	
	GENRL	Fatigue/ FATIGUE	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N	
		Injection site pain/ INJECTION SITE PAIN	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N	
	GENRL	Chills/ CHILLS	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N	
		Pyrexia/ FEVER	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N	
	16-55/ C4591001 1013 10131595	SURG	Nasal polypectomy/ NASAL POLYPECTOMY	2	17DEC2020	67/1	1	No	O	NA/TCN	R (17DEC2020)	N/N
	16-55/ C4591001 1013 10131597	INJ&P	Meniscus injury/ MENISCAL TEAR#	4	08MAR2021	19/C	2	No	O	NA	RG	N/N
16-55/ C4591001 1013 10131599	GENRL	Injection site pain/ INJECTION SITE PAIN	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131600	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	21SEP2020	1/3	2	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
	RESP	Nasal congestion/ NASAL CONGESTION	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1013 10131601	GENRL	Injection site pain/ INJECTION SITE PAIN	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1013 10131603	GENRL	Injection site pain/ INJECTION SITE PAIN	1	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N
	RESP	Oropharyngeal pain/ SORE THROAT	1	25SEP2020	4/2	1	Yes		NA	R (26SEP2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	1	28SEP2020	7/2	1	Yes		NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 1013 10131607	GENRL	Injection site pain/ INJECTION SITE PAIN	1	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN	1	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131612	GENRL	Injection site pain/ INJECTION SITE PAIN	1	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1013 10131614†	GENRL	Fatigue/ FATIGUE	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1013 10131630	GENRL	Fatigue/ FATIGUE	1	26OCT2020	22/2	2	Yes		NA	R (27OCT2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	26OCT2020	1/3	1	Yes		NA/TC	R (28OCT2020)	N/N
		Pain/ GENERALIZED BODY ACHES	1	26OCT2020	22/2	2	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001 1013 10131633	GENRL	Pain/ BODY ACHES	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		Pyrexia/ LOW GRADE FEVER	1	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1013 10131634	MUSC	Tendonitis/ LEFT WRIST TENDONITIS	2	25JAN2021	91/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1013 10131637	GENRL	Injection site pain/ INJECTION SITE PAIN	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Arthralgia/ JOINT PAIN	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N	
	GENRL	Chills/ CHILLS	2	27OCT2020	2/3	3	Yes		NA/TC	R (29OCT2020)	N/N	
		Injection site nodule/ HARD NODULE INJECTION SITE LEFT	2	27OCT2020	2/4	1	Yes		NA	R (30OCT2020)	N/N	
		Injection site swelling/ INJECTION SITE SWELLING	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N	
		Pain/ GENERALIZED BODY ACHES	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N	
		Pyrexia/ LOW GRADE FEVER	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N	
	MUSC	Arthralgia/ JOINT PAIN FINGERS LEFT ARM	2	27OCT2020	2/4	1	Yes		NA	R (30OCT2020)	N/N	
	NERV	Headache/ FRONTAL HEADACHES	2	27OCT2020	2/2	1	Yes		NA/TC	R (28OCT2020)	N/N	
		Headache/ HEADACHE	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N	
	GENRL	Pyrexia/ LOW GRADE TEMP	2	28OCT2020	3/3	1	Yes		NA/TC	R (30OCT2020)	N/N	
16-55/ C4591001 1013 10131639	GENRL	Injection site pain/ INJECTION SITE PAIN	2	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N	
	NERV	Headache/ HEADACHE	2	30OCT2020	2/2	1	Yes		NA/TC	R (31OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131643	NERV	Headache/ FRONTAL HEADACHE	1	06OCT2020	1/2	2	Yes		NA	R (07OCT2020)	N/N
	PSYCH	Insomnia/ INSOMNIA	1	06OCT2020	1/2	2	Yes		NA	R (07OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
	MUSC	Arthralgia/ GENERALIZED JOINT PAIN	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
		Myalgia/ MUSCLE PAIN	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001 1013 10131644	SURG	Toe operation/ 5 TOES RIGHT FOOT HAMMER TOE RELEASE	2	03NOV2020	9/1	2	No	O	NA/TC	R (03NOV2020)	N/N
16-55/ C4591001 1013 10131645	GENRL	Chills/ CHILLS	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
		Pain/ BODY ACHES	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1013 10131653	VASC	Deep vein thrombosis/ RIGHT LOWER EXTREMITY DEEP VEIN THROMBOSIS	2	15NOV2020	20/C	3	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1013 10131656	METAB	Diabetic ketoacidosis/ DIABETIC KETOACIDOSIS	2	18JAN2021	84/4	3	No	O	NA/TC	R (21JAN2021)	Y/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1013 10131657	GENRL	Injection site pain/ INJECTION SITE PAIN	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N	
16-55/ C4591001 1013 10131658	BLOOD	Lymphadenopathy/ LYMPH NODE SWELLING LEFT AUXILLARY	2	28OCT2020	2/3	1	Yes		NA	R (30OCT2020)	N/N	
16-55/ C4591001 1013 10131664	GENRL	Injection site pain/ INJECTION SITE PAIN	1	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N	
16-55/ C4591001 1013 10131666	INJ&P	Ligament rupture/ TORN LIGAMENTS TO LEFT FOOT	1	09OCT2020	2/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1013 10131676	GENRL	Pain/ BODY ACHES	2	03NOV2020	2/3	1	Yes		NA	R (05NOV2020)	N/N	
16-55/ C4591001 1013 10131678	GENRL	Fatigue/ FATIGUE	1	12OCT2020	1/2	2	Yes		NA	R (13OCT2020)	N/Y	
		Injection site pain/ INJECTION SITE PAIN	1	12OCT2020	1/3	2	Yes		NA	R (14OCT2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	02NOV2020	1/4	1	Yes		NA	R (05NOV2020)	N/N	
	GENRL	Chills/ CHILLS	2	03NOV2020	2/1	1	Yes		NA	R (03NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1013 10131681	GENRL	Fatigue/ FATIGUE	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N	
		Pain/ BODY ACHES	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N	
		Pyrexia/ LOW GRADE FEVER	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N	
		Fatigue/ FATIGUE	1	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N	
		NERV	Headache/ HEADACHE	1	13OCT2020	2/5	2	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 1013 10131685	GASTR	Diarrhoea/ DIARRHEA	1	14OCT2020	3/2	1	Yes		NA	R (15OCT2020)	N/N	
	GENRL	Pain/ BODY ACHES	1	14OCT2020	3/4	2	Yes		NA/TC	R (17OCT2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	13OCT2020	2/6	2	Yes		NA	R (18OCT2020)	N/N	
16-55/ C4591001 1013 10131689	GENRL	Fatigue/ FATIGUE	2	02NOV2020	1/3	1	Yes		NA/TC	R (04NOV2020)	N/N	
		MUSC	Injection site pain/ INJECTION SITE PAIN	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C4591001	GENRL	Pain/ BODY ACHES	2	06NOV2020	2/2	1	Yes		NA/TC	R (07NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131693	GENRL	Pain/ BODY ACHES	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1013 10131696	INFEC	Tinea infection/ RINGWORM#	4	04MAR2021	57/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1013 10131697	GENRL	Injection site pain/ INJECTION SITE PAIN	1	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
1013 10131708	NERV	Headache/ HEADACHE	1	14OCT2020	2/4	1	Yes		NA/TC	R (17OCT2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	03NOV2020	1/4	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Chills/ CHILLS	2	04NOV2020	2/1	3	Yes		NA/TC	R (04NOV2020)	N/N
		Pain/ BODY ACHES	2	04NOV2020	2/4	2	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1013 10131709	GENRL	Injection site pain/ INJECTION SITE PAIN	1	14OCT2020	1/5	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Injection site pruritus/ PRURITUS AT INJECTION SITE	2	03NOV2020	1/3	1	Yes		NA	R (05NOV2020)	N/N
16-55/ C4591001	GENRL	Pain/ BODY ACHES	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1013 10131713	NERV	Dizziness/ LIGHTHEADEDNESS	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N	
16-55/ C4591001 1013 10131718	GENRL	Chills/ CHILLS	2	04NOV2020	3/2	1	Yes		NA	R (05NOV2020)	N/N	
		Fatigue/ FATIGUE	2	04NOV2020	3/2	1	Yes		NA	R (05NOV2020)	N/N	
	HEPAT	Cholecystitis/ CHOLECYSTITIS#	3	07MAR2021	12/4	2	No	O	NA/TC	R (10MAR2021)	Y/N	
16-55/ C4591001 1013 10131721	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	06NOV2020	2/6	2	Yes		NA	R (11NOV2020)	N/N	
		Injection site swelling/ SWELLING AT INJECTION SITE	2	06NOV2020	2/6	2	Yes		NA	R (11NOV2020)	N/N	
16-55/ C4591001 1013 10131729	GENRL	Chills/ CHILLS	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N	
	MUSC	Myalgia/ MUSCLE PAIN	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N	
16-55/ C4591001 1013 10131737	GENRL	Injection site pain/ injection site pain	1	15OCT2020	1/4	1	Yes		NA	R (18OCT2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131744	NERV	Headache/ HEADACHE (FRONTAL)	2	04NOV2020	1/2	1	Yes		NA	R (05NOV2020)	N/N
	GENRL	Chills/ CHILLS	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N
		Fatigue/ FATIGUE	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1013 10131749		Pain/ BODY ACHES	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1013 10131752	GENRL	Fatigue/ FATIGUE	1	19OCT2020	1/8	1	Yes		NA	R (26OCT2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	1	19OCT2020	1/8	1	Yes		NA	R (26OCT2020)	N/N
	GENRL	Pain/ BODY ACHES	1	20OCT2020	2/7	1	Yes		NA	R (26OCT2020)	N/N
	RESP	Cough/ COUGH	1	20OCT2020	2/7	1	Yes		NA	R (26OCT2020)	N/N
		Nasal congestion/ NASAL CONGESTION	1	20OCT2020	2/7	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C4591001 1013 10131759	GENRL	Injection site pain/ INJECTION SITE PAIN	1	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131771	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	12NOV2020	3/3	1	Yes		NA	R (14NOV2020)	N/N
		Injection site swelling/ SWELLING AT INJECTION SITE	2	12NOV2020	3/3	2	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	2	12NOV2020	3/2	1	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1013 10131772	GENRL	Chills/ CHILLS	2	11NOV2020	1/2	1	Yes		NA/TC	R (12NOV2020)	N/N
		Injection site pruritus/ PRURITUS AT INJECTION SITE	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1013 10131783	GENRL	Injection site pain/ INJECTION SITE PAIN	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1013 10131790	GENRL	Chills/ CHILLS	2	11NOV2020	1/2	2	Yes		NA	R (12NOV2020)	N/N
	GENRL	Pain/ BODY ACHES	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
	NERV	Headache/ HEADACHE	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ FATIGUE	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131793	GENRL	Injection site pain/ INJECTION SITE PAIN	1	21OCT2020	1/2	1	Yes	NA	R	(22OCT2020)	N/N
		Fatigue/ FATIGUE	2	12NOV2020	2/1	1	Yes	NA	R	(12NOV2020)	N/N
		Pain/ BODY ACHES	2	12NOV2020	2/1	1	Yes	NA/TC	R	(12NOV2020)	N/N
16-55/ C4591001 1013 10131794	NERV	Headache/ FRONTAL HEADACHE	1	22OCT2020	2/2	1	Yes	NA/TC	R	(23OCT2020)	N/N
16-55/ C4591001 1013 10131796	GENRL	Injection site pain/ INJECTION SITE PAIN	1	21OCT2020	1/3	1	Yes	NA	R	(23OCT2020)	N/N
16-55/ C4591001 1013 10131800	GENRL	Fatigue/ FATIGUE	1	22OCT2020	1/2	2	Yes	NA	R	(23OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	23OCT2020	2/2	2	Yes	NA	R	(24OCT2020)	N/N
		Pain/ BODY ACHES	1	23OCT2020	2/2	2	Yes	NA	R	(24OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	12NOV2020	2/1	2	Yes	NA	R	(12NOV2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	12NOV2020	2/4	2	Yes	NA	R	(15NOV2020)	N/N
		Pain/ BODY ACHES	2	12NOV2020	2/2	2	Yes	NA/TC	R	(13NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131802	GENRL	Injection site pain/ INJECTION SITE PAIN	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
		Injection site swelling/ INJECTION SITE SWELLING	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1013 10131808	NERV	Headache/ TEMPORAL HEADACHE	1	22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N
	NERV	Headache/ TEMPORAL HEADACHE	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1013 10131809	INJ&P	Limb injury/ SHOULDER INJURY LEFT	1	11NOV2020	21/14	2	No	O	NA/TC	R (24NOV2020)	N/N
16-55/ C4591001 1013 10131815	GENRL	Fatigue/ FATIGUE	2	12NOV2020	2/1	2	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1013 10131817	GENRL	Injection site erythema/ INJECTION SITE ERYTHEMA	1	23OCT2020	2/5	1	Yes		NA	R (27OCT2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	1	23OCT2020	2/5	1	Yes		NA	R (27OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	23JAN2021	73/C	1	No	O	NA/TC	RG	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151006	GENRL	Chills/ Chills#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
		Fatigue/ Fatigue#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
	INV	Body temperature increased/ Increased body temperature 99F#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
	NERV	Headache/ Headache#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1015 10151009	MUSC	Myalgia/ Myalgias#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
	INV	Body temperature increased/ Increased body temperature#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
	MUSC	Arthralgia/ General joint pain#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001	NERV	Headache/ Head ache#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
	INJ&P	Exposure during pregnancy/ Exposure During Partner Pregnancy	2	25NOV2020	84/C		No	O	NA	UNK	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1015 10151011	MUSC	Pain in extremity/ Leg pain	2	05SEP2020	2/2	1	No	O	NA	R (06SEP2020)	N/N
1015 10151015	NERV	Syncope/ syncope*		14AUG2020	1/1	1	No	O	NA/TCN	R (14AUG2020)	N/N
1015 10151017	GENRL	Chills/ Chills#	4	08JAN2021	3/2	1	Yes		NA	R (09JAN2021)	N/N
10151018	INV	Body temperature increased/ Increased body temperature#	4	08JAN2021	3/2	1	Yes		NA	R (09JAN2021)	N/N
	MUSC	Myalgia/ Muscle aches#	4	08JAN2021	3/2	1	Yes		NA	R (09JAN2021)	N/N
	NERV	Headache/ Headache#	4	08JAN2021	3/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site bruising/ Bruising at injection site#	3	21DEC2020	1/4	1	Yes		NA	R (24DEC2020)	N/N
1015 10151021	GENRL	Chills/ Chills#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	NERV	Headache/ Headache#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N	
16-55/ C4591001 1015 10151023	GASTR	Diarrhoea/ Diarrhea	1	21AUG2020	8/1	1	Yes		NA	R (21AUG2020)	N/N	
16-55/ C4591001 1015 10151026	GENRL	Chills/ Chills#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N	
16-55/ C4591001 1015 10151029	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/Y	
	GENRL	Injection site pain/ Injection site pain#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/Y	
16-55/ C4591001 1015 10151031	GENRL	Fatigue/ Fatigue#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N	
16-55/ C4591001 1015 10151035	BLOOD	Lymphadenopathy/ Swollen lymph node - left armpit axillary	2	04SEP2020	1/5	1	Yes		NA	R (08SEP2020)	N/N	
16-55/ C4591001 1015 10151041	GASTR	Abdominal pain upper/ Stomach cramps	1	08SEP2020	23/2	1	No	CD	NA	R (09SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1015 10151045	GASTR	Nausea/ Nausea	1	08SEP2020	23/2	1	No	CD	NA	R (09SEP2020)	N/N	
		Diarrhoea/ Diarrhea	1	17AUG2020	1/1	1	Yes		NA	R (17AUG2020)	N/N	
	GENRL	Fatigue/ Fatigue#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	1/3	1	Yes		NA	R (18FEB2021)	N/N	
	MUSC	Injection site pain/ Injection site pain#	4	16FEB2021	1/3	2	Yes		NA/TC	R (18FEB2021)	N/N	
16-55/ C4591001 1015 10151046	MUSC	Myalgia/ Myalgia#	4	16FEB2021	1/3	2	Yes		NA/TC	R (18FEB2021)	N/N	
		Chills/ Chills	2	12SEP2020	5/2	1	Yes		NA	R (13SEP2020)	N/N	
	MUSC	Pyrexia/ Fever	2	12SEP2020	5/2	1	Yes		NA	R (13SEP2020)	N/N	
	MUSC	Myalgia/ Muscle Aches	2	12SEP2020	5/2	1	Yes		NA	R (13SEP2020)	N/N	
16-55/ C4591001 1015 10151047	GENRL	Injection site pain/ injection site pain#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N	
	EYE	Corneal irritation/ Right corneal irritation	1	17AUG2020	1/4	2	No	O	NA	R (20AUG2020)	N/N	
	GENRL	Shoulder injury related to vaccine administration/	2	09SEP2020	1/153	3	Yes		NA	R (08FEB2021)	Y/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151049		SIRVA - shoulder injury related to vaccine administration									
	RESP	Oropharyngeal pain/ Sore throat	2	21SEP2020	13/2	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
		Injection site pain/ Injection site pain#	3	22DEC2020	1/2	2	Yes		NA	R (23DEC2020)	N/N
	INV	Body temperature increased/ Increased body temperature#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	GASTR	Vomiting/ Single episode of vomiting#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Chills/ Chills#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
		Fatigue/ Fatigue#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
		Injection site urticaria/ Hives around injection site#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
		Pyrexia/ Fever 100.1 F#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1015 10151051	NERV	Headache/ Headache#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Soreness of injection site arm	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ Fever 101.2	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151053	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1015 10151054	GENRL	Malaise/ general malaise	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ low grade fever (100.0 F)	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1015 10151055	GENRL	Fatigue/ Fatigue	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	INV	Body temperature increased/ Increased temperature of 99 degrees Fahrenheit	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1015 10151056	GENRL	Injection site pain/ Injection site pain#	3	18DEC2020	1/5	1	Yes		NA/TC	R (22DEC2020)	N/N
	GENRL	Malaise/ Malaise#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Chills/ chills#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
		Injection site pain/ injection site pain#	4	07JAN2021	2/1	1	Yes		NA/TC	R (07JAN2021)	N/N
		Malaise/ general malaise#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/4	1	Yes		NA	R (06FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1015 10151058												
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	09SEP2020	1/3	2	Yes		NA	R (11SEP2020)	N/N	
1015 10151061												
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	1/3	1	Yes		NA	R (18FEB2021)	N/N	
	MUSC	Myalgia/ Myalgias#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Soreness at injection site	1	19AUG2020	1/2	1	Yes		NA	R (20AUG2020)	N/Y	
1015 10151063												
16-55/ C4591001	GENRL	Vaccination site pain/ Pain in arm at site of tetanus shot	2	28OCT2020	49/2	1	No	CD	NA	R (29OCT2020)	N/N	
1015 10151068												
	GENRL	Injection site pain/ Pain at injection site#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	11JAN2021	1/4	1	Yes		NA/TC	R (14JAN2021)	N/N	
	MUSC	Myalgia/ myalgia#	4	11JAN2021	1/4	1	Yes		NA/TC	R (14JAN2021)	N/N	
	NERV	Headache/ Headache#	4	11JAN2021	1/4	1	Yes		NA/TC	R (14JAN2021)	N/N	
16-55/ C4591001	GENRL	Chills/ Chills#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N	
1015 10151069												

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151071	INV	Injection site pain/ Injection site pain#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
		Body temperature increased/ Increased body temperature#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ Muscle aches#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	NERV	Headache/ Headache#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1015 10151071	INJ&P	Exposure during pregnancy/ Exposure during pregnancy#	3	07JAN2021	18/C		No	O	NA	UNK	N/N
16-55/ C4591001 1015 10151073	GENRL	Chills/ Chills#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Fatigue/ Fatigue#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Injection site pain/ Injection site pain#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Pain/ Body aches#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1015 10151077	GENRL	Headache/ Headache#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Fatigue/ Fatigue	1	21AUG2020	2/3	1	Yes		NA	R (23AUG2020)	N/N
		Injection site pain/ Soreness over the injection ste	1	21AUG2020	2/3	1	Yes		NA	R (23AUG2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151080	MUSC	Arthralgia/ Shoulder pain located lateral to deltoid muscle, near acromion.	2	09SEP2020	1/84	1	Yes		NA/TC	R (01DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	19DEC2020	2/1	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N
		Injection site pain/ Injection site pain#	4	08JAN2021	1/4	2	Yes		NA/TC	R (11JAN2021)	N/N
	NERV	Headache/ Headache#	4	09JAN2021	2/3	2	Yes		NA/TC	R (11JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ Arm soreness at injection site	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11SEP2020	1/4	1	Yes		NA/TC	R (14SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1015 10151085	NERV	Injection site pain/ Pain at injection site	2	11SEP2020	1/4	1	Yes		NA/TC	R (14SEP2020)	N/N	
		Pyrexia/ Fever	2	11SEP2020	1/4	1	Yes		NA/TC	R (14SEP2020)	N/N	
		Headache/ Headache	2	12SEP2020	2/3	1	Yes		NA/TC	R (14SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	11JAN2021	1/4	1	Yes		NA/TC	R (14JAN2021)	N/N	
16-55/ C4591001 1015 10151088	GENRL	Fatigue/ Fatigue#	3	18DEC2020	1/4	1	Yes		NA/TC	R (21DEC2020)	N/N	
16-55/ C4591001 1015 10151089	GENRL	Injection site pain/ Injection site pain#	3	18DEC2020	1/4	1	Yes		NA/TC	R (21DEC2020)	N/N	
		Chills/ Chills#	4	09JAN2021	2/2	2	Yes		NA/TC	R (10JAN2021)	N/N	
		Fatigue/ Fatigue#	4	09JAN2021	2/2	2	Yes		NA/TC	R (10JAN2021)	N/N	
		Pyrexia/ Fever 101.6#	4	09JAN2021	2/2	2	Yes		NA/TC	R (10JAN2021)	N/N	
	MUSC	Myalgia/ myalgia#	4	09JAN2021	2/2	2	Yes		NA/TC	R (10JAN2021)	N/N	
GENRL	Lymphadenopathy/ Swollen left axillary lymph node	2	11SEP2020	1/8	1	Yes		NA	R (18SEP2020)	N/N		
	GENRL	Pyrexia/ Fever	2	11SEP2020	1/3	1	Yes		NA/TC	R (13SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151092	INJ&P	Procedural pain/ Whole arm pain - received injection	2	11SEP2020	1/3	1	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Pyrexia/ Fever T 100.3F	2	16SEP2020	3/2	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1015 10151100	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	1/4	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1015 10151101	METAB	Gout/ Gout	2	01OCT2020	17/12	1	Yes		NA/TC	R (12OCT2020)	N/N
16-55/ C4591001 1015 10151102	PREG	Exposure during pregnancy/ Exposure during pregnancy (partner)#	2	22JAN2021	130/C		No	O	NA	UNK	N/N
	GENRL	Chills/ Chills	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1015 10151104		Injection site pain/ Soreness at injection site	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
	GASTR	Abdominal discomfort/ GI distress#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151105	GENRL	Fatigue/ Fatigue#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
		Injection site pain/ injection site pain#	4	06JAN2021	1/2	1	Yes		NA/TC	R (07JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	06JAN2021	1/2	1	Yes		NA/TC	R (07JAN2021)	N/N
16-55/ C4591001 1015 10151107	GENRL	Injection site pain/ Pain at injection site#	3	19DEC2020	2/3	1	Yes		NA	R (21DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	09JAN2021	2/2	1	Yes		NA/TC	R (10JAN2021)	N/N
16-55/ C4591001 1015 10151108	GENRL	Injection site pain/ Pain at injection site#	3	21DEC2020	1/2	1	Yes		NA/TC	R (22DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	22DEC2020	2/1	1	Yes		NA/TC	R (22DEC2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Aches#	3	22DEC2020	2/2	1	Yes		NA/TC	R (23DEC2020)	N/N
	GENRL	Chills/ Chills#	4	11JAN2021	1/2	2	Yes		NA	R (12JAN2021)	N/N
		Fatigue/ Fatigue#	4	11JAN2021	1/2	2	Yes		NA	R (12JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	11JAN2021	1/4	1	Yes		NA	R (14JAN2021)	N/N
		Pain/ Body aches#	4	11JAN2021	1/2	2	Yes		NA	R (12JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151112	NERV	Pyrexia/ Fever 102 F#	4	11JAN2021	1/2	2	Yes		NA	R (12JAN2021)	N/N
		Headache/ Headache#	4	11JAN2021	1/2	2	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1015 10151112	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/3	1	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1015 10151115	GENRL	Injection site pain/ Injection site soreness	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1015 10151116	GENRL	Malaise/ General malaise	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1015 10151119	GENRL	Injection site pain/ Pain at injection site#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/Y
16-55/ C4591001 1015 10151120	GENRL	Chills/ Chills#	4	05JAN2021	1/2	1	Yes		NA/TC	R (06JAN2021)	N/N
	GENRL	Chills/ Chills#	4	06JAN2021	1/2	1	Yes		NA/TC	R (07JAN2021)	N/N
		Pyrexia/ Fever 103#	4	06JAN2021	1/2	2	Yes		NA	R (07JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1015 10151122	MUSC	Pain in extremity/ Soreness in left arm	1	26AUG2020	1/4	2	Yes		NA	R (29AUG2020)	N/Y	
	GENRL	Chest discomfort/ Tightness in chest	1	07SEP2020	13/3	1	No	O	NA	R (09SEP2020)	N/N	
	GENRL	Injection site pain/ Soreness in injection site	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/Y	
	GASTR	Diarrhoea/ Diarrhea	2	19OCT2020	34/2	1	No	O	NA	R (20OCT2020)	N/N	
		Vomiting/ Vomitting	2	19OCT2020	34/2	1	No	O	NA	R (20OCT2020)	N/N	
16-55/ C4591001 1015 10151126	MUSC	Arthralgia/ Bilateral joint pain in elbow and knees#	2	21JAN2021	127/2	1	Yes		NA	R (22JAN2021)	N/N	
16-55/ C4591001 1015 10151130	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N	
16-55/ C4591001 1015 10151131	GENRL	Vessel puncture site induration/ 3mm induration in left antecubital area at the phlebotomy site	1	28AUG2020	2/98	1	No	O	NA	R (03DEC2020)	N/N	
16-55/ C4591001 1015 10151132	GENRL	Injection site pain/ Soreness at injection site	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N	
		Pain/ Body aches	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151134	NERV	Pyrexia/ Fever 101.2	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		Headache/ Headache	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	EAR	Vertigo/ Worsening and continuing episode of Veritgo	1	28AUG2020	2/116	2	Yes		P	R (21DEC2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
		Nausea/ Nausea	1	28AUG2020	2/5	1	Yes		NA	R (01SEP2020)	N/N
	NERV	Headache/ Headache	1	28AUG2020	2/5	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Chills/ Chills#	4	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1015 10151135		Injection site pain/ Injection site pain#	4	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
	NERV	Headache/ Headache#	4	14JAN2021	2/2	2	Yes		NA/TC	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/4	1	Yes		NA	R (25DEC2020)	N/N
	GENRL	Chills/ Chills#	4	15JAN2021	2/1	1	Yes		NA/TC	R (15JAN2021)	N/N
		Fatigue/ Fatigue#	4	15JAN2021	2/1	1	Yes		NA/TC	R (15JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1015 10151137	NERV	Injection site pain/ Injection site pain#	4	15JAN2021	2/1	1	Yes		NA/TC	R (15JAN2021)	N/N	
		Pyrexia/ Fever 100.4#	4	15JAN2021	2/1	1	Yes		NA/TC	R (15JAN2021)	N/N	
		Headache/ Headache#	4	15JAN2021	2/1	1	Yes		NA/TC	R (15JAN2021)	N/N	
		Chills/ Chills#	4	13JAN2021	1/4	1	Yes		NA	R (16JAN2021)	N/N	
	MUSC	Injection site pain/ Injection site pain#	4	13JAN2021	1/4	1	Yes		NA	R (16JAN2021)	N/N	
		Pyrexia/ Fever 100.7F#	4	13JAN2021	1/4	1	Yes		NA	R (16JAN2021)	N/N	
		Myalgia/ Muscle aches#	4	13JAN2021	1/4	1	Yes		NA	R (16JAN2021)	N/N	
	RESP	Nasal congestion/ Nasal congestion	2	29SEP2020	12/2	1	No	O	NA	R (30SEP2020)	N/N	
	GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N	
GENRL	Chills/ chills#	4	11JAN2021	1/4	1	Yes		NA	R (14JAN2021)	N/N		



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151148	NERV	Fatigue/ fatigue#	4	11JAN2021	1/4	1	Yes		NA	R (14JAN2021)	N/N
		Headache/ headache#	4	11JAN2021	1/4	1	Yes		NA/TC	R (14JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	12JAN2021	2/3	1	Yes		NA	R (14JAN2021)	N/N
	GASTR	Diarrhoea/ Single episode of diarrhea	1	02SEP2020	3/1	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Injection site soreness	2	23SEP2020	2/9	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N
	GENRL	Implant site pain/ Pain at left breast implant#	3	21DEC2020	6/5	1	Yes		NA	R (25DEC2020)	N/N
16-55/ C4591001 1015 10151153	GENRL	Implant site pain/ Pain in left breast implant#	4	06JAN2021	1/4	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
16-55/ C4591001 1015 10151154	GENRL	Fatigue/ Fatigue	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ Soreness at injection site	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1015 10151157	MUSC	Pyrexia/ Fever	2	23SEP2020	2/2	2	Yes		NA/TC	R (24SEP2020)	N/N	
		Myalgia/ Muscle aches	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N	
		Pain/ Body aches	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N	
16-55/ C4591001 1015 10151159	GENRL	Pyrexia/ Fever - 99.2	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N	
		Injection site pain/ Injection Site Pain#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N	
16-55/ C4591001 1015 10151161	GENRL	Injection site pain/ Soreness of injection site	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N	
	NERV	Pyrexia/ Low grade temperature	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N	
		Headache/ Headache	1	01SEP2020	1/3	3	Yes		NA	R (03SEP2020)	N/N	
		Pyrexia/ Fever - 100.7	2	21SEP2020	1/1	1	Yes		NA/TC	R (21SEP2020)	N/Y	
	INJ&P	Procedural pain/ Whole arm pain - received IP	2	21SEP2020	1/3	2	Yes		NA/TC	R (23SEP2020)	N/Y	
	MUSC	Myalgia/ Myalgias	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1015 10151162	GENRL	Fatigue/ Fatigue#	4	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1015 10151165	GENRL	Injection site pain/ Injection site pain#	3	24DEC2020	2/1	1	Yes		NA	R (24DEC2020)	N/N
16-55/ C4591001 1015 10151166	MUSC	Myalgia/ Upper left arm pain - pain in the deltoid, bicep and tripep muscles with movement	1	02SEP2020	1/7	1	Yes		NA	R (08SEP2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/3	1	Yes		NA	R (24DEC2020)	N/N
	NERV	Headache/ Headache#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	11JAN2021	1/4	1	Yes		NA	R (14JAN2021)	N/Y
	NERV	Headache/ Headache#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/Y
16-55/ C4591001 1015 10151167	GENRL	Injection site pain/ Arm injection site sorness (Pain)	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
		Pyrexia/ Fever	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
	NERV	Headache/ Headache	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1015 10151170	GENRL	Chills/ Chills	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N	
		Injection site pain/ Injection site soreness	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N	
		Pyrexia/ Fever - 102.0	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N	
	MUSC	Myalgia/ Muscle aches	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site soreness	1	02SEP2020	1/3	3	Yes		NA/TC	R (04SEP2020)	N/N	
	16-55/ C4591001 1015 10151171	GENRL	Fatigue/ Fatigue	2	23SEP2020	1/4	2	Yes		NA/TC	R (26SEP2020)	N/N
			Injection site pain/ Soreness at injection site	2	23SEP2020	1/3	2	Yes		NA/TC	R (25SEP2020)	N/N
			Pyrexia/ Fever - 99.6	2	23SEP2020	1/4	2	Yes		NA/TC	R (26SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	23SEP2020	1/4	2	Yes		NA/TC	R (26SEP2020)	N/N
	16-55/ C4591001 1015 10151172	GENRL	Chills/ Chills#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
MUSC		Myalgia/ Muscle aches#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N	
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/Y	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1015 10151174		Injection site pain/ Pain at injection site	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/Y
		Pyrexia/ Fever 99.5	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/Y
	GENRL	Chills/ Chills	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
		Fatigue/ Fatigue	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ Fever 102.6	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
	GENRL	Pyrexia/ Fever 100.2	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1015 10151175	GENRL	Injection site pain/ Injection site soreness in left arm	1	03SEP2020	1/20	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	05JAN2021	1/1	1	Yes		NA	R (05JAN2021)	N/N
16-55/ C4591001 1015 10151176	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		Injection site pain/ Soreness at injection site	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151177	GENRL	Injection site pain/ Soreness at injection site	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/Y
		Pyrexia/ Mild fever	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/Y
	GENRL	Chills/ Chills	2	25SEP2020	1/3	2	Yes		NA/TC	R (27SEP2020)	N/N
		Injection site pain/ Muscle pain at injection site	2	25SEP2020	1/3	2	Yes		NA/TC	R (27SEP2020)	N/N
		Pain/ Body aches	2	25SEP2020	1/3	2	Yes		NA/TC	R (27SEP2020)	N/N
		Pyrexia/ Fever - 100.0	2	25SEP2020	1/3	2	Yes		NA/TC	R (27SEP2020)	N/N
	NERV	Headache/ Headache	2	25SEP2020	1/3	2	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1015 10151179	GENRL	Fatigue/ fatigue#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ injection site pain#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1015 10151180	GENRL	Chills/ Chills#	4	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N
		Fatigue/ Fatigue#	4	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1015 10151183	GENRL	Pain/ Body aches#	4	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N	
		Chills/ chills#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N	
		Injection site pain/ injection site pain#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N	
		INV	Body temperature increased/ increased body temperature#	4	06JAN2021	1/2	1	Yes		NA/TC	R (07JAN2021)	N/N
16-55/ C4591001 1015 10151184	MUSC	Myalgia/ myalgia#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N	
	GENRL	Pain/ Body aches	1	04SEP2020	1/2	1	Yes		NA/TC	R (05SEP2020)	N/Y	
	GENRL	Pyrexia/ Fever - 99.4	1	04SEP2020	1/2	1	Yes		NA/TC	R (05SEP2020)	N/Y	
		Pyrexia/ Fever - 99.0	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N	
MUSC	Myalgia/ Muscle pain	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N		
NERV	Headache/ Headache	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N		
16-55/ C4591001 1015 10151185	GENRL	Injection site pain/ Soreness at injection site	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/Y	
	GENRL	Injection site pain/ Injection site pain#	3	23DEC2020	1/3	1	Yes		NA	R (25DEC2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1015 10151187	GENRL	Injection site pain/ Injection site pain#	4	15JAN2021	1/3	1	Yes		NA/TC	R (17JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	15JAN2021	1/3	2	Yes		NA/TC	R (17JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N	
	REPRO	Vaginal lesion/ Vaginal lesion#	4	18JAN2021	4/11	1	No	O	NA/TC	R (28JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue	2	28SEP2020	1/4	2	Yes		NA	R (01OCT2020)	N/N	
			Injection site pain/ Soreness at injection site	2	28SEP2020	1/4	2	Yes		NA	R (01OCT2020)	N/N
			Injection site paraesthesia/ Tingling at injection site, down arm	2	28SEP2020	1/1	1	Yes		NA	R (28SEP2020)	N/Y
			Pyrexia/ Fever 99.9	2	28SEP2020	1/4	2	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ Generalized muscle aches	2	28SEP2020	1/4	2	Yes		NA	R (01OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N	
	GENRL	Fatigue/ Fatigue#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N	
			Injection site pain/ Injection site pain#	4	11JAN2021	1/4	2	Yes		NA	R (14JAN2021)	N/N
	INV	Body temperature increased/ Increased body temperature#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N	
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1015 10151188		Pyrexia/ Fever 100.3	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N	
	MUSC	Myalgia/ Muscle aches	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N	
16-55/ C4591001 1015 10151191	GENRL	Fatigue/ Fatigue#	3	04FEB2021	1/4	1	Yes		NA/TC	R (07FEB2021)	N/N	
	MUSC	Myalgia/ Myalgias#	3	04FEB2021	1/4	1	Yes		NA/TC	R (07FEB2021)	N/N	
16-55/ C4591001 1015 10151192	GENRL	Injection site pain/ Soreness at injection site	1	07SEP2020	1/4	1	Yes		NA	R (10SEP2020)	N/Y	
	GENRL	Pyrexia/ Fever - 101.0	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N	
16-55/ C4591001 1015 10151193	GENRL	Injection site pain/ Injection site pain#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N	
	GENRL	Fatigue/ Fatigue#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N	
	MUSC	Myalgia/ General muscle aches#	4	14JAN2021	2/2	2	Yes		NA/TC	R (15JAN2021)	N/N	
16-55/ C4591001 1015 10151199	GENRL	Injection site pain/ Soreness at injection site	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1015 10151202	GENRL	Pain/ Body aches#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
	INV	Body temperature increased/ Increased body temperature#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
16-55/ C4591001 1015 10151203	GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N	
		Injection site pain/ Soreness of injection site	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N	
	SKIN	Rash/ Rash - both shins	2	15OCT2020	16/6	2	No	O	NA	R (20OCT2020)	N/N	
	SKIN	Rash/ Rash - left knee	2	25OCT2020	26/102	2	Yes		NA/TC	RS (03FEB2021)	N/N	
	GENRL	Peripheral swelling/ Right lower leg swollen	2	26OCT2020	27/101	2	Yes		NA/TC	RS (03FEB2021)	N/N	
16-55/ C4591001 1015 10151205	RESP	Rhinorrhoea/ Nasal discharge	1	10SEP2020	2/8	3	No	O	NA/TC	R (17SEP2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N	
	GENRL	Fatigue/ Fatigue#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N	
	NERV	Headache/ Headache#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N	
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1015 10151207	NERV	Headache/ Worsening headache	2	29SEP2020	1/1	1	Yes	NA/TC		R (29SEP2020)	N/Y
	GENRL	Fatigue/ Fatigue#	4	07JAN2021	1/2	1	Yes	NA		R (08JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	07JAN2021	1/4	2	Yes	NA/TC		R (10JAN2021)	N/N
16-55/ C4591001 1015 10151209	GENRL	Fatigue/ Fatigue#	3	17DEC2020	1/2	1	Yes	NA		R (18DEC2020)	N/N
		Injection site pain/ Injection site pain#	3	17DEC2020	1/3	1	Yes	NA		R (19DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	07JAN2021	1/5	1	Yes	NA		R (11JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	07JAN2021	1/5	1	Yes	NA		R (11JAN2021)	N/N
16-55/ C4591001 1015 10151210	GENRL	Chills/ Chills	2	01OCT2020	1/3	1	Yes	NA/TC		R (03OCT2020)	N/N
		Fatigue/ Fatigue	2	01OCT2020	1/3	1	Yes	NA/TC		R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	01OCT2020	1/3	1	Yes	NA/TC		R (03OCT2020)	N/N
16-55/ C4591001 1015 10151211	GENRL	Injection site pain/ Soreness at injection site	1	10SEP2020	1/2	1	Yes	NA/TC		R (11SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151212	GENRL	Injection site pain/ Soreness at injection site	1	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Migraine/ Migraine	1	17SEP2020	8/3	2	No	O	NA/TC	R (19SEP2020)	N/N
	INV	Body temperature increased/ body temperature increased#	3	16DEC2020	1/2	1	Yes		NA/TC	R (17DEC2020)	N/N
	MUSC	Myalgia/ Muscle aches#	3	16DEC2020	1/2	1	Yes		NA/TC	R (17DEC2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	17DEC2020	2/2	1	Yes		NA/TC	R (18DEC2020)	N/N
16-55/ C4591001 1015 10151214	GENRL	Fatigue/ Fatigue	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	MUSC	Myalgia/ Muscle ache near chest area	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1015 10151217	NERV	Migraine/ Worsening Migraine	1	11SEP2020	1/3	1	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Pyrexia/ Fever	1	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1015 10151220	GENRL	Injection site pain/ Injection site pain#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
		Fatigue/ Fatigue#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
		Pain/ Body aches#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
	NERV	Headache/ Headache#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1015 10151221	GENRL	Injection site pain/ Pain at injection site	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1015 10151222	GENRL	Chills/ Chills	2	08OCT2020	2/2	2	Yes		NA	R (09OCT2020)	N/N
		Pyrexia/ Fever - 100.7	2	08OCT2020	2/2	2	Yes		NA	R (09OCT2020)	N/N
	MUSC	Pain in extremity/ Sore arm - whole arm received investigational product	2	08OCT2020	2/2	2	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1015 10151223	GENRL	Pyrexia/ Fever - 100.5F#	4	10FEB2021	2/1	1	Yes		NA/TC	R (10FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	10FEB2021	2/2	2	Yes		NA/TC	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	10FEB2021	2/1	2	Yes		NA/TC	R (10FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1015 10151224	GENRL	Injection site pain/ Pain at injectin site	2	14OCT2020	1/4	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 1015 10151225	NERV	Dizziness/ Dizziness	2	08OCT2020	1/5	1	Yes		NA	R (12OCT2020)	N/N
	BLOOD	Lymphadenopathy/ Swollen neck lymph nodes - both sides#	3	23DEC2020	2/2	1	Yes		NA/TC	R (24DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
		Pyrexia/ Fever 100.7#	3	23DEC2020	2/2	1	Yes		NA/TC	R (24DEC2020)	N/N
	MUSC	Myalgia/ General muscle aches#	3	23DEC2020	2/2	1	Yes		NA/TC	R (24DEC2020)	N/N
	GENRL	Chills/ Chills#	4	14JAN2021	1/3	2	Yes		NA	R (16JAN2021)	N/N
		Fatigue/ Fatigue#	4	14JAN2021	1/3	2	Yes		NA	R (16JAN2021)	N/N
		Pyrexia/ Fever 101.0#	4	14JAN2021	1/3	2	Yes		NA/TC	R (16JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	14JAN2021	1/3	2	Yes		NA/TC	R (16JAN2021)	N/N
	NERV	Headache/ Headache#	4	14JAN2021	1/3	2	Yes		NA/TC	R (16JAN2021)	N/N
16-55/ C4591001 1015 10151226	GENRL	Fatigue/ Fatigue	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1015 10151229	MUSC	Myalgia/ Muscle aches	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N	
	GASTR	Diarrhoea/ Diarrhea	2	13OCT2020	7/1	1	No	O	NA	R (13OCT2020)	N/N	
16-55/ C4591001 1015 10151231	GENRL	Swelling face/ Swollen face	2	01NOV2020	19/1	1	No	O	NA/TC	R (01NOV2020)	N/N	
16-55/ C4591001 1015 10151233	SKIN	Pruritus/ Itching all over body	2	01NOV2020	19/1	1	No	O	NA/TC	R (01NOV2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	1	24SEP2020	1/3	1	Yes		NA/TC	R (26SEP2020)	N/N	
16-55/ C4591001 1015 10151234	INV	Body temperature increased/ Increased temperature - 99.0	1	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N	
		Pyrexia/ Increased fever from 99.0 to 100.4	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N	
	INJ&P	Administration related reaction/ Sore arm - whole arm that received IP	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N	
	NERV	Headache/ Headache	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N	
16-55/ C4591001 1015 10151234	GENRL	Asthenia/ Low energygy	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151235	GENRL	Fatigue/ Fatigue#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
		Injection site pain/ Injection site pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Arthralgia/ Generalized joint pain#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1015 10151236	GENRL	Fatigue/ Fatigue#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
		Pyrexia/ Fever 100.2#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1015 10151240	GENRL	Pyrexia/ Fever#	4	06JAN2021	2/2	1	Yes		NA/TC	R (07JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	06JAN2021	2/2	1	Yes		NA/TC	R (07JAN2021)	N/N
16-55/ C4591001 1015 10151241	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/4	1	Yes		NA	R (10OCT2020)	N/N
	NERV	Headache/ Headache	1	12OCT2020	6/1	1	No	O	NA	R (12OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151246	GENRL	Chills/ Chills	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N
		Injection site pain/ Injection site pain	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N
	GENRL	Injection site pain/ Soreness at IP injection site	1	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1015 10151248	GENRL	Injection site pain/ Injection site pain	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/3	1	Yes		NA/TC	R (24DEC2020)	N/N
16-55/ C4591001 1015 10151249	GENRL	Injection site pain/ Injection site pain#	4	14JAN2021	1/3	2	Yes		NA/TC	R (16JAN2021)	N/Y
	GENRL	Chills/ Chills#	4	15JAN2021	2/2	2	Yes		NA/TC	R (16JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	15JAN2021	2/2	2	Yes		NA/TC	R (16JAN2021)	N/N
	NERV	Headache/ Worsening headache#	4	17JAN2021	4/2	2	Yes		NA/TC	R (18JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N
	MUSC	Myalgia/ Mild general muscle aches#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1015 10151250	NERV	Headache/ Headache#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N	
16-55/ C4591001 1015 10151252	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N	
		Pyrexia/ Fever	1	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N	
16-55/ C4591001 1015 10151255	GENRL	Injection site pain/ Injection site pain#	3	04JAN2021	1/3	1	Yes		NA	R (06JAN2021)	N/N	
16-55/ C4591001 1015 10151259	GENRL	Fatigue/ Fatigue	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N	
		Injection site pain/ Soreness at injection site	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N	
	GENRL	Chills/ Chills	2	17NOV2020	1/4	1	Yes		NA	R (20NOV2020)	N/N	
		Fatigue/ Exhaustion	2	17NOV2020	1/4	1	Yes		NA	R (20NOV2020)	N/N	
		Injection site pain/ Injection site arm pain	2	17NOV2020	1/4	1	Yes		NA	R (20NOV2020)	N/N	
16-55/ C4591001 1015 10151260	GENRL	Fatigue/ Fatigue#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/Y	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1015 10151261	MUSC	Myalgia/ myalgia#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/Y	
	GENRL	Injection site pain/ Injection site pain	1	27OCT2020	1/8	1	Yes		NA	R (03NOV2020)	N/N	
	GENRL	Chills/ Chills	2	17NOV2020	1/2	1	Yes		NA	R (18NOV2020)	N/N	
16-55/ C4591001 1015 10151262		Pyrexia/ Fever	2	17NOV2020	1/2	1	Yes		NA	R (18NOV2020)	N/N	
	GENRL	Malaise/ General malaise	1	29OCT2020	2/2	1	Yes		NA/TC	R (30OCT2020)	N/N	
	MUSC	Arthralgia/ Generalized joint aches	1	29OCT2020	2/7	1	Yes		NA/TC	R (04NOV2020)	N/N	
16-55/ C4591001 1015 10151263	GENRL	Fatigue/ Fatigue	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N	
	MUSC	Myalgia/ Muscle aches	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N	
16-55/ C4591001 1016 10161003	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/1	1	Yes		NA/TC	R (05FEB2021)	N/N	
	GASTR	Nausea/ nausea#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
		Pain/ generalized body aches#	3	03FEB2021	1/3	2	Yes		NA/TC	R (05FEB2021)	N/N
		Pyrexia/ subjective fever#	3	03FEB2021	1/3	1	Yes		NA/TC	R (05FEB2021)	N/N
16-55/ C4591001 1016 10161009	MUSC	Muscle spasms/ Back Muscle Cramp	2	04SEP2020	18/3	3	No	O	NA/TC/TCN	R (06SEP2020)	N/N
16-55/ C4591001 1016 10161020	INFEC	Urinary tract infection/ Urinary Tract Infection	2	08SEP2020	21/7	1	No	O	NA/TC	R (14SEP2020)	N/N
16-55/ C4591001 1016 10161021	GENRL	Chills/ chills#	4	07JAN2021	1/1	2	Yes		NA	R (07JAN2021)	N/N
		Pain/ body aches#	4	07JAN2021	1/1	2	Yes		NA	R (07JAN2021)	N/N
		Pyrexia/ fever#	4	07JAN2021	1/1	2	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1016 10161028	SKIN	Dermatitis contact/ Contact dermatitis	1	08AUG2020	6/8	2	No	O	NA/TC	R (15AUG2020)	N/N
16-55/ C4591001 1016 10161031	GASTR	Salivary gland calculus/ Left Parotid Sialolithiasis	2	21SEP2020	29/2	1	No	O	NA/TC	R (22SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1016 10161051	GENRL	Pyrexia/ fever#	4	21JAN2021	2/1	1	Yes		NA	R (21JAN2021)	N/N	
16-55/ C4591001 1016 10161054	INFEC	Herpes zoster/ zoster without complications(shingles)	2	06SEP2020	13/C	1	No	O	NA/TC	N	N/N	
	SKIN	Dermatitis contact/ contact dermatitis, right thigh and right side of neck	2	06SEP2020	13/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1016 10161057	VASC	Lymphoedema/ lymphedema	2	19SEP2020	24/5	2	No	O	NA/TC	R (23SEP2020)	N/N	
	CONG	BRCA2 gene mutation/ BRCA 2 Gene positive#	3	DEC2020	1/C	1	No	O	NA/TCN	N	N/N	
16-55/ C4591001 1016 10161069	NERV	Dysgeusia/ odd taste in mouth	1	07AUG2020	2/3	1	Yes		NA	R (09AUG2020)	N/N	
16-55/ C4591001 1016 10161073	RENAL	Haematuria/ hematuria	1	12AUG2020	7/2	1	No	O	NA	R (13AUG2020)	N/N	
16-55/ C4591001 1016 10161080	MUSC	Neck pain/ cervicalgia	2	21SEP2020	26/3	1	No	O	NA	R (23SEP2020)	N/N	
16-55/ C4591001	GENRL	Fatigue/ fatigue#	4	05JAN2021	1/C	2	Yes		NA	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1016 10161082		Pain/ generalized body aches#	4	05JAN2021	1/C	2	Yes		NA/TC	N	N/N	
	MUSC	Arthralgia/ joint pain#	4	05JAN2021	1/C	2	Yes		NA/TC	N	N/N	
	GENRL	Pyrexia/ fever#	4	06JAN2021	2/C	2	Yes		NA/TC	N	N/N	
	NERV	Headache/ headache#	4	06JAN2021	2/C	1	Yes		NA/TC	N	N/N	
16-55/ C4591001 1016 10161085	GENRL	Fatigue/ fatigue#	4	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N	
		Pyrexia/ fever#	4	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N	
	MUSC	Myalgia/ muscle pain#	4	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N	
16-55/ C4591001 1016 10161087	GENRL	Injection site swelling/ injection site swelling	1	10AUG2020	1/10	3	Yes		P/TC	R (19AUG2020)	N/N	
16-55/ C4591001 1016 10161093	EYE	Vision blurred/ Blurry vision in Left Eye	2	08SEP2020	8/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1016 10161103	INFEC	Cellulitis/ cellulitis of face#	4	31JAN2021	19/11	1	No	O	NA/TC	R (10FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INJ&P	Exposure during pregnancy/ exposure during pregnancy#	4	03FEB2021	22/C		No	O	NA	UNK	N/N
16-55/ C4591001 1016 10161105	NERV	Headache/ headache#	3	02FEB2021	13/3	1	No	O	NA/TC	R (04FEB2021)	N/N
	RESP	Nasal congestion/ nasal congestion#	3	02FEB2021	13/3	1	No	O	NA	R (04FEB2021)	N/N
16-55/ C4591001 1016 10161107	GASTR	Nausea/ Nausea	2	04SEP2020	4/2	1	Yes		NA	R (05SEP2020)	N/N
	RESP	Oropharyngeal pain/ Sore Throat	2	04SEP2020	4/2	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1016 10161120	NERV	Brachial plexopathy/ left brachial nerve plexopathy#	3	11JAN2021	20/18	3	No	O	NA	R (28JAN2021)	Y/N
16-55/ C4591001 1016 10161126	MUSC	Back pain/ Low Back Pain	1	17AUG2020	4/4	2	No	O	NA/TC	R (20AUG2020)	N/N
16-55/ C4591001 1016 10161128	NEOPL	Intraductal proliferative breast lesion/ ductal carcinoma in situ, right breast	2	26OCT2020	48/45	2	No	O	NA/TCN	R (09DEC2020)	Y/N
16-55/ C4591001 1016 10161154	GENRL	Pyrexia/ fever	2	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1016 10161181	GENRL	Injection site pain/ Injection Site Pain	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
	MUSC	Arthralgia/ Joint Pain, Generalized	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
		Myalgia/ Generalized Muscle Pain	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
16-55/ C4591001 1016 10161183	GENRL	Injection site pain/ injection site pain, left deltoid#	3	23FEB2021	1/3	1	Yes		NA/TC	R (25FEB2021)	N/N
	GASTR	Vomiting/ vomiting#	3	24FEB2021	2/1	2	Yes		NA	R (24FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	24FEB2021	2/2	2	Yes		NA	R (25FEB2021)	N/N
		Pain/ generalized body aches#	3	24FEB2021	2/2	2	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1016 10161186	GENRL	Injection site pain/ injection site pain	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1016 10161192	INFEC	Sinusitis/ sinusitis	2	08OCT2020	23/4	1	No	O	NA/TC	R (11OCT2020)	N/N
16-55/ C4591001 1016 10161193	GENRL	Chills/ chills	2	15SEP2020	1/1	2	Yes		NA	R (15SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1016 10161210	MUSC	Myalgia/ muscle pain	2	15SEP2020	1/1	2	Yes		NA	R (15SEP2020)	N/N
	GASTR	Vomiting/ vomiting	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Chills/ chills	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1016 10161216		Pyrexia/ fever	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	INJ&P	Radius fracture/ Left Radial Head Fracture	1	04SEP2020	4/C	2	No	O	NA/TCN	N	N/N
	GASTR	Nausea/ nausea#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1016 10161218		Oral pruritus/ itching in mouth#	3	18DEC2020	1/2	1	Yes		NA/TC	R (19DEC2020)	N/N
	GENRL	Chills/ chills#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	SKIN	Pruritus/ facial itching#	3	18DEC2020	1/2	2	Yes		NA/TCN	R (19DEC2020)	N/N
	VASC	Flushing/ facial flushing#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Chills/ chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Fatigue/ fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1016 10161226	MUSC	Myalgia/ muscle pain, unknown	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	GASTR	Nausea/ nausea	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Chills/ chills	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1016 10161230		Pyrexia/ fever	2	23SEP2020	1/3	1	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Chills/ chills	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ fever	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Vessel puncture site haematoma/ hematoma at blood draw site	2	21OCT2020	29/C	1	No	O	NA	N	N/N
16-55/ C4591001 1016 10161231	RESP	Nasal congestion/ nasal congestion	1	11SEP2020	10/4	1	No	O	NA/TC	R (14SEP2020)	N/N
	SKIN	Rash/ diffuse rash(everywhere but more on neck,chest,back)	1	11SEP2020	10/4	1	No	O	NA/TC	R (14SEP2020)	N/N
16-55/ C4591001 1016 10161242	MUSC	Myalgia/ muscle pain#	4	09FEB2021	2/C	2	Yes		NA/TC	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1016 10161245	PSYCH	Depression/ worsening depression	1	10SEP2020	7/C	1	No	O	NA/TC	N	N/N	
	GENRL	Injection site pain/ injection site pain	2	24SEP2020	1/4	2	Yes		NA	R (27SEP2020)	N/N	
16-55/ C4591001 1016 10161248	GENRL	Pyrexia/ fever	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N	
16-55/ C4591001 1016 10161258	GENRL	Chills/ chills#	3	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N	
16-55/ C4591001 1016 10161265	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	29NOV2020	63/		No	O	NA	UNK	N/N	
16-55/ C4591001 1016 10161268	INJ&P	Skin laceration/ laceration to nose	2	25OCT2020	27/8	1	No	O	NA	R (01NOV2020)	N/N	
16-55/ C4591001 1016 10161272	GENRL	Chills/ chills#	4	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N	
		Pyrexia/ fever, 102.1#	4	06FEB2021	2/2	3	Yes		NA/TC	R (07FEB2021)	N/N	
	NERV	Headache/ headache#	4	06FEB2021	2/3	2	Yes		NA	R (08FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1016 10161276	SKIN	Dermatitis contact/ contact dermatitis on bilateral lower legs	2	26OCT2020	28/8	1	No	O	NA/TC	R (02NOV2020)	N/N	
16-55/ C4591001 1016 10161277	CARD	Atrial fibrillation/ atrial fibrillation	2	09OCT2020	8/4	2	No	O	NA/TC	R (12OCT2020)	Y/N	
16-55/ C4591001 1016 10161289	GENRL	Chills/ chills	1	18SEP2020	1/3	2	Yes		NA/TC	R (20SEP2020)	N/N	
		Pyrexia/ fever	1	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N	
	INJ&P	Concussion/ concussion	2	31OCT2020	25/C	2	No	O	NA	RG	N/N	
		Facial bones fracture/ facial fractures	2	31OCT2020	25/C	3	No	O	NA/TC	RG	Y/N	
		Road traffic accident/ motor vehicle accident	2	31OCT2020	25/1	3	No	O	NA	R (31OCT2020)	N/N	
16-55/ C4591001 1016 10161300	GENRL	Pyrexia/ Fever	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N	
16-55/ C4591001 1016 10161317	MUSC	Pain in extremity/ right hand pain	2	17NOV2020	12/19	1	No	O	NA	R (05DEC2020)	N/N	
16-55/ C4591001	GENRL	Chills/ chills	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1016 10161333		Pyrexia/ fever	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N	
16-55/ C4591001 1016 10161342	GASTR	Diarrhoea/ worsening of diarrhea	1	22OCT2020	1/7	2	Yes		NA	R (28OCT2020)	N/N	
16-55/ C4591001 1016 10161347	GASTR	Nausea/ nausea	2	24NOV2020	2/2	2	Yes		NA	R (25NOV2020)	N/N	
	MUSC	Myalgia/ muscle aches	2	24NOV2020	2/2	1	Yes		NA	R (25NOV2020)	N/N	
	NERV	Headache/ headache	2	24NOV2020	2/2	2	Yes		NA	R (25NOV2020)	N/N	
16-55/ C4591001 1016 10161348	METAB	Glucose tolerance impaired/ prediabetes	1	23NOV2020	19/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1016 10161349	SKIN	Rash erythematous/ rash, top ten toes(red rash)	1	09NOV2020	4/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1018 10181028	NERV	Cervical radiculopathy/ cervical radiculopathy C5-C6	1	12AUG2020	10/14	2	No	O	NA/TC/TCN	R (25AUG2020)	N/N	
16-55/ C4591001	INFEC	Appendicitis/ Appendicitis	2	06JAN2021	136/3	4	No	O	NA/TC/TCN	R (08JAN2021)	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1018 10181031 16-55/ C4591001 1018 10181048	GENRL	Fatigue/ Fatigue#	4	13JAN2021	3/4	3	Yes		NA/TC	R (16JAN2021)	N/N	
16-55/ C4591001 1018 10181049	INJ&P	Pyrexia/ Fever#	4	13JAN2021	3/4	2	Yes		NA/TC	R (16JAN2021)	N/N	
16-55/ C4591001 1018 10181049	INJ&P	Ligament sprain/ Right Ankle Sprain	1	15AUG2020	12/2	1	No	O	NA/TC	R (16AUG2020)	N/N	
16-55/ C4591001 1018 10181050	GASTR	Food poisoning/ Food Poisoning	1	01SEP2020	29/3	1	No	O	NA	R (03SEP2020)	N/N	
16-55/ C4591001 1018 10181062	EYE	Dry eye/ Right Eye Dryness	1	08AUG2020	4/15	1	No	O	NA	R (22AUG2020)	N/N	
	INJ&P	Contusion/ Right third finger contusion	1	21AUG2020	17/8	2	No	O	NA/TCN	R (28AUG2020)	N/N	
	MUSC	Arthralgia/ right ankle pain	1	23AUG2020	19/8	2	No	O	NA	R (30AUG2020)	N/N	
	NERV	Presyncope/ Vasovagal Reaction (to Blood draw)	2	25SEP2020	31/1	1	No	O	NA	R (25SEP2020)	N/N	
16-55/ C4591001 1018 10181064	INFEC	Hordeolum/ Hordeolum	2	12SEP2020	15/7	2	No	O	NA/TC/TCN	R (18SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1018 10181081	INFEC	Paronychia/ Left Hallux Ingrown Toenail (Infected)	1	14AUG2020	10/C	2	No	O	NA/TC/TCN	RG	N/N	
16-55/ C4591001 1018 10181084	GENRL	Fatigue/ Fatigue	2	26AUG2020	1/9	1	Yes		NA	R (03SEP2020)	N/N	
	GENRL	Chest pain/ Sharp Pain, Mid-Sternal	2	27AUG2020	2/1	1	No	O	NA	R (27AUG2020)	N/N	
16-55/ C4591001 1018 10181089	GENRL	Pain/ Body aches/pains, Full body	2	28AUG2020	2/1	3	Yes		NA/TC	R (28AUG2020)	N/N	
	NERV	Headache/ headache	2	28AUG2020	2/1	3	Yes		NA	R (28AUG2020)	N/N	
16-55/ C4591001 1018 10181090	VASC	Deep vein thrombosis/ Deep Vein Thrombosis, left leg	2	27NOV2020	93/C	3	No	O	NA/TC	RG	Y/N	
	RESP	Pulmonary embolism/ Pulmonary Embolism, bilateral, segmental and sub segmental	2	14DEC2020	110/C	4	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1018 10181111	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	2	24NOV2020	85/C		No	O	NA	UNK	N/N	
16-55/ C4591001 1018 10181118	GENRL	Medical device pain/ Pain in mouth due to dental implant	1	31AUG2020	22/3	1	No	O	NA/TC	R (02SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1018 10181120	GASTR	Abdominal pain/ Abdominal Pain	1	24AUG2020	15/7	1	No	O	NA/TC	R (30AUG2020)	N/N	
16-55/ C4591001 1018 10181133	SURG	Wisdom teeth removal/ Wisdom tooth extraction	1	20AUG2020	9/1	1	No	O	NA/TC	R (20AUG2020)	N/N	
16-55/ C4591001 1018 10181144	NERV	Headache/ Headache	2	11SEP2020	2/14	2	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 1018 10181145	NERV	Headache/ Headache	2	14SEP2020	12/1	1	No	O	NA	R (14SEP2020)	N/N	
	SKIN	Dermatitis allergic/ Allergic reaction (entire body), rash	2	14SEP2020	12/2	2	No	O	NA	R (15SEP2020)	N/N	
16-55/ C4591001 1018 10181159	NERV	Paraesthesia/ Right Leg Paresthesia	2	20OCT2020	47/C	2	Yes		NA/TC	RG	Y/N	
16-55/ C4591001 1018 10181174	GENRL	Fatigue/ Fatigue	2	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N	
16-55/ C4591001 1018 10181182	GENRL	Injection site pain/ Injection Site Pain, Left deltoid	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1018 10181184	INJ&P	Ligament sprain/ Back Sprain/Strain	2	01OCT2020	22/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1018 10181185	GENRL	Injection site pain/ Pain at the injection side - Left Shoulder	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N	
	INV	Body temperature increased/ Elevation of Body temperature 98.7 F	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N	
	MUSC	Arthralgia/ Generalized Joints Pain	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N	
16-55/ C4591001 1018 10181186	GASTR	Faeces soft/ Soft Stools	2	02SEP2020	1/6	1	Yes		NA	R (07SEP2020)	N/N	
		Nausea/ Nausea	2	02SEP2020	1/6	1	Yes		NA	R (07SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	02SEP2020	1/8	1	Yes		NA	R (09SEP2020)	N/N	
	NERV	Headache/ Headache	2	02SEP2020	1/1	1	Yes		NA/TC	R (02SEP2020)	N/N	
	RESP	Nasal congestion/ Nasal Congestion	2	28SEP2020	27/18	2	No	O	NA/TC	R (15OCT2020)	N/N	
16-55/ C4591001 1018 10181188	GENRL	Injection site pain/ Injection site tenderness	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1018 10181195		Injection site swelling/ Swelling at injection site	1	21AUG2020	1/1	1	Yes		NA	R (21AUG2020)	N/N	
16-55/ C4591001 1018 10181199	GENRL	Injection site swelling/ Injection Site swelling	1	11SEP2020	22/2	1	Yes		NA	R (12SEP2020)	N/N	
16-55/ C4591001 1018 10181200	GENRL	Injection site erythema/ Injection Site Redness	1	21AUG2020	1/2	2	Yes		NA	R (22AUG2020)	N/N	
		Injection site pain/ Injection Site Pain	1	21AUG2020	1/2	2	Yes		NA	R (22AUG2020)	N/N	
		Injection site swelling/ Injection Site Swelling	1	21AUG2020	1/2	2	Yes		NA	R (22AUG2020)	N/N	
	GENRL	Chills/ Chills	2	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N	
		Pain/ Body Aches	2	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N	
		Pyrexia/ Fever - 102.1	2	11SEP2020	2/2	3	Yes		NA/TC	R (12SEP2020)	N/N	
	NERV	Headache/ Headache	2	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N	
16-55/ C4591001 1018 10181201	GENRL	Injection site pain/ Injection Site Pain	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N	
	NERV	Headache/ Headache	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1018 10181206	GENRL	Chills/ Chills	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N	
		Pyrexia/ Fever	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N	
	GASTR	Nausea/ Nausea	2	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N	
	GENRL	Chills/ Chills	2	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N	
		Pyrexia/ Fever	2	13SEP2020	2/2	1	Yes		NA/TC	R (14SEP2020)	N/N	
	NERV	Headache/ Headache	2	13SEP2020	2/2	1	Yes		NA/TC	R (14SEP2020)	N/N	
16-55/ C4591001 1018 10181207	GENRL	Injection site pain/ Injection site soreness	1	23AUG2020	2/7	1	Yes		NA/TC	R (29AUG2020)	N/N	
16-55/ C4591001 1018 10181208	INJ&P	Post procedural discomfort/ Nasal swab site discomfort right nostril	1	23AUG2020	2/12	1	No	O	NA	R (03SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	11SEP2020	1/3	2	Yes		NA	R (13SEP2020)	N/N	
		Injection site pain/ Soreness at the injection site	2	11SEP2020	1/5	1	Yes		NA/TC	R (15SEP2020)	N/N	
	GENRL	Pyrexia/ Fever - 100.5 F	2	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N	
	GENRL	Pyrexia/ Fever 101.0	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	2	13SEP2020	3/C	1	Yes		NA	RG	N/N
	NERV	Headache/ Headache	2	13SEP2020	3/C	1	Yes		NA/TC	RG	N/N
16-55/ C4591001 1018 10181215	GENRL	Injection site pain/ Soreness at the injection side	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		Pain/ Body aches	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		Pyrexia/ Fever 100.9	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1018 10181221	SKIN	Pruritus allergic/ Pruritus, extremities (Food or Cosmetics)	2	26SEP2020	2/4	1	No	O	NA	R (29SEP2020)	N/N
	SKIN	Urticaria/ Urticaria, extremities	2	27SEP2020	3/2	2	No	O	NA	R (28SEP2020)	N/N
16-55/ C4591001 1018 10181222	NERV	Headache/ Headache	1	29AUG2020	1/1	1	Yes		NA/TC	R (29AUG2020)	N/Y
	GENRL	Injection site pain/ Mild injection site pain	1	30AUG2020	2/1	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C4591001 1018 10181224	GENRL	Injection site pain/ Injection site pain	1	30AUG2020	2/4	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	19SEP2020	2/5	2	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1018 10181226	MUSC	Pyrexia/ Low-Grade Fever	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N	
		Myalgia/ Muscle Pain	2	19SEP2020	2/4	1	Yes		NA	R (22SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	30AUG2020	2/4	2	Yes		NA	R (02SEP2020)	N/N	
	MUSC	Pyrexia/ Fever	1	30AUG2020	2/1	1	Yes		NA	R (30AUG2020)	N/N	
		Pain in extremity/ Arm pain, left side	1	30AUG2020	2/6	2	Yes		NA/TC	R (04SEP2020)	N/N	
	NERV	Headache/ Headache	1	30AUG2020	2/1	1	Yes		NA	R (30AUG2020)	N/N	
GENRL	Pyrexia/ Fever	2	18SEP2020	1/2	1	Yes		NA/TC	R (19SEP2020)	N/N		
16-55/ C4591001 1018 10181228	GASTR	Nausea/ Nausea	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N	
	NERV	Headache/ Headache	1	20SEP2020	21/3	1	Yes		NA/TC	R (22SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N	
16-55/ C4591001 1018 10181230	NERV	Injection site pain/ Soreness at the injection site	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N	
		Headache/ Headache	1	06SEP2020	7/2	2	Yes		NA/TC	R (07SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1018 10181234	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N	
	MUSC	Arthralgia/ Joint Aches	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N	
	VASC	Hypertension/ Worsening Hypertension	2	07OCT2020	14/C	1	No	O	NA/TC	RG	N/N	
	GENRL	Fatigue/ Fatigue	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N	
		Injection site pain/ Pain, injection site	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N	
	GENRL	Chills/ Chills	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N	
	NERV	Headache/ Headache	1	02SEP2020	2/1	1	Yes		NA/TC	R (02SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
	NERV	Headache/ Headache	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N	
	SKIN	Urticaria/ Urticaria, Bilateral Arms progressing to lower extremities	2	25SEP2020	2/C	2	Yes		NA/TC	RG	N/N	
16-55/ C4591001 1018 10181244	GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001	GENRL	Pyrexia/ Fever	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1018 10181246	INV	Blood pressure increased/ Elevated Blood Pressure	2	27OCT2020	33/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1018 10181247	METAB	Hyperlipidaemia/ Hyperlipidemia	2	20OCT2020	26/C	1	No	O	NA/TC	N	N/N	
	INV	Blood pressure increased/ Elevated Blood Pressure without Dx of Hypertension	2	27OCT2020	33/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1018 10181256	NERV	Headache/ Headache	1	02SEP2020	1/6	1	Yes		NA	R (07SEP2020)	N/N	
	GENRL	Injection site pain/ Injection Pain	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N	
	GENRL	Chills/ Chill	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N	
		Injection site pain/ Injection Pain	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N	
	NERV	Headache/ Headache	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N	
16-55/ C4591001 1018 10181261	GENRL	Pyrexia/ Fever, low grade	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N	
	MUSC	Myalgia/ Muscle aches	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	NERV	Migraine/ migraine	2	08OCT2020	16/2	1	No	CD	NA/TC	R (09OCT2020)	N/N	
16-55/ C4591001 1018 10181267	VASC	Hypertension/ Worsening of hypertension	2	12OCT2020	18/8	1	No	O	NA/TC	R (19OCT2020)	N/N	
16-55/ C4591001 1018 10181279	GENRL	Pain/ Body aches	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N	
		Pyrexia/ Fever, low grade	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001 1018 10181283	GENRL	Injection site pain/ Soreness at the Left Shoulder - Injection site	1	12SEP2020	1/3	1	Yes		NA	R (14SEP2020)	N/N	
16-55/ C4591001 1018 10181284	GENRL	Fatigue/ fatigue	2	02OCT2020	1/1	1	Yes		NA	R (02OCT2020)	N/N	
	GENRL	Injection site pain/ injection site pain	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N	
16-55/ C4591001 1018 10181287	GENRL	Injection site pain/ Soreness at injection site	1	15SEP2020	2/1	1	Yes		NA/TC	R (15SEP2020)	N/N	
	GENRL	Injection site pain/ Soreness at injection site	2	05OCT2020	1/5	1	Yes		NA/TC	R (09OCT2020)	N/N	
16-55/ C4591001	GASTR	Diarrhoea/ diarrhea	1	15SEP2020	2/1	1	No	O	NA	R (15SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1018 10181288 16-55/ C4591001 1018 10181294	GASTR	Palatal disorder/ Palate irritation	1	17SEP2020	3/5	1	No	O	NA	R (21SEP2020)	N/N	
16-55/ C4591001 1018 10181295	RESP	Paranasal sinus discomfort/ Sinus pressure	1	17SEP2020	3/1	1	No	O	NA	R (17SEP2020)	N/N	
16-55/ C4591001 1018 10181295	REPRO	Erectile dysfunction/ erectile dysfunction	1	18SEP2020	3/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1018 10181305	GASTR	Diarrhoea/ Loose Stool	1	27SEP2020	7/1	1	No	O	NA	R (27SEP2020)	N/N	
16-55/ C4591001 1018 10181314	INJ&P	Bone contusion/ Right Rib Contusion	1	24OCT2020	12/11	1	No	O	NA	R (03NOV2020)	N/N	
16-55/ C4591001 1018 10181323	GASTR	Nausea/ Nausea	1	16OCT2020	3/3	1	Yes		NA	R (18OCT2020)	N/N	
	NERV	Headache/ Headache	1	16OCT2020	3/3	1	Yes		NA/TC	R (18OCT2020)	N/N	
	MUSC	Limb discomfort/ Left arm heaviness	2	04NOV2020	1/1	1	Yes		NA	R (04NOV2020)	N/Y	
	NERV	Headache/ Headache	2	04NOV2020	1/1	1	Yes		NA	R (04NOV2020)	N/Y	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1018 10181324	GENRL	Injection site pain/ Injection site pain	1	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N	
	MUSC	Back pain/ Worsening of back pain	1	28OCT2020	15/7	2	No	O	NA	R (03NOV2020)	N/N	
	EAR	Vertigo/ Vertigo	2	04NOV2020	1/3	3	Yes		NA	R (06NOV2020)	N/N	
	GENRL	Chills/ Chills	2	04NOV2020	1/3	2	Yes		NA	R (06NOV2020)	N/N	
		Pain/ Generalized Body aches	2	04NOV2020	1/2	2	Yes		NA	R (05NOV2020)	N/N	
		Pyrexia/ Fever	2	04NOV2020	1/3	3	Yes		NA/TC	R (06NOV2020)	N/N	
	MUSC	Back pain/ Worsening of chronic back pain	2	04NOV2020	1/C	2	No	O	NA	RG	N/N	
16-55/ C4591001 1018 10181326	GENRL	Injection site pain/ Pain, Injection Site	1	14OCT2020	1/3	2	Yes		NA/TC	R (16OCT2020)	N/N	
	NERV	Headache/ Headache	1	14OCT2020	1/2	2	Yes		NA/TC/TCN	R (15OCT2020)	N/N	
	GASTR	Noninfective gingivitis/ Pain/Inflammation, Gums, lower, frontal	1	15OCT2020	2/C	2	Yes		NA/TC/TCN	RG	N/N	
16-55/ C4591001 1018 10181329	GENRL	Fatigue/ Fatigue	1	14OCT2020	1/1	1	Yes		NA	R (14OCT2020)	N/N	
		Injection site pain/ Soreness at the injection site	1	14OCT2020	1/1	1	Yes		NA	R (14OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1018 10181345	GENRL	Chills/ Chills#	4	11FEB2021	2/C	2	Yes		NA/TC	RG	N/N
	MUSC	Myalgia/ Muscle pain#	4	11FEB2021	2/C	2	Yes		NA/TC	RG	N/N
	NERV	Headache/ Headache#	4	11FEB2021	2/C	2	Yes		NA/TC	RG	N/N
16-55/ C4591001 1019 10191002	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	26SEP2020	27/C		No	CD	NA	UNK	N/N
16-55/ C4591001 1019 10191047	GENRL	Injection site pain/ Injection Pain Moderate	2	08SEP2020	1/2	2	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Injection Pain Mild	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1019 10191063	NERV	Head discomfort/ Head Pressure	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1019 10191110	GENRL	Injection site pain/ Pain at injection site#	3	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	INJ&P	Contusion/ Bruise on left upper arm#	3	22JAN2021	15/12	1	No	O	NA	R (02FEB2021)	N/N
16-55/ C4591001	RESP	Asthma/ Worsening of Asthma	2	12OCT2020	22/6	1	No	O	NA	R (17OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1019 10191140 16-55/ C4591001 1019 10191145	NEOPL	Breast cancer/ Ductal carcinoma right Breast	2	13NOV2020	52/C	3	No	O	NA/TC	N	Y/N	
		Invasive ductal breast carcinoma/ Ductal Carcinoma Left Breast	2	13NOV2020	52/C	3	No	O	NA/TC	N	Y/N	
		Metastases to lymph nodes/ Right Axillary Metastases	2	13NOV2020	52/C	3	No	O	NA/TC	N	Y/N	
	INJ&P	Intentional overdose/ Overdose Intentional#	2	09MAR2021	168/2	3	No	CD	NA	RS (10MAR2021)	Y/N	
	PSYCH	Suicide attempt/ Attempted Suicide#	2	09MAR2021	168/2	3	No	CD	NA	RS (10MAR2021)	Y/N	
16-55/ C4591001 1019 10191157	GENRL	Injection site pain/ injection site soreness	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N	
		Pain/ general body aches	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N	
16-55/ C4591001 1019 10191159	GENRL	Chills/ Chills	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N	
		Fatigue/ Fatigue	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N	
16-55/ C4591001 1019 10191175	GENRL	Pain/ Moderate Body Aches	1	10SEP2020	2/6	2	Yes		NA	R (15SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1019 10191181	GENRL	Injection site pain/ Injection Site Soreness#	3	19JAN2021	1/3	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1019 10191184	GENRL	Injection site pain/ Pain at injection site#	3	04JAN2021	1/1	1	Yes		NA	R (04JAN2021)	N/N
16-55/ C4591001 1019 10191195	GENRL	Injection site pain/ Soreness at injection site#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
16-55/ C4591001 1019 10191197	GENRL	Injection site pain/ Soreness at injection site Mild#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1019 10191198	NERV	Headache/ Mild Headache#	3	30DEC2020	1/1	1	Yes		NA	R (30DEC2020)	N/N
16-55/ C4591001 1019 10191206	GENRL	Pain/ Body Aches	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1019 10191211	NERV	Headache/ Mild Headache#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
16-55/ C4591001 1019 10191213	NERV	Hypoaesthesia/ Left Upper extremity numbness ulnar distal numbness	1	15SEP2020	1/8	2	Yes		NA	R (22SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1019 10191215	NERV	Hypoaesthesia/ Ulnar Distal Numbness	2	06OCT2020	1/3	2	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site erythema/ Localized erythematoses dermal reaction Left deltoid at injection site#	4	10JAN2021	3/4	2	Yes		NA	R (13JAN2021)	N/N
	BLOOD	Lymphadenopathy/ Axial Lymph Node Swelling Left	1	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
	GENRL	Injection site pain/ Left arm site injection pain	1	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
	GENRL	Chills/ chills	2	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
		Fatigue/ Fatigue	2	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
		Injection site pain/ L Arm Pain Injection Site	2	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1019 10191216	INJ&P	Ligament sprain/ Left Ankle Sprain	2	10NOV2020	20/86	1	No	O	NA	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	3	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	MUSC	Myalgia/ General Muscle Aches#	3	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1019 10191226	GENRL	Fatigue/ Mild Fatigue	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	INFEC	COVID-19/ COVID-19 Illness	2	28DEC2020	76/27	3	No	O	NA	R (23JAN2021)	Y/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1019 10191234	GENRL	Injection site pain/ Left Arm Soreness at Injection Site#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1019 10191242	GENRL	Injection site pain/ Injection Site Pain	1	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	30JAN2021	2/1	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1019 10191249	GASTR	Nausea/ Nausea	2	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
		Pain/ Body Aches	2	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001 1019 10191254	INFEC	Urinary tract infection/ Urinary Tract Infection	1	15OCT2020	11/10	3	No	O	NA/TC	R (24OCT2020)	Y/N
	GASTR	Diverticulum/ Diverticulosis	1	24OCT2020	20/C	1	No	O	NA	N	N/N
	NEOPL	Benign pancreatic neoplasm/ Serious cystadenoma of Pancreas	1	24OCT2020	20/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1019 10191255	INFEC	Ear infection/ Worsening Left Ear Infection	2	25DEC2020	60/7	2	No	O	NA/TC	R (31DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1019 10191260	MUSC	Myalgia/ Muscle Soreness#	3	20JAN2021	2/4	1	Yes		NA	R (23JAN2021)	N/N	
	GENRL	Injection site pain/ Left upper arm pain injection site	2	03NOV2020	2/1	1	Yes		NA	R (03NOV2020)	N/N	
16-55/ C4591001 1019 10191262	NERV	Headache/ Headache	2	03NOV2020	2/1	1	Yes		NA	R (03NOV2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain#	3	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N	
16-55/ C4591001 1019 10191262	NERV	Headache/ Headache	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N	
16-55/ C4591001 1019 10191264	NERV	Headache/ Headache	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N	
16-55/ C4591001 1019 10191270	GASTR	Nausea/ Nausea Mild	2	03NOV2020	2/1	1	Yes		NA	R (03NOV2020)	N/N	
	GENRL	Chills/ Chills Mild	2	03NOV2020	2/1	1	Yes		NA	R (03NOV2020)	N/N	
16-55/ C4591001 1019 10191270	GENRL	Fatigue/ Mild Fatigue#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
		Injection site pain/ Mild Soreness at Injection Site#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Soreness#	3	30DEC2020	1/3	1	Yes		NA	R (01JAN2021)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1019 10191280 16-55/ C4591001	GENRL	Injection site pain/ Injection site muscle ache	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N	
1019 10191290 16-55/ C4591001	GENRL	Injection site pruritus/ Pruritus at injection site#	3	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N	
1019 10191292 16-55/ C4591001	GENRL	Injection site pain/ Injection Site Soreness	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N	
1019 10191293 16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N	
1019 10191301 16-55/ C4591001	GENRL	Injection site pain/ Mild Soreness at Injection Site#	3	19JAN2021	1/4	1	Yes		NA	R (22JAN2021)	N/N	
1019 10191312 16-55/ C4591001	MUSC	Myalgia/ General Muscle Aches, Mild#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N	
1021 10211032 16-55/ C4591001	GENRL	Chills/ Body chills	1	20AUG2020	8/1	1	No	O	NA	R (20AUG2020)	N/N	
16-55/ C4591001	GASTR	Nausea/ Nausea	2	28SEP2020	15/2	1	No	O	NA	R (29SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1021 10211083 16-55/ C4591001 1021 10211104	GASTR	Diarrhoea/ Diarrhea	2	18SEP2020	2/1	2	Yes		NA	R (18SEP2020)	N/N
		Nausea/ Nausea	2	18SEP2020	2/1	2	Yes		NA	R (18SEP2020)	N/N
		Vomiting/ Vomiting	2	18SEP2020	2/1	2	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at Injection Site	2	18SEP2020	2/3	2	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1021 10211117	GENRL	Fatigue/ Fatigue	1	29AUG2020	2/3	2	Yes		NA	R (31AUG2020)	N/N
		Pyrexia/ Fever	1	29AUG2020	2/3	2	Yes		NA	R (31AUG2020)	N/N
	GENRL	Pyrexia/ Fever	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
	RESP	Asthma/ Worsening of Asthma	2	19SEP2020	2/C	2	Yes		NA	N	N/N
16-55/ C4591001 1021 10211127	CARD	Acute left ventricular failure/ NYHA Class IV Acute on Chronic Systolic Heart Failure	2	19OCT2020	27/3	3	No	O	NA/TC	R (21OCT2020)	Y/N
	METAB	Hypokalaemia/ Hypokalemia	2	19OCT2020	27/3	3	No	CD	NA/TC	R (21OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	CARD	Cardiac failure congestive/ Acute on Chronic Combined Systolic and Diastolic Congestive Heart Failure	2	30NOV2020	69/20	4	No	O	NA/TC/W	F (19DEC2020)	Y/N	
16-55/ C4591001 1021 10211156	INFEC	Conjunctivitis/ R Eye Conjunctivits	1	22SEP2020	19/6	2	No	O	NA/TC	R (27SEP2020)	N/N	
16-55/ C4591001 1021 10211185	RESP	Asthma/ Worsening of Asthma	2	12OCT2020	14/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1021 10211212	INJ&P	Tooth fracture/ Ruptured Tooth	1	27SEP2020	13/2	2	No	O	NA/TC/TCN	R (28SEP2020)	N/N	
16-55/ C4591001 1021 10211223	GENRL	Injection site pain/ muscle soreness at injection site	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
		Pyrexia/ fever	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001 1021 10211235	GENRL	Fatigue/ fatigue	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N	
16-55/ C4591001 1021 10211239	METAB	Hypercholesterolaemia/ Worsening of Hypercholesterolemia	2	29JAN2021	110/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001	GENRL	Chills/ Chills	2	12OCT2020	1/2	2	Yes		NA/TC	R (13OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1021 10211240		Fatigue/ Fatigue	2	12OCT2020	1/2	2	Yes		NA/TC	R (13OCT2020)	N/N	
16-55/ C4591001 1021 10211242	MUSC	Osteoarthritis/ Osteoarthritis Left Leg	2	03NOV2020	22/C	2	No	O	NA/TC	N	N/N	
	GENRL	Chills/ Chills#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N	
		Pyrexia/ Fever#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N	
16-55/ C4591001 1021 10211244	GENRL	Injection site pain/ Left Arm Soreness at Injection Site	2	12OCT2020	1/4	1	Yes		NA/TC	R (15OCT2020)	N/N	
16-55/ C4591001 1021 10211247	GASTR	Vomiting/ Vomiting#	4	26FEB2021	3/3	2	Yes		NA	R (28FEB2021)	N/N	
16-55/ C4591001 1022 10221010	GENRL	Injection site pain/ Mild Injection Site Pain#	3	18DEC2020	2/2	1	Yes		NA	R (19DEC2020)	N/N	
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
16-55/ C4591001 1022 10221013	GENRL	Fatigue/ Moderate Fatigue#	4	04JAN2021	1/C	2	Yes		NA	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	4	05JAN2021	2/C	2	Yes		NA	N	N/N
		Pyrexia/ Low Grade Fever#	4	05JAN2021	2/C	1	Yes		NA	N	N/N
16-55/ C4591001 1022 10221017	GENRL	Injection site pain/ Pain at the injection site	2	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
		Pyrexia/ Fever	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	2	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1022 10221018	GENRL	Injection site pain/ Mild Injection Site Pain	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Fatigue/ Moderate Fatigue	2	09SEP2020	2/4	2	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1022 10221019	GENRL	Injection site pain/ Mild Injection Site Pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1022 10221020	INFEC	Urinary tract infection/ Urinary Tract Infection	2	07OCT2020	27/6	1	No	O	NA/TC	R (12OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221023	GENRL	Injection site pain/ Mild Injection Site Pain#	3	21JAN2021	2/7	1	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ Mild headache#	3	21JAN2021	2/7	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		Pain/ Body Aches	2	09SEP2020	1/1	2	Yes		NA	R (09SEP2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ Headache	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1022 10221024	GENRL	Pyrexia/ Fever	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Axillary pain/ Axillary Pain	1	18AUG2020	1/4	1	Yes		NA	R (21AUG2020)	N/N
	MUSC	Groin pain/ Groin Pain	1	18AUG2020	1/4	1	Yes		NA	R (21AUG2020)	N/N
	GASTR	Diarrhoea/ Loose Stools	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	BLOOD	Lymphadenopathy/ Lymphadenopathy of Head (left side)	2	22SEP2020	15/43	1	Yes		NA	R (03NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221025	GENRL	Injection site pain/ Mild Injection Site Pain#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N
		Chills/ Mild Chills#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
		Pyrexia/ Low Grade Fever#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
		Myalgia/ Generalized Myalgias#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
		Headache/ Exacerbation of Headache#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
	NERV	Headache/ Headache	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
	GASTR	Nausea/ Nausea	2	09SEP2020	2/1	1	Yes		NA/TC	R (09SEP2020)	N/N
	GENRL	Pain/ Body Aches	2	09SEP2020	2/2	2	Yes		NA/TC	R (10SEP2020)	N/N
	NERV	Headache/ Headache	2	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1022 10221027	GENRL	Injection site pain/ Injection Site Pain	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
MUSC	Arthralgia/ Medial Pain left knee	2	20SEP2020	10/C	1	No	O	NA	N	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Mild Injection Site Pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1022 10221028	GENRL	Fatigue/ Mild Fatigue#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1022 10221030	GENRL	Chills/ Chills#	4	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N
		Fatigue/ Mild Fatigue#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ Mild Headache#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1022 10221031	GENRL	Fatigue/ Fatigue#	3	17DEC2020	1/4	1	Yes		NA	R (20DEC2020)	N/N
		Injection site pain/ Mild Injection Site Pain#	3	17DEC2020	1/4	1	Yes		NA	R (20DEC2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	3	17DEC2020	1/4	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Injection site pain/ Mild Injection site pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Mild Injection Site Pain	1	20AUG2020	1/1	1	Yes		NA	R (20AUG2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1022 10221033											
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N
1022 10221035											
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
1022 10221040											
16-55/ C4591001	GENRL	Injection site pain/ Mild Injection Site Pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
1022 10221043											
	GENRL	Chills/ Chills#	4	05JAN2021	1/1	1	Yes		NA	R (05JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
		Pyrexia/ Low Grade Fever#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Moderate Injection Site Pain#	3	18JAN2021	1/2	2	Yes		NA	R (19JAN2021)	N/N
1022 10221048											
	GENRL	Chills/ Moderate Chills#	4	09FEB2021	2/1	2	Yes		NA	R (09FEB2021)	N/N
		Fatigue/ Mild fatigue#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221049	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1022 10221051	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/2	2	Yes		NA	R (25AUG2020)	N/N
16-55/ C4591001 1022 10221052	GASTR	Nausea/ Nausea	1	24AUG2020	1/1	2	Yes		NA	R (24AUG2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Chills/ Mild Chills#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ Mild Headache#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1022 10221054	GENRL	Chills/ Chills	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		Injection site pain/ Pain at the injection site	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ Headache	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1022 10221055	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/Y	
	GENRL	Fatigue/ Fatigue	2	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N	
		Injection site pain/ Injection site pain	2	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N	
	MUSC	Myalgia/ Generalized Myalgias	2	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N	
	RESP	Oropharyngeal pain/ Sore Throat	2	21SEP2020	6/4	1	No	O	NA	R (24SEP2020)	N/N	
		Paranasal sinus discomfort/ Sinus Pressure	2	21SEP2020	6/4	1	No	O	NA	R (24SEP2020)	N/N	
		Upper-airway cough syndrome/ Post Nasal Drainage	2	21SEP2020	6/4	1	No	O	NA	R (24SEP2020)	N/N	
16-55/ C4591001 1022 10221062	GENRL	Injection site pain/ Moderate Injection Site Pain#	3	16DEC2020	1/3	2	Yes		NA	R (18DEC2020)	N/N	
	NERV	Headache/ Moderate Headache#	3	17DEC2020	2/2	2	Yes		NA	R (18DEC2020)	N/N	
	GENRL	Chills/ Mild Chills#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N	
	MUSC	Myalgia/ Generalized Myalgias#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N	
16-55/ C4591001 1022 10221064	GENRL	Injection site pain/ Injection Site Pain	1	25AUG2020	1/3	2	Yes		NA	R (27AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Nausea/ Nausea	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
	GENRL	Chills/ Moderate Chills	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ Generalized myalgias	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1022 10221066	GENRL	Injection site pain/ Mild Injection Site Pain#	3	16DEC2020	1/3	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Fatigue/ Mild Fatigue#	3	17DEC2020	2/2	1	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1022 10221069	GENRL	Fatigue/ Mild Fatigue#	4	18JAN2021	1/4	1	Yes		NA	R (21JAN2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	18JAN2021	1/1	1	Yes		NA	R (18JAN2021)	N/N
	NERV	Headache/ Mild Headache#	4	18JAN2021	1/4	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1022 10221070	GENRL	Injection site pain/ Injection site pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C4591001 1022 10221074	GENRL	Injection site pain/ Mind Injection site pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221076	GENRL	Chills/ Chills	2	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N
		Fatigue/ Moderate fatigue	2	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Moderate pain at the injection site	2	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ Fever	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ Mild Headache	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	27AUG2020	1/1	1	Yes		NA	R (27AUG2020)	N/N
	NERV	Headache/ Headache	1	27AUG2020	1/1	1	Yes		NA/TC	R (27AUG2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
		Pyrexia/ Fever#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
NERV	Headache/ Mild headache#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N	
GENRL	Fatigue/ Mild Fatigue#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N	
16-55/ C4591001 1022 10221078	GENRL	Injection site pain/ Moderate Injection Site Pain#	3	21DEC2020	1/2	2	Yes		NA	R (22DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Axillary pain/ Left Armpit soreness#	4	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
		Chills/ Chills#	4	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
		Injection site bruising/ Injection Site Bruising#	4	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ Moderate Injection Site Pain#	4	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ Mild Headache#	4	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
	INFEC	Genital herpes simplex/ HSV2 outbreak Genital#	4	19JAN2021	8/11	1	No	O	NA	R (29JAN2021)	N/N
16-55/ C4591001 1022 10221080	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
		Malaise/ Malaise	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	PSYCH	Abnormal dreams/ Unusually Vivid Dreams	1	27AUG2020	1/2	2	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001 1022 10221081	GENRL	Injection site bruising/ Bruise at the injection site	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	SKIN	Night sweats/ Mild Night Sweats#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221084	GENRL	Fatigue/ Fatigue#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	MUSC	Back pain/ Musculoskeletal Pain upper back	1	14SEP2020	19/5	2	No	O	NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ Mild Headache#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ Headache*		28AUG2020	1/1	2	Yes		NA	R (28AUG2020)	N/N
	GENRL	Injection site pain/ Moderate Injection site pain	1	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	16DEC2020	1/3	1	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1022 10221098	GENRL	Fatigue/ Mild Fatigue#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Injection site pain/ Mild Injection Site Pain#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
	NERV	Headache/ Mild headache#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Pyrexia/ Fever#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	PSYCH	Insomnia/ Insomnia#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1022 10221100	GENRL	Injection site pain/ Moderate Injection site pain	1	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/Y
16-55/ C4591001 1022 10221101	GENRL	Injection site pain/ Mild Injection Site Pain#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
		Pyrexia/ Low grade fever#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1022 10221105	GENRL	Injection site pain/ Mild Injection Site Pain#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221106	GENRL	Fatigue/ Fatigue#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ Mild injection Site Pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GASTR	Nausea/ Nausea	1	02SEP2020	2/1	2	Yes		NA	R (02SEP2020)	N/N
		Vomiting/ Vomiting	1	02SEP2020	2/1	2	Yes		NA	R (02SEP2020)	N/N
	GENRL	Chills/ Chills	1	02SEP2020	2/1	2	Yes		NA	R (02SEP2020)	N/N
		Injection site pain/ Moderate Injection site pain	1	02SEP2020	2/1	2	Yes		NA	R (02SEP2020)	N/N
	SKIN	Hyperhidrosis/ Sweats	1	02SEP2020	2/1	2	Yes		NA	R (02SEP2020)	N/N
	GENRL	Chills/ Chills	2	22SEP2020	2/C	2	Yes		NA	N	N/N
		Injection site pain/ Moderate Injection site pain	2	22SEP2020	2/C	2	Yes		NA	N	N/N
	Pyrexia/ Fever	2	22SEP2020	2/C	1	Yes		NA	N	N/N	
	MUSC	Myalgia/ Moderate Generalized Myalgias	2	22SEP2020	2/C	2	Yes		NA	N	N/N
16-55/ C4591001 1022 10221108	GENRL	Injection site pain/ Mild Injection site pain	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/Y

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221110	MUSC	Myalgia/ Moderate Myalgias	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ Moderate Headache	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
	GENRL	Chills/ Moderate Chills	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
	BLOOD	Lymphadenopathy/ Left Axillary Adenopathy	2	24SEP2020	3/5	1	Yes		NA	R (28SEP2020)	N/N
	GENRL	Injection site pain/ Achy pain around injection site	1	11SEP2020	10/18	1	Yes		NA	R (28SEP2020)	N/N
	GASTR	Nausea/ Mild Nausea	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1022 10221111	GENRL	Chills/ Chills	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	20JAN2021	1/5	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Chills/ Mild Chills#	3	21JAN2021	2/1	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Fatigue/ Mild Fatigue#	3	21JAN2021	2/4	1	Yes		NA	R (24JAN2021)	N/N
GENRL	Fatigue/ Mild Fatigue#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N	
	Injection site pain/ Mild Injection Site Pain#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221112	GASTR	Diarrhoea/ Diarrhea	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/Y
	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/Y
	NERV	Headache/ Headache	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	24SEP2020	1/4	2	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1022 10221115	GENRL	Injection site pain/ Moderate Injection Site Pain#	3	18DEC2020	1/3	2	Yes		NA	R (20DEC2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	06JAN2021	1/1	1	Yes		NA	R (06JAN2021)	N/N
		Pyrexia/ Low Grade Fever#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1022 10221120	GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	1/7	2	Yes		NA	R (09SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Mild Injection site pain	1	03SEP2020	1/5	1	Yes		NA	R (07SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1022 10221122	GASTR	Nausea/ Moderate Nausea	1	04SEP2020	2/1	2	Yes		NA	R (04SEP2020)	N/N	
	GENRL	Chills/ Mild Chills#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N	
		Fatigue/ Mild Fatigue#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N	
		Injection site pain/ Mild Injection Site Pain#	3	23DEC2020	1/3	1	Yes		NA	R (25DEC2020)	N/N	
	MUSC	Myalgia/ Generalized Myalgias#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N	
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N	
16-55/ C4591001 1022 10221123	GENRL	Injection site pain/ Mild Injection site pain	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
	MUSC	Myalgia/ Moderate Myalgias	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1022 10221125	GENRL	Chills/ Moderate Chills	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N	
		Pyrexia/ Fever	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N	
16-55/ C4591001 1022 10221126	GENRL	Chills/ Mild Chills#	4	01FEB2021	1/1	1	Yes		NA	R (01FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221127	GENRL	Fatigue/ Moderate Fatigue#	4	07JAN2021	1/2	2	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	RESP	Paranasal sinus discomfort/ Sinus Pressure#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1022 10221128	GENRL	Oedema peripheral/ Bilateral Hand Edema	1	05SEP2020	2/1	1	No	O	NA	R (05SEP2020)	N/N
	RESP	Rhinorrhoea/ Rhinorrhea	1	05SEP2020	2/1	1	No	O	NA	R (05SEP2020)	N/N
	REPRO	Breast cyst/ Right Breast Cyst	2	20OCT2020	27/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ Moderate Injection Site Pain#	3	17DEC2020	1/3	2	Yes		NA	R (19DEC2020)	N/N
	MUSC	Myalgia/ Mild Generalized Myalgias#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Fatigue/ Mild Fatigue#	3	18DEC2020	2/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Chills/ Chills#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Fatigue/ Mild fatigue#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	Pyrexia/ Fever#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221131 16-55/ C4591001 1022 10221133	MUSC	Myalgia/ Generalized Myalgias#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	MUSC	Myalgia/ Mild Myalgias#	4	07JAN2021	1/4	1	Yes		NA	R (10JAN2021)	N/N
	MUSC	Myalgia/ Generalized Moderate Myalgias*		04SEP2020	1/2	2	Yes		NA	R (05SEP2020)	N/N
	NERV	Headache/ Moderate Headache*		04SEP2020	1/2	2	Yes		NA	R (05SEP2020)	N/N
	GENRL	Chills/ Mild Chills	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
		Pyrexia/ Fever	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ Mild Headache	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Injection site pain/ Moderate Injection Site Pain#	3	19JAN2021	1/3	2	Yes		NA	R (21JAN2021)	N/N
	1022 10221134	GASTR	Diarrhoea/ Mild Diarrhea#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)
	NERV	Headache/ Mild Headache#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Chills/ Chills#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221136	MUSC	Injection site pain/ Mild injection Site Pain#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
		Pyrexia/ Fever#	4	09FEB2021	1/1	1	Yes		NA	R (09FEB2021)	N/N
		Myalgia/ Generalized Myalgias#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
		Headache/ Headache#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Injection site pain/ Moderate Injection site pain	2	29SEP2020	2/1	2	Yes		NA	R (29SEP2020)	N/N
	NERV	Cervical radiculopathy/ C7 left sided radiculopathy	2	30SEP2020	2/C	2	No	O	NA/TCN	N	N/N
	NERV	Headache/ Mild Headache	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	NERV	Headache/ Mild Headache	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	19JAN2021	1/3	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Chills/ Chills#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1022 10221138		Fatigue/ Fatigue#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221139		Pyrexia/ Fever#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ Mild Headache#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	GASTR	Diarrhoea/ Episodes of loose stools	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain	2	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N
	NERV	Pyrexia/ Fever	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1022 10221142	NERV	Headache/ Headache	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N
	INJ&P	Arthropod bite/ Mosquito Bite inner thigh	2	10OCT2020	13/7	1	No	O	NA/TC	R (16OCT2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	19JAN2021	1/4	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Fatigue/ Mild Fatigue#	3	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	3	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1022 10221143	BLOOD	Lymphadenopathy/ Swollen Gland in left arm#	4	10FEB2021	2/5	1	Yes		NA	R (14FEB2021)	N/N	
	GENRL	Fatigue/ Mild Fatigue#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N	
		Pyrexia/ Fever#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N	
	MUSC	Myalgia/ Generalized Myalgias#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N	
		Pain in extremity/ Pain in whole left arm#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N	
	GENRL	Fatigue/ Mild Fatigue#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N	
		Injection site pain/ Mild Injection Site Pain#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N	
	16-55/ C4591001 1022 10221144	GENRL	Injection site pain/ Injection Site pain	1	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		GENRL	Chills/ Mild Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Injection site pain/ Mild injection site pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Myalgia/ Mild generalized myalgias	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N	
16-55/ C4591001 1022 10221147	SKIN	Mechanical urticaria/ Worsening of Dermographism of TRUNK	1	13SEP2020	5/43	1	No	O	NA	R (25OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221156	GENRL	Injection site pain/ Mild Injection Site Pain#	3	20JAN2021	1/5	1	Yes		NA	R (24JAN2021)	N/N
	NERV	Headache/ Mild Headache#	3	20JAN2021	1/3	1	Yes		NA/TC	R (22JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		Pyrexia/ Fever#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Chills/ Chills	2	05OCT2020	1/1	2	Yes		NA	R (05OCT2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
	NERV	Headache/ Headache	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
	16-55/ C4591001 1022 10221164	GENRL	Injection site pain/ Mild Injection Site Pain	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)
	MUSC	Flank pain/ Moderate left flank pain	1	02OCT2020	16/C	2	No	O	NA/TC/TCN	N	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221179		Injection site papule/ Erythematous Papules around injection site	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
	EAR	Vertigo positional/ Benign Paroxysmal Positional Vertigo	2	16OCT2020	9/C	2	No	O	NA	N	N/N
	NEOPL	Plasma cell myeloma/ IGA Kappa Multiple Myeloma	2	27NOV2020	51/C	2	No	O	NA	N	Y/N
	GENRL	Injection site pain/ Injection site pain#	3	23DEC2020	1/3	1	Yes		NA	R (25DEC2020)	N/N
	GASTR	Nausea/ Nausea#	4	16JAN2021	2/1	2	Yes		NA/TC	R (16JAN2021)	N/N
		Vomiting/ Vomiting#	4	16JAN2021	2/1	2	Yes		NA	R (16JAN2021)	N/N
	GENRL	Pyrexia/ Fever 102.0#	4	16JAN2021	2/1	2	Yes		NA/TC	R (16JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16JAN2021	2/1	2	Yes		NA/TC	R (16JAN2021)	N/N
	GENRL	Fatigue/ Worsening Fatigue#	4	17JAN2021	3/2	1	Yes		NA	R (18JAN2021)	N/N
	16-55/ C4591001 1024 10241004	GASTR	Diarrhoea/ Diarrhea	1	14AUG2020	3/1	1	No	O	NA	R (14AUG2020)
16-55/ C4591001 1024 10241061	GENRL	Pain/ Body Aches	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain#	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1024 10241064	GENRL	Fatigue/ Fatigue#	3	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N	
16-55/ C4591001 1024 10241080	MUSC	Arthralgia/ Joint Pain - Elbows	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 1024 10241104		Arthralgia/ Joint pain - Knees	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N	
		Arthralgia/ Joint pain - Neck	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 1024 10241114	GENRL	Chills/ chills	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N	
	GENRL	Pain/ generalized body aches	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N	
16-55/ C4591001 1024 10241121†	GENRL	Injection site pain/ Injection Site Pain#	4	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N	
16-55/ C4591001 1024 10241129	GENRL	Chills/ chills	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N	
	NERV	Headache/ headache	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1027 10271049	GENRL	Chills/ Chills#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Fatigue/ Fatigue#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1027 10271061	GENRL	Fatigue/ FATIGUE	1	22AUG2020	2/3	1	Yes		NA	R (24AUG2020)	N/N
		Pain/ BODY ACHES	1	22AUG2020	2/3	1	Yes		NA	R (24AUG2020)	N/N
16-55/ C4591001 1027 10271105	IMMUN	Drug hypersensitivity/ Allergic Reaction to investigational product	1	29AUG2020	2/14	2	Yes		P/TC	R (11SEP2020)	N/N
	RESP	Pharyngeal swelling/ Throat Swelling	1	29AUG2020	2/11	2	Yes		NA/TC	R (08SEP2020)	N/N
	GASTR	Gastroesophageal reflux disease/ GERD	1	08SEP2020	12/C	1	No	O	NA/TC	RG	N/N
	GENRL	Chest pain/ Left-sided chest pain	1	08SEP2020	12/1	1	No	O	NA/TC	R (08SEP2020)	N/N
	MUSC	Back pain/ Lower back pain	1	08SEP2020	12/4	1	No	O	NA	R (11SEP2020)	N/N
	MUSC	Muscular weakness/ Right leg weakness	1	10SEP2020	14/1	2	No	O	NA/TCN	R (10SEP2020)	N/N
	MUSC	Back pain/ Mid back pain	1	11SEP2020	15/4	1	No	O	NA	R (14SEP2020)	N/N
	NERV	Hypoaesthesia/ Right arm numbness	1	11SEP2020	15/1	1	No	O	NA	R (11SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1027 10271129	PSYCH	Attention deficit hyperactivity disorder/ Attention Deficit Hyperactivity Disorder	2	19OCT2020	27/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1027 10271173	GENRL	Fatigue/ Fatigue post Covid Vaccination 4#	4	06JAN2021	1/4	1	Yes		NA	R (09JAN2021)	N/N	
		Pain/ Body Aches post Covid Vaccination 4#	4	06JAN2021	1/4	1	Yes		NA	R (09JAN2021)	N/N	
	INV	Body temperature increased/ Increased body temperature post Vaccination 4#	4	06JAN2021	1/4	1	Yes		NA	R (09JAN2021)	N/N	
16-55/ C4591001 1028 10281002	GENRL	Pain/ generalized body ache#	4	13MAR2021	2/C	1	Yes		NA	N	N/N	
	INV	Body temperature increased/ elevated body temperature#	4	13MAR2021	2/1	1	Yes		NA	R (13MAR2021)	N/N	
16-55/ C4591001 1028 10281003	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	29NOV2020	87/C		Yes		NA/W	N	N/N	
16-55/ C4591001 1028 10281022	GENRL	Injection site pain/ Left Arm Pain at injection site	1	19AUG2020	1/2	2	Yes		NA	R (20AUG2020)	N/N	
	GENRL	Fatigue/ fatigue	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N	
		Pain/ body aches	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281023	MUSC	Pain in extremity/ left arm soreness	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
	BLOOD	Leukocytosis/ leukocytosis	2	05OCT2020	19/1	2	No	O	NA	R (05OCT2020)	N/N
	GASTR	Abdominal pain/ abdominal pain	2	05OCT2020	19/1	2	No	O	NA/TC	R (05OCT2020)	N/N
		Nausea/ nausea	2	05OCT2020	19/2	2	No	O	NA/TC	R (06OCT2020)	N/N
	METAB	Dehydration/ dehydration	2	05OCT2020	19/1	2	No	O	NA/TC	R (05OCT2020)	N/N
RENAL	Acute kidney injury/ acute kidney injury	2	05OCT2020	19/1	2	No	O	NA	R (05OCT2020)	N/N	
16-55/ C4591001 1028 10281026	MUSC	Pain in extremity/ bilateral hand pain	2	14SEP2020	4/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C4591001 1028 10281027	GENRL	Chills/ CHILLS	2	12SEP2020	2/2	2	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1028 10281028		Pain/ BODY ACHES	2	12SEP2020	2/2	2	Yes		NA/TC	R (13SEP2020)	N/N
	BLOOD	Lymphadenopathy/ enlarged lymph glands left armpit#	3	19FEB2021	2/2	2	Yes		NA	R (20FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	19FEB2021	2/2	2	Yes		NA	R (20FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache#	3	19FEB2021	2/2	2	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1028 10281030	NERV	Dystonia/ Dystonia	1	23AUG2020	4/1	2	No	CD	NA/TC	R (23AUG2020)	N/N
16-55/ C4591001 1028 10281031	GASTR	Cheilitis/ RASH RIGHT UPPER LIP	1	01SEP2020	13/64	2	No	O	NA/TC	R (03NOV2020)	N/N
16-55/ C4591001 1028 10281033	INV	Body temperature increased/ elevated body temperature	1	21AUG2020	2/2	2	Yes		NA	R (22AUG2020)	N/N
	SOCCI	Miscarriage of partner/ miscarriage for pregnant partner	2	22DEC2020	103/1	2	No	O	NA	R (22DEC2020)	Y/N
16-55/ C4591001 1028 10281035	GENRL	Injection site erythema/ left arm redness at injection site	1	21AUG2020	1/3	2	Yes		NA	R (23AUG2020)	N/N
		Injection site pain/ left arm soreness at injection site	1	21AUG2020	1/3	2	Yes		NA	R (23AUG2020)	N/N
		Injection site swelling/ left arm swelling at injection site	1	21AUG2020	1/3	2	Yes		NA	R (23AUG2020)	N/N
	GENRL	Injection site pain/ left arm soreness at injection site	2	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
		Injection site swelling/ left arm swelling at injection site	2	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001	GASTR	Haemorrhoids/ internal hemorrhoids	2	28SEP2020	15/C	2	No	O	NA	N	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1028 10281043 16-55/ C4591001	GENRL	Injection site pain/ left arm soreness at injection site#	4	18JAN2021	1/3	2	Yes		NA	R (20JAN2021)	N/N	
1028 10281044 16-55/ C4591001	INV	Body temperature increased/ increased body temperature	1	27AUG2020	4/1	2	Yes		NA	R (27AUG2020)	N/N	
1028 10281050	INFEC	Viral upper respiratory tract infection/ Non-COVID viral Upper respiratory infection	2	05OCT2020	20/6	2	No	O	NA	R (10OCT2020)	N/N	
	RESP	Asthma/ mild asthma exacerbation	2	05OCT2020	20/6	2	No	O	NA/TC	R (10OCT2020)	N/N	
		Rhinitis allergic/ allergic rhinitis	2	05OCT2020	20/6	2	No	O	NA	R (10OCT2020)	N/N	
	GENRL	Pain/ generalized body aches#	4	25FEB2021	2/4	2	Yes		NA	R (28FEB2021)	N/N	
	GASTR	Abdominal discomfort/ upset stomach#	4	26FEB2021	3/3	2	Yes		NA	R (28FEB2021)	N/N	
	GASTR	Diarrhoea/ diarrhea#	4	27FEB2021	4/2	2	Yes		NA	R (28FEB2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ left arm soreness at injection site.	1	27AUG2020	2/3	2	Yes		NA	R (29AUG2020)	N/N	
1028 10281059	REPRO	Breast mass/ left breast lump	1	27AUG2020	2/34	2	No	O	NA	R (29SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Diarrhoea/ diarrhea	1	01SEP2020	7/1	2	Yes		NA	R (01SEP2020)	N/N
	NEOPL	Invasive ductal breast carcinoma/ invasive ductal carcinoma stage 1B, left breast	2	30SEP2020	15/C	2	No	O	NA/TC	N	Y/N
16-55/ C4591001 1028 10281060	GENRL	Fatigue/ Fatigue	1	27AUG2020	2/8	2	Yes		NA	R (03SEP2020)	N/N
	INJ&P	Upper limb fracture/ Closed fracture of right elbow	2	28OCT2020	42/2	2	No	O	NA/TC/TCN	R (29OCT2020)	Y/N
16-55/ C4591001 1028 10281062	NERV	Migraine/ worsening of migraines	1	15SEP2020	21/23	2	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1028 10281065	MUSC	Pain in extremity/ SORE ARM, LEFT	1	27AUG2020	1/2	2	Yes		NA	R (28AUG2020)	N/Y
	GENRL	Injection site erythema/ left arm redness at injection site	2	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ left arm pain at injection site	2	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ headache	2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1028 10281070	GENRL	Fatigue/ fatigue#	4	26JAN2021	2/C	2	Yes		NA	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281075	GENRL	Injection site erythema/ LEFT ARM INJECTION SITE REDNESS	1	28AUG2020	1/7	2	Yes		NA	R (03SEP2020)	N/N
		Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	28AUG2020	1/7	2	Yes		NA	R (03SEP2020)	N/N
		Injection site pruritus/ LEFT ARM INJECTION SITE ICHINESS	1	28AUG2020	1/7	2	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ injection site soreness left	2	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ headache	2	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N
	GASTR	Vomiting/ vomiting	2	19SEP2020	2/1	2	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ chills	2	19SEP2020	2/1	2	Yes		NA	R (19SEP2020)	N/N
		Chills/ rigors	2	19SEP2020	2/1	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1028 10281077	GENRL	Injection site pain/ LEFT ARM SORENESS AT INJECTION SITE	1	28AUG2020	1/3	2	Yes		NA	R (30AUG2020)	N/N
16-55/ C4591001 1028 10281078	GASTR	Nausea/ NAUSEA	1	29AUG2020	2/1	2	Yes		NA	R (29AUG2020)	N/N
	GENRL	Pain/ body aches	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281079	INV	Body temperature increased/ increased body temperature	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site erythema/ redness at injection site left deltoid#	3	21DEC2020	1/8	2	Yes		NA	R (28DEC2020)	N/N
		Injection site swelling/ swelling at injection site left deltoid#	3	21DEC2020	1/8	2	Yes		NA	R (28DEC2020)	N/N
	GASTR	Abdominal pain upper/ stomach ache#	4	11JAN2021	1/2	2	Yes		NA	R (12JAN2021)	N/N
	INV	Body temperature increased/ elevated body temperature#	4	11JAN2021	1/4	2	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ headache#	4	11JAN2021	1/4	2	Yes		NA	R (14JAN2021)	N/N
	MUSC	Myalgia/ generalized muscle aches#	4	12JAN2021	2/3	2	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1028 10281085	NERV	Headache/ increase in headaches	1	02SEP2020	3/48	2	Yes		NA	R (19OCT2020)	N/N
	INFEC	Ear infection/ bilateral ear infection	1	05SEP2020	6/12	2	No	O	NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1028 10281087	GENRL	Injection site erythema/ redness at injection site left arm	2	22SEP2020	2/7	2	Yes		NA	R (28SEP2020)	N/N
		Injection site pain/ pain at injection site left arm	2	22SEP2020	2/7	2	Yes		NA	R (28SEP2020)	N/N
		Injection site swelling/ swelling at injection site left arm	2	22SEP2020	2/7	2	Yes		NA	R (28SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281088	GASTR	Nausea/ nausea	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
	GENRL	Chills/ chills	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ fever	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
	NERV	Headache/ headache	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
	RESP	Oropharyngeal pain/ sore throat	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1028 10281089	GENRL	Pain/ body aches	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ fever	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1028 10281090	GENRL	Chills/ body chills	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ headache	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1028 10281096	GENRL	Injection site pain/ injection site pain, left	1	01SEP2020	1/3	2	Yes		NA	R (03SEP2020)	N/N
	GENRL	Chills/ body chills	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281098	GENRL	Fatigue/ fatigue	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
		Chills/ chills	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1028 10281100	GENRL	Injection site pain/ pain at injection site left side#	3	15FEB2021	1/C	2	Yes		NA	N	N/N
	GENRL	Injection site swelling/ swelling at injection site left side#	3	16FEB2021	2/C	2	Yes		NA	N	N/N
16-55/ C4591001 1028 10281103	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	03SEP2020	2/7	2	Yes		NA	R (09SEP2020)	N/N
		Injection site pruritus/ ITCHINESS AT INJECTION SITE	1	03SEP2020	2/7	2	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1028 10281104	GENRL	Fatigue/ fatigue	1	03SEP2020	2/2	2	Yes		NA	R (04SEP2020)	N/N
	INV	Body temperature increased/ increased body temperature	1	03SEP2020	2/2	2	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1028 10281105	MUSC	Myalgia/ right deltoid muscle pain	1	04SEP2020	3/3	2	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001	MUSC	Pain in extremity/ Left Arm Soreness	1	04SEP2020	2/1	2	Yes		NA	R (04SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1028 10281112	GASTR	Haemorrhoids/ internal hemorrhoids	2	18NOV2020	56/C	2	No	O	NA	N	N/N	
		Large intestine polyp/ colon polyp, benign	2	18NOV2020	56/1	2	No	O	NA/TCN	R (18NOV2020)	N/N	
		Rectal polyp/ rectal polyp, benign	2	18NOV2020	56/1	2	No	O	NA/TCN	R (18NOV2020)	N/N	
16-55/ C4591001 1028 10281121	MUSC	Myalgia/ muscle aches	1	05SEP2020	2/2	2	Yes		NA	R (06SEP2020)	N/N	
	NERV	Headache/ headache	1	05SEP2020	2/2	2	Yes		NA	R (06SEP2020)	N/N	
	MUSC	Myalgia/ muscle aches	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N	
	NERV	Headache/ headache	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1028 10281122	GENRL	Injection site pain/ left arm soreness at injection site#	3	16DEC2020	1/2	2	Yes		NA	R (17DEC2020)	N/Y	
		Injection site reaction/ left arm stiffness at injection site#	3	16DEC2020	1/2	2	Yes		NA	R (17DEC2020)	N/Y	
	GENRL	Injection site bruising/ bruising at injection site left arm#	4	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/N	
		Injection site pain/ left arm soreness at injection site#	4	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/Y	
		Injection site reaction/ left arm stiffness at injection site#	4	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/Y	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281124	GENRL	Injection site pain/ left arm soreness at injection site	1	04SEP2020	1/3	2	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1028 10281131	NERV	Headache/ headache	1	06SEP2020	2/2	2	Yes		NA	R (07SEP2020)	N/N
	GENRL	Chills/ Chills	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ Fever	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ Headache	2	25SEP2020	1/3	2	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1028 10281141	GENRL	Fatigue/ fatigue	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N
		Pain/ body aches	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1028 10281143	GENRL	Chills/ chills	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
	INV	Body temperature increased/ increased body temperature	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281150	GENRL	Injection site pain/ left deltoid injection site soreness#	3	08JAN2021	1/4	2	Yes		NA	R (11JAN2021)	N/N
	GENRL	Injection site warmth/ left deltoid injection site warm#	3	09JAN2021	2/1	2	Yes		NA	R (09JAN2021)	N/N
	GENRL	Injection site pain/ injection site soreness right deltoid#	4	28JAN2021	1/4	2	Yes		NA	R (31JAN2021)	N/N
	GENRL	Injection site warmth/ injection site warmth right deltoid#	4	29JAN2021	2/3	2	Yes		NA	R (31JAN2021)	N/N
		Pain/ general body aches#	4	29JAN2021	2/1	2	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1028 10281153	GENRL	Pain/ generalized body ache#	4	12MAR2021	2/2	1	Yes		NA	R (13MAR2021)	N/N
	NERV	Headache/ headache#	4	12MAR2021	2/2	1	Yes		NA	R (13MAR2021)	N/N
16-55/ C4591001 1028 10281155	GENRL	Chills/ chills	2	30SEP2020	2/18	2	Yes		NA	R (17OCT2020)	N/N
		Injection site pain/ left arm injection site soreness	2	30SEP2020	2/15	2	Yes		NA	R (14OCT2020)	N/N
		Pyrexia/ fever	2	30SEP2020	2/18	2	Yes		NA/TC	R (17OCT2020)	N/N
	NERV	Headache/ headache	2	30SEP2020	2/18	2	Yes		NA	R (17OCT2020)	N/N
	MUSC	Bone pain/ bone aches	2	01OCT2020	3/17	2	Yes		NA	R (17OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281158	NERV	Myalgia/ muscle aches	2	01OCT2020	3/17	2	Yes		NA	R (17OCT2020)	N/N
		Migraine/ worsening of migraine	2	01OCT2020	3/17	2	No	O	NA	R (17OCT2020)	N/N
	EYE	Lacrimation increased/ watery eyes	2	05OCT2020	7/C	2	Yes		NA	N	N/N
	EYE	Vitreous detachment/ posterior vitreous detachment right eye	2	09NOV2020	42/C	2	No	O	NA	N	N/N
	METAB	Impaired fasting glucose/ impaired fasting glucose	1	15SEP2020	6/C	2	No	O	NA/TC	N	N/N
	GASTR	Nausea/ nausea	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
	GENRL	Pain/ body aches	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1028 10281167	INV	Body temperature increased/ increased body temperature	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
	NERV	Headache/ worsening headache	2	03OCT2020	2/2	2	Yes		NA/TC	R (04OCT2020)	N/N
	GENRL	Injection site pain/ left arm soreness at injection site	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1028 10281170	INV	Heart rate increased/ increased heart rate	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Chills/ body chills	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1028 10281174	MUSC	Pyrexia/ fever	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N	
		Arthralgia/ joint aches	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N	
		Myalgia/ muscle aches	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N	
	NERV	Headache/ headache	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N	
	NERV	Dizziness/ lightheadedness	1	14SEP2020	1/1	2	Yes		NA	R (14SEP2020)	N/Y	
16-55/ C4591001 1028 10281177	GENRL	Chills/ chills	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N	
16-55/ C4591001 1028 10281183	GENRL	Fatigue/ fatigue	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N	
		Pain/ body aches	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N	
		Pyrexia/ fever	2	06OCT2020	2/2	2	Yes		NA/TC	R (07OCT2020)	N/N	
		Fatigue/ fatigue	2	07OCT2020	2/3	2	Yes		NA	R (09OCT2020)	N/N	
		Injection site pain/ left arm injection site pain	2	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N	
Pain/ body aches	2	07OCT2020	2/3	2	Yes		NA	R (09OCT2020)	N/N			

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281184	INV	Body temperature increased/ elevated body temperature	2	07OCT2020	2/3	2	Yes		NA	R (09OCT2020)	N/N
	NERV	Headache/ headache	2	07OCT2020	2/3	2	Yes		NA/TC	R (09OCT2020)	N/N
	NERV	Presyncope/ vasovagal episode*		15SEP2020	1/1	2	No	O	NA/TCN	R (15SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site left arm#	3	18FEB2021	1/2	2	Yes		NA	R (19FEB2021)	N/N
	GENRL	Injection site pain/ left arm soreness at injection site	1	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site erythema/ injection site redness#	3	19DEC2020	2/3	2	Yes		NA	R (21DEC2020)	N/N
		Injection site pain/ injection site pain left deltoid#	3	19DEC2020	2/3	2	Yes		NA	R (21DEC2020)	N/N
		Injection site swelling/ swelling of injection site left deltoid#	3	19DEC2020	2/3	2	Yes		NA	R (21DEC2020)	N/N
	GENRL	Pyrexia/ Fever#	4	09JAN2021	2/1	2	Yes		NA	R (09JAN2021)	N/N
	GENRL	Pain/ body aches	2	08OCT2020	1/4	2	Yes		NA/TC	R (11OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	09OCT2020	2/1	2	Yes		NA	R (09OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue	2	10OCT2020	3/4	2	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1028 10281200	GENRL	Injection site pain/ right arm soreness (injection site)#	3	07JAN2021	1/2	2	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1028 10281202	INJ&P	Upper limb fracture/ left arm fracture	1	23SEP2020	6/32	2	No	O	NA/TCN	R (24OCT2020)	N/N
16-55/ C4591001 1028 10281205	GENRL	Injection site pain/ right arm soreness at injection site#	3	26JAN2021	1/4	2	Yes		NA	R (29JAN2021)	N/N
	BLOOD	Lymphadenopathy/ enlarged lymph glands left armpit#	4	16FEB2021	1/6	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1028 10281207	GENRL	Pyrexia/ fever	1	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	1	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	14OCT2020	2/2	2	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 1028 10281208	INFEC	Tooth infection/ tooth infection left lower side	1	06OCT2020	16/13	2	No	O	NA/TC	R (18OCT2020)	N/N
	MUSC	Back pain/ acute back pain	2	16DEC2020	66/6	2	No	O	NA/TC	R (21DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281213	NERV	Presyncope/ vasovagal episode*		30SEP2020	1/1	1	No	O	NA	R (30SEP2020)	N/N
16-55/ C4591001 1028 10281221	GENRL	Injection site pain/ left arm soreness at injection site	1	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ left arm soreness (injection site)#	3	26JAN2021	1/8	2	Yes		NA	R (02FEB2021)	N/Y
	GENRL	Injection site hypoesthesia/ left arm numbness at injection site#	4	16FEB2021	1/3	2	Yes		NA	R (18FEB2021)	N/Y
16-55/ C4591001 1028 10281223	GENRL	Injection site pain/ left arm soreness at injection site	1	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
	INV	Body temperature increased/ increased body temperature	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1028 10281224	GENRL	Fatigue/ fatigue	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1028 10281227	GENRL	Injection site pain/ left arm soreness at injection site	1	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ left deltoid soreness at injection site	1	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1028 10281228	GENRL	Pyrexia/ fever	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N	
	MUSC	Arthralgia/ achiness in shoulders	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N	
	NERV	Headache/ headache	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N	
	GENRL	Fatigue/ fatigue	2	16OCT2020	3/2	2	Yes		NA	R (17OCT2020)	N/N	
	INFEC	Trichomoniasis/ trichomoniasis	2	28OCT2020	15/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001	REPRO	Erectile dysfunction/ ERECTILE DYSFUNCTION	2	15JAN2021	93/C	2	No	O	NA/TC	N	N/N	
1028 10281229	GENRL	Chills/ chills	2	20OCT2020	2/2	2	Yes		NA	R (21OCT2020)	N/N	
16-55/ C4591001	GENRL	Pain/ body aches	2	20OCT2020	2/2	2	Yes		NA	R (21OCT2020)	N/N	
1028 10281237	NERV	Pyrexia/ fever	2	20OCT2020	2/2	2	Yes		NA/TC	R (21OCT2020)	N/N	
	NERV	Headache/ headache	2	20OCT2020	2/2	2	Yes		NA	R (21OCT2020)	N/N	
16-55/ C4591001	GENRL	Injection site nodule/ injection site nodule left arm#	3	16FEB2021	1/11	2	Yes		NA	R (26FEB2021)	N/N	
1028 10281246												

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281247	GENRL	Injection site pain/ pain at injection site left arm#	3	17FEB2021	2/7	2	Yes		NA/TC	R (23FEB2021)	N/N
	GENRL	Injection site erythema/ redness injection site left deltoid	1	07OCT2020	1/15	2	Yes		NA	R (21OCT2020)	N/N
		Injection site swelling/ swelling injection site left deltoid	1	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N
	GASTR	Vomiting/ vomiting	2	28OCT2020	1/2	2	Yes		NA	R (29OCT2020)	N/N
	GENRL	Pain/ body aches	2	28OCT2020	1/3	2	Yes		NA	R (30OCT2020)	N/N
	GENRL	Chills/ chills	2	29OCT2020	2/2	2	Yes		NA	R (30OCT2020)	N/N
	INV	Body temperature increased/ increased body temperature	2	29OCT2020	2/2	2	Yes		NA/TC	R (30OCT2020)	N/N
	NERV	Headache/ headache	2	29OCT2020	2/2	2	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1028 10281253	GENRL	Pain/ body aches	1	13OCT2020	1/2	2	Yes		NA	R (14OCT2020)	N/N
		Pyrexia/ fever	1	13OCT2020	1/2	2	Yes		NA	R (14OCT2020)	N/N
	GENRL	Chills/ chills	2	03NOV2020	1/2	2	Yes		NA	R (04NOV2020)	N/N
		Injection site erythema/ injection site redness right arm	2	03NOV2020	1/2	2	Yes		NA	R (04NOV2020)	N/N
		Injection site swelling/ injection site swelling right arm	2	03NOV2020	1/2	2	Yes		NA	R (04NOV2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1028 10281256	GASTR	Pain/ body aches	2	03NOV2020	1/2	2	Yes		NA	R (04NOV2020)	N/N	
		Nausea/ nausea	2	04NOV2020	2/1	2	Yes		NA	R (04NOV2020)	N/N	
	Vomiting/ vomiting	2	04NOV2020	2/1	2	Yes		NA	R (04NOV2020)	N/N		
	GENRL	Pyrexia/ fever	2	05NOV2020	2/2	2	Yes		NA	R (06NOV2020)	N/N	
16-55/ C4591001 1028 10281257	GENRL	Chills/ chills	2	06NOV2020	2/1	2	Yes		NA	R (06NOV2020)	N/N	
16-55/ C4591001 1028 10281271	INV	Pain/ body aches	2	06NOV2020	2/1	2	Yes		NA/TC	R (06NOV2020)	N/N	
		Body temperature increased/ increased body temperature	2	06NOV2020	2/1	2	Yes		NA	R (06NOV2020)	N/N	
16-55/ C4591001 1028 10281274	MUSC	Myalgia/ generalized muscle pain	1	26OCT2020	6/3	2	Yes		NA	R (28OCT2020)	N/N	
	NERV	Headache/ worsening headache	1	26OCT2020	6/3	2	Yes		NA	R (28OCT2020)	N/N	
	NERV	Headache/ worsening of headache	1	22OCT2020	1/4	2	Yes		NA/TC	R (25OCT2020)	N/N	
	GENRL	Fatigue/ fatigue	1	23OCT2020	2/4	2	Yes		NA	R (26OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills	2	13NOV2020	2/2	2	Yes		NA	R (14NOV2020)	N/N
		Fatigue/ fatigue	2	13NOV2020	2/2	2	Yes		NA	R (14NOV2020)	N/N
	INV	Body temperature increased/ elevated body temperature	2	13NOV2020	2/2	2	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1028 10281275	GENRL	Chills/ chills#	4	05MAR2021	1/2	2	Yes		NA	R (06MAR2021)	N/N
16-55/ C4591001 1028 10281276	GASTR	Nausea/ nausea	2	13NOV2020	2/2	2	Yes		NA	R (14NOV2020)	N/N
	GENRL	Chills/ chills	2	13NOV2020	2/2	2	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	2	13NOV2020	2/2	2	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1028 10281279	IMMUN	Food allergy/ allergy reaction: avocado	2	13DEC2020	25/1	2	No	O	NA/TC	R (13DEC2020)	N/N
16-55/ C4591001 1028 10281284	INFEC	Urinary tract infection/ urinary tract infection	2	27NOV2020	11/3	2	No	O	NA/TC	R (29NOV2020)	N/N
16-55/ C4591001 1028 10281285	GENRL	Pain/ body aches#	3	17FEB2021	1/2	2	Yes		NA/TC	R (18FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	NERV	Headache/ headache#	3	17FEB2021	1/2	2	Yes		NA/TC	R (18FEB2021)	N/N	
16-55/ C4591001 1028 10281287	INV	Body temperature increased/ increased body temperature	1	29OCT2020	2/1	2	Yes		NA	R (29OCT2020)	N/N	
	GENRL	Injection site pain/ injection site soreness left deltoid	2	17NOV2020	2/1	2	Yes		NA	R (17NOV2020)	N/N	
		Malaise/ general malaise	2	17NOV2020	2/1	2	Yes		NA	R (17NOV2020)	N/N	
16-55/ C4591001 1030 10301011	GENRL	Fatigue/ fatigue#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N	
		Injection site pain/ left arm pain from injection site#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N	
16-55/ C4591001 1030 10301022	GENRL	Injection site pain/ right arm pain from injection site#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N	
16-55/ C4591001 1030 10301026	GENRL	Injection site pain/ left arm pain from injection#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N	
16-55/ C4591001 1030 10301030	INFEC	Urinary tract infection/ urinary tract infection	1	05SEP2020	5/11	1	No	O	NA/TC	R (15SEP2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ left arm pain from injection#	3	28DEC2020	1/2	1	Yes		NA	R (29DEC2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1030 10301041	GENRL	Injection site pain/ left arm soreness from injection site#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001 1030 10301049	MUSC	Pain in extremity/ left arm pain	1	01OCT2020	24/5	1	Yes		NA	R (05OCT2020)	N/N
16-55/ C4591001 1030 10301055	RENAL	Nephrolithiasis/ kidney stone	1	30SEP2020	22/10	2	No	O	NA	R (09OCT2020)	N/N
16-55/ C4591001 1030 10301061	GENRL	Fatigue/ Fatigue#	2	22DEC2020	82/2	1	Yes		NA	R (23DEC2020)	N/N
1030 10301069		Injection site pain/ Right Arm injection site pain#	2	22DEC2020	82/2	1	Yes		NA	R (23DEC2020)	N/N
	NERV	Headache/ Headache#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Chills/ chills#	4	12JAN2021	1/2	2	Yes		NA	R (13JAN2021)	N/N
	INV	Body temperature increased/ Elevated Body Temperature#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ Generalized muscle aches#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ left arm pain from injection site#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1030 10301075	GENRL	Chills/ chills#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N	
16-55/ C4591001 1030 10301077	GENRL	Injection site pain/ left arm pain at injection point#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N	
16-55/ C4591001 1030 10301099	GENRL	Injection site pain/ left arm pain from injection site#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N	
16-55/ C4591001 1030 10301110	INFEC	Pharyngitis streptococcal/ pharyngitis streptococcal#	2	17JAN2021	101/14	2	No	O	NA/TC	R (30JAN2021)	Y/N	
16-55/ C4591001 1030 10301113	GENRL	Injection site pain/ left arm pain from injection site#	3	30DEC2020	1/3	1	Yes		NA	R (01JAN2021)	N/N	
16-55/ C4591001 1030 10301134	GENRL	Injection site pain/ left arm soreness from injection#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N	
16-55/ C4591001 1030 10301146	GENRL	Fatigue/ fatigue#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N	
		Injection site pain/ left arm soreness from injection site#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1036 10361021	GENRL	Chills/ Subject developed chills after injection	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
	RESP	Cough/ Subject developed cough after injection.	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
16-55/ C4591001 1036 10361074	GENRL	Chills/ Chills#	4	18FEB2021	1/C	1	Yes		NA	N	N/N
	GENRL	Pain/ Body Soreness#	4	18FEB2021	1/3	1	Yes		NA/TC	R (20FEB2021)	N/N
		Pyrexia/ Fever#	4	19FEB2021	2/C	1	Yes		NA/TC	N	N/N
16-55/ C4591001 1036 10361125	GASTR	Nausea/ Nausea#	4	19FEB2021	2/2	2	Yes		NA	R (20FEB2021)	N/N
	GENRL	Asthenia/ Body Weakness#	4	19FEB2021	2/2	2	Yes		NA	R (20FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	19FEB2021	2/2	2	Yes		NA	R (20FEB2021)	N/N
		Pyrexia/ Feverish#	4	19FEB2021	2/2	2	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1036 10361126	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/Y
	NERV	Headache/ Headache	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1036 10361141	GENRL	Lethargy/ Lethargy	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N	
		Injection site pain/ muscle pain at injection site#	3	04FEB2021	1/C	1	Yes		NA	N	N/N	
16-55/ C4591001 1036 10361144	GENRL	Injection site pain/ Injection Site Pain*		26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N	
	GASTR	Diarrhoea/ Diarrhea	1	28OCT2020	3/5	1	Yes		NA	R (01NOV2020)	N/N	
	GENRL	Pain/ Body Aches	1	28OCT2020	3/5	1	Yes		NA	R (01NOV2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	29OCT2020	4/3	1	Yes		NA	R (31OCT2020)	N/N	
	NERV	Headache/ Headache	1	29OCT2020	4/3	1	Yes		NA	R (31OCT2020)	N/N	
	RESP	Rhinorrhoea/ Rhinorrhea	1	29OCT2020	4/3	1	Yes		NA	R (31OCT2020)	N/N	
16-55/ C4591001 1037 10371007	GENRL	Fatigue/ FATIGUE	2	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N	
		Pyrexia/ LOW GRADE FEVER	2	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N	
16-55/ C4591001 1037 10371008	GENRL	Fatigue/ FATIGUE	2	09SEP2020	1/1	1	Yes		NA/TC	R (09SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1037 10371041	GASTR	Pyrexia/ LOW GRADE FEVER	2	09SEP2020	1/1	2	Yes		NA/TC	R (09SEP2020)	N/N	
		Diarrhoea/ DIARRHEA	2	11SEP2020	1/13	1	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 1037 10371047	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	21SEP2020	11/1	1	Yes		NA/TC	R (21SEP2020)	N/N	
	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	29SEP2020	20/17	2	No	O	NA/TC	R (15OCT2020)	N/N	
16-55/ C4591001 1037 10371051	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	09DEC2020	87/9	2	No	O	NA/TC	R (17DEC2020)	N/N	
16-55/ C4591001 1037 10371052	GENRL	Pyrexia/ LOW GRADE FEVER	1	24AUG2020	1/2	1	Yes		NA	R (25AUG2020)	N/N	
	GASTR	Diarrhoea/ DIARRHEA	1	25AUG2020	2/30	1	No	CD	NA	R (23SEP2020)	N/N	
	EAR	Ear pain/ EAR ACHE	2	18SEP2020	5/11	1	No	O	NA/TC	R (28SEP2020)	N/N	
	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	18SEP2020	5/3	1	Yes		NA	R (20SEP2020)	N/N	
	RESP	Dyspnoea/ INCREASED SHORTNESS OF BREATH#	2	31JAN2021	140/C	3	No	O	NA/TC/TCN	N	Y/N	
16-55/ C4591001	GENRL	Fatigue/ FATIGUE	2	14SEP2020	1/3	2	No	O	NA	R (16SEP2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1037 10371067	SKIN	Dermatitis allergic/ ALLERGIC RASH	1	26AUG2020	1/26	1	No	O	NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1037 10371076	IMMUN	Seasonal allergy/ WORSENING OF SEASONAL ALLERGIES	1	09SEP2020	15/12	2	No	O	NA/TC	R (20SEP2020)	N/N
	RESP	Wheezing/ WORSENING OF WHEEZING	1	09SEP2020	15/12	2	No	O	NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1037 10371124	GENRL	Pyrexia/ FEVER	1	03SEP2020	2/1	2	Yes		NA/TC	R (03SEP2020)	N/N
	GENRL	Pyrexia/ LOW GRADE FEVER	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C4591001 1037 10371125	GENRL	Chills/ CHILLS	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1037 10371154	GENRL	Chills/ Chills	2	06OCT2020	1/1	1	Yes		NA	R (06OCT2020)	N/N
		Pyrexia/ Low grade fever	2	06OCT2020	1/1	1	Yes		NA	R (06OCT2020)	N/N
	MUSC	Myalgia/ Generalized muscle aches	2	06OCT2020	1/1	1	Yes		NA	R (06OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1037 10371170	GENRL	Injection site pain/ LEFT ARM PAIN AT INJECTION SITE	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ LEFT ARM PAIN AT INJECTION SITE	2	29SEP2020	1/4	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1037 10371183	GENRL	Injection site pain/ RIGHT ARM SORENESS INJECTION SITE	2	02OCT2020	2/14	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 1037 10371198	PSYCH	Anxiety disorder/ ANXIETY DISORDER	2	OCT2020	1/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1037 10371214	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY#	4	08FEB2021	29/C	1	No	O	NA	N	N/N
16-55/ C4591001 1037 10371216	GENRL	Injection site induration/ INJECTION SITE REACTION LEFT ARM INDURATION	1	16SEP2020	2/5	1	Yes		NA	R (20SEP2020)	N/N
		Injection site pain/ PAIN AT LEFT UPPER ARM INJECTION SITE	1	16SEP2020	2/5	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	1	16SEP2020	2/5	1	Yes		NA	R (20SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1037 10371223	GENRL	Injection site erythema/ ERYTHEMA AT INJECTION SITE LEFT UPPER ARM	1	17SEP2020	3/4	2	Yes		NA/TCN	R (20SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	MUSC	Pyrexia/ FEVER	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1037 10371236	MUSC	Myalgia/ MUSCLE ACHES	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	1	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1037 10371237	RESP	Dysphonia/ WORSENING OF HOARSENESS	2	20OCT2020	13/25	1	No	O	NA/TC/TCN	R (13NOV2020)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	2	09OCT2020	2/1	2	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1037 10371272	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Pyrexia/ FEVER	2	15OCT2020	1/4	2	Yes		NA/TC	R (18OCT2020)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE ACHES	2	15OCT2020	1/4	2	Yes		NA/TC	R (18OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1037 10371277	MUSC	Pain in extremity/ ARM PAIN LEFT	1	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		Pain in jaw/ JAW PAIN LEFT	1	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Chills/ Chills	2	17OCT2020	2/2	2	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C4591001 1037 10371290	INFEC	Tooth infection/ TOOTH INFECTION	1	06OCT2020	12/8	2	No	O	NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 1037 10371306	NERV	Headache/ HEADACHE	1	30SEP2020	1/1	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1037 10371308	MUSC	Pain in extremity/ RIGHT LEG PAIN	2	27NOV2020	40/6	1	No	O	NA	R (02DEC2020)	N/N
16-55/ C4591001 1037 10371309	MUSC	Muscle spasms/ LEFT LEG MUSCLE SPASMS	1	06OCT2020	7/6	2	No	O	NA	R (11OCT2020)	N/N
16-55/ C4591001 1037 10371312	GASTR	Abdominal pain upper/ PAIN IN LEFT UPPER QUADRANT	2	24OCT2020	2/C	1	No	O	NA	N	N/N
16-55/ C4591001	GASTR	Diarrhoea/ DIARRHEA	1	04OCT2020	3/6	1	Yes		NA	R (09OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1037 10371317	INV	Blood glucose increased/ ELEVATED GLUCOSE	1	10OCT2020	9/9	1	No	O	NA	R (18OCT2020)	N/N
	SKIN	Rash/ RASH ON CHEST	1	17OCT2020	16/10	1	No	O	NA	R (26OCT2020)	N/N
16-55/ C4591001 1037 10371330	SKIN	Dermatitis contact/ CONTACT DERMATITIS LEGS AND BREASTS	2	24NOV2020	29/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1037 10371336	GENRL	Chills/ CHILLS	1	20OCT2020	8/1	1	Yes		NA/TC	R (20OCT2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	1	20OCT2020	8/1	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 1037 10371342	GASTR	Diarrhoea/ DIARRHEA	2	07NOV2020	2/3	1	Yes		NA	R (09NOV2020)	N/N
	GENRL	Chills/ CHILLS	2	07NOV2020	2/3	1	Yes		NA	R (09NOV2020)	N/N
		Pyrexia/ FEVER	2	07NOV2020	2/3	1	Yes		NA	R (09NOV2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN	2	07NOV2020	2/3	2	Yes		NA/TC	R (09NOV2020)	N/N
	NERV	Headache/ HEADACHE	2	07NOV2020	2/3	2	Yes		NA/TC	R (09NOV2020)	N/N
16-55/ C4591001	RENAL	Nephrolithiasis/ RIGHT KIDNEY RENAL STONE	2	26DEC2020	46/3	2	No	O	NA/TC	R (28DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1037 10371353 16-55/ C4591001	GENRL	Injection site pain/ LEFT SHOULDER MUSCLE ACHE AT INJECTION SITE	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N	
1037 10371359 16-55/ C4591001	GENRL	Fatigue/ fatigue	1	09SEP2020	23/2	1	Yes		NA	R (10SEP2020)	N/N	
1038 10381002 16-55/ C4591001	GENRL	Chills/ Chills	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N	
1038 10381003		Pain/ Body aches	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N	
	GENRL	Fatigue/ fatigue	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
		Pain/ body aches	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
16-55/ C4591001 1038 10381014	GASTR	Nausea/ nausea	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
	GENRL	Chills/ chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
		Pyrexia/ low grade fever	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine Subject	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1038 10381016 16-55/ C4591001 1038 10381022	GENRL	Chills/ Chills	1	22AUG2020	2/1	1	Yes	NA/TC		R (22AUG2020)	N/N
		Injection site erythema/ Redness at injection site	1	22AUG2020	2/1	1	Yes	NA/TC		R (22AUG2020)	N/N
		Injection site swelling/ swelling at injection site	1	22AUG2020	2/1	1	Yes	NA/TC		R (22AUG2020)	N/N
		Pain/ Body aching	1	22AUG2020	2/1	1	Yes	NA/TC		R (22AUG2020)	N/N
16-55/ C4591001 1038 10381023	GENRL	Fatigue/ fatigue	2	10SEP2020	2/8	1	Yes	NA		R (17SEP2020)	N/N
16-55/ C4591001 1038 10381044	GENRL	Injection site pain/ Pain at Injection Site#	3	14JAN2021	2/8	1	Yes	NA		R (21JAN2021)	N/N
		Injection site pruritus/ Itching at Injection Site#	3	14JAN2021	2/8	1	Yes	NA		R (21JAN2021)	N/N
		Injection site swelling/ Swelling at Injections Site#	3	14JAN2021	2/8	1	Yes	NA		R (21JAN2021)	N/N
16-55/ C4591001 1038 10381091	GENRL	Pain/ body aches	2	26SEP2020	2/2	1	Yes	NA		R (27SEP2020)	N/N
		Pyrexia/ fever	2	26SEP2020	2/2	1	Yes	NA		R (27SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1038 10381094	GENRL	Fatigue/ Fatigue	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
		Injection site pain/ Injection Site Tenderness	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Chills/ chills	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
		Fatigue/ fatigue	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ injection site tenderness	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ headache	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1038 10381095	GENRL	Injection site pain/ Injection site tenderness	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1038 10381096	GENRL	Chills/ chills	1	06SEP2020	3/2	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1038 10381121	NERV	Restless legs syndrome/ Restless Leg Syndrome	2	29OCT2020	23/C	1	No	O	NA/TC	N	N/N
	RESP	Sleep apnoea syndrome/ Obstructive Sleep Apnea	2	29OCT2020	23/C	1	No	O	NA/TCN	N	N/N
16-55/ C4591001	GASTR	Nausea/ nausea	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1038 10381131	GENRL	Chills/ chills	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N	
		Pain/ aching	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N	
		Pyrexia/ fever	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N	
16-55/ C4591001 1038 10381133	GENRL	Injection site pain/ injection site tenderness	1	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/Y	
16-55/ C4591001 1038 10381136	GENRL	Injection site pain/ injection site tenderness	1	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	1	29SEP2020	9/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1038 10381138	GASTR	Diarrhoea/ diarrhea#	3	05JAN2021	2/1	2	Yes		NA	R (05JAN2021)	N/N	
		Vomiting/ vomiting#	3	05JAN2021	2/1	2	Yes		NA	R (05JAN2021)	N/N	
	GENRL	Chills/ chills#	3	05JAN2021	2/1	1	Yes		NA/TC	R (05JAN2021)	N/N	
		Pyrexia/ fever#	3	05JAN2021	2/1	2	Yes		NA	R (05JAN2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection Arm Soreness#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1039 10391003	GENRL	Pain/ GENERALIZED ACHING	2	12SEP2020	2/7	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1039 10391004	MUSC	Myalgia/ left arm muscle soreness#	3	19JAN2021	2/3	2	Yes		NA	R (21JAN2021)	N/N
1039 10391009	GENRL	Fatigue/ Fatigue#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1039 10391011	GENRL	Injection site pain/ Injection site soreness#	4	11FEB2021	1/2	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1039 10391016	RESP	Oropharyngeal pain/ sore throat	1	25AUG2020	2/2	1	No	O	NA	R (26AUG2020)	N/N
16-55/ C4591001 1039 10391017	GENRL	Injection site pain/ left arm injection site pain#	3	18JAN2021	1/4	2	Yes		NA	R (21JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	08FEB2021	1/4	1	Yes		NA	R (11FEB2021)	N/N
		Pyrexia/ Fever (101)#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ generalized muscle aches#	4	08FEB2021	1/4	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Chills/ chills#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	NERV	Headache/ headache#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	INFEC	Taeniasis/ taeriasis#	4	12FEB2021	5/26	1	No	O	NA/TC	R (09MAR2021)	N/N
	GASTR	Abdominal pain upper/ left upper abdomen pain#	4	21FEB2021	14/3	1	No	O	NA	R (23FEB2021)	N/N
16-55/ C4591001 1039 10391025	GENRL	Injection site pain/ injection site soreness#	3	22JAN2021	1/5	1	Yes		NA	R (26JAN2021)	N/N
		Pain/ generalized body aches#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1039 10391026	MUSC	Pain in extremity/ right upper arm pain	1	25AUG2020	1/5	1	Yes		NA	R (29AUG2020)	N/N
	RENAL	Dysuria/ dysuria,increased frequency	1	01SEP2020	8/53	1	No	O	NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1039 10391036	GENRL	Injection site pain/ INJECTION SITE SORENESS	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Asthenia/ generalized weakness	1	27AUG2020	2/1	1	Yes		NA	R (27AUG2020)	N/N
	NERV	Tension headache/ TENSION HEADACHE	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1039 10391045	GENRL	Chills/ chills	2	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	2	17SEP2020	2/1	2	Yes		NA	R (17SEP2020)	N/N	
	NERV	Injection site pain/ INJECTION SITE PAIN	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N	
		Headache/ headache	2	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N	
	RESP	Oropharyngeal pain/ sore throat	1	28AUG2020	1/2	1	No	O	NA	R (29AUG2020)	N/N	
	GENRL	Injection site pain/ injection site soreness#	3	05JAN2021	1/4	1	Yes		NA	R (08JAN2021)	N/N	
		Pain/ left side body aches#	3	05JAN2021	1/4	1	Yes		NA	R (08JAN2021)	N/N	
		MUSC	Myalgia/ generalized muscle aches#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	16-55/ C4591001 1039 10391057	GENRL	Chills/ chills#	3	18JAN2021	1/2	2	Yes		NA	R (19JAN2021)	N/N
		GENRL	Pain/ general body ache#	3	18JAN2021	1/2	2	Yes		NA/TC	R (19JAN2021)	N/N
	Injection site pain/ Injection Site Pain#		4	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N	
16-55/ C4591001 1039 10391058	GENRL	Chills/ chills	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1039 10391065	MUSC	Fatigue/ fatigue	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N	
		Joint stiffness/ multiple joint stiffness	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N	
		Headache/ headache	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N	
	GENRL	Fatigue/ fatigue#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N	
	GENRL	Injection site pain/ injection arm soreness#	4	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N	
16-55/ C4591001 1039 10391067	GENRL	Pyrexia/ fever#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N	
	GENRL	Injection site pain/ injection site pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N	
	GENRL	Injection site pain/ injection site pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1039 10391076	MUSC	Myalgia/ GENERALIZED MYALGIAS	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N	
	GENRL	Injection site pain/ left arm injection site soreness	1	02SEP2020	1/5	1	Yes		NA	R (06SEP2020)	N/N	
	GENRL	Injection site pain/ left arm injection site pain#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1039 10391085	GENRL	Fatigue/ fatigue	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1039 10391086	INJ&P	Wrist fracture/ broken left wrist	2	12DEC2020	80/34	1	No	O	NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ injection arm soreness#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1039 10391087	GENRL	Injection site pain/ injection site pain#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Chills/ chills#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
		Fatigue/ fatigue#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ injection site pain#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
		Pyrexia/ fever#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ muscle aches#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ headache#	4	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
16-55/ C4591001 1039 10391097	GENRL	Chills/ CHILLS	2	25SEP2020	1/4	2	Yes		NA	R (28SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Fatigue/ FATIGUE	2	25SEP2020	1/5	2	Yes		NA	R (29SEP2020)	N/N	
		Injection site pain/ INJECTION SITE PAIN	2	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/N	
		Pain/ GENERALIZED ACHING	2	25SEP2020	1/4	2	Yes		NA/TC	R (28SEP2020)	N/N	
		Pyrexia/ FEVER	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N	
16-55/ C4591001 1039 10391099	GENRL	Injection site pain/ left arm injection site soreness#	3	28JAN2021	1/5	1	Yes		NA	R (01FEB2021)	N/N	
	INFEC	Urinary tract infection/ UTI#	3	11FEB2021	15/9	1	No	O	NA	R (19FEB2021)	N/N	
16-55/ C4591001 1039 10391104	GENRL	Injection site pain/ injection site soreness	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N	
	GENRL	Pyrexia/ fever	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N	
16-55/ C4591001 1039 10391108	GENRL	Injection site pain/ left arm injection site soreness#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	
		Injection site pain/ Injection Site Soreness#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE SORENESS	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1039 10391109	GENRL	Fatigue/ Fatigue#	4	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N
16-55/ C4591001 1039 10391110	GENRL	Injection site pain/ injection site pain	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
1039 10391112	GENRL	Injection site pain/ injection site pain	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
		Pyrexia/ fever	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1039 10391114	GENRL	Fatigue/ fatigue	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ left arm injection site pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	NERV	Piriformis syndrome/ left hip piriformi syndrome#	3	24JAN2021	11/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1039 10391115	GENRL	Injection site pain/ injection site pain	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	1	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1039 10391119	GENRL	Fatigue/ fatigue	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Injection site pain/ injection site soreness	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		Pain/ bodyache	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1039 10391120	GENRL	Fatigue/ fatigue#	3	19JAN2021	1/3	1	Yes		NA	R (21JAN2021)	N/N
		Injection site pain/ injection site soreness#	3	19JAN2021	1/3	1	Yes		NA/TC	RS (21JAN2021)	N/N
		Chills/ Chills#	4	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
		Headache/ Headache#	4	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
		Lymphadenopathy/ Lymphadenopathy Left armpit#	4	12FEB2021	4/4	1	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1039 10391127	GENRL	Fatigue/ fatigue	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
		Pain/ Aches-generalized	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		Pyrexia/ fever	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ FATIGUE	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1039 10391128	NERV	Headache/ HEADACHE	1	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N	
	GENRL	Fatigue/ FATIGUE	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N	
		Pyrexia/ FEVER	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N	
	MUSC	Myalgia/ MYALGIAS	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N	
	NERV	Headache/ HEADACHE	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N	
16-55/ C4591001 1039 10391136	GENRL	Injection site pain/ injection arm soreness#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N	
	GENRL	Injection site pain/ Injection Site Soreness#	4	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N	
16-55/ C4591001 1039 10391153	INV	Body temperature increased/ Increased Body temperature	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
	NERV	Paraesthesia/ Finger tingling in injection arm	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
16-55/ C4591001 1039 10391157	GENRL	Injection site pain/ injection site pain	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	2	17OCT2020	2/2	2	Yes		NA	R (18OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ generalized muscle aches	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	18OCT2020	3/1	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1039 10391166	GENRL	Injection site pain/ injection site soreness#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1039 10391168	GENRL	Injection site pain/ Injection Arm Soreness#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Injection site pain/ Injection Arm Soreness#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1039 10391172	GENRL	Injection site pain/ injection site soreness	1	03OCT2020	2/3	1	Yes		NA/TC	R (05OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	23OCT2020	1/3	1	Yes		NA/TC	R (25OCT2020)	N/N
		Pain/ generalized aching	2	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	24OCT2020	2/1	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Chills/ chills	2	25OCT2020	3/1	1	Yes		NA/TC	R (25OCT2020)	N/N
16-55/ C4591001 1039 10391175	PSYCH	Anxiety/ recurrent anxiety	1	05OCT2020	1/C	1	No	O	NA	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1039 10391176	GENRL	Chills/ Chills#	4	09FEB2021	2/1	1	Yes		NA/TC	R (09FEB2021)	N/N
	GENRL	Fatigue/ fatigue	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1039 10391178	GENRL	Injection site pain/ injection arm soreness#	3	13JAN2021	1/1	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1039 10391180	GENRL	Fatigue/ fatigue#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
	MUSC	Myalgia/ generalized muscle aches#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
	CARD	Palpitations/ pounding heart	1	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/Y
	NERV	Dizziness/ lightheaded	1	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/Y
	MUSC	Pain in extremity/ Injection Arm Pain#	3	18JAN2021	1/4	2	Yes		NA/TC	R (21JAN2021)	N/N
16-55/ C4591001 1039 10391181	GENRL	Pyrexia/ Fever(100.4)#	3	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
	NERV	Paraesthesia/ left arm tingling	2	28OCT2020	1/8	1	Yes		NA	R (04NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1039 10391185	INFEC	Chronic sinusitis/ exacerbation of chronic sinusitis	1	28OCT2020	21/7	1	No	O	NA/TC	R (03NOV2020)	N/N	
16-55/ C4591001 1039 10391198	GENRL	Pain/ generalized achiness#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N	
	NERV	Headache/ headache#	3	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N	
	NERV	Migraine with aura/ ocular migraine#	3	27JAN2021	7/4	2	No	O	NA	R (30JAN2021)	N/N	
	GASTR	Vomiting/ Vomitting#	4	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N	
	GENRL	Chills/ Chills#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N	
	NERV	Headache/ Headache#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N	
	GENRL	Pain/ general Body Aches#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N	
16-55/ C4591001 1039 10391199	GENRL	Injection site pain/ injection site soreness	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N	
16-55/ C4591001 1039 10391208	MUSC	Arthralgia/ Left posterior shoulder pain	2	17NOV2020	8/36	1	No	O	NA/TC	R (22DEC2020)	N/N	
	GENRL	Injection site pain/ Injection Site Soreness#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1039 10391212	GENRL	Injection site pain/ Injection Site Soreness#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1039 10391212	GENRL	Injection site pain/ Injection Site Soreness#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1039 10391214	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/1	1	Yes		NA	R (11NOV2020)	N/Y
	GENRL	Injection site pain/ Injection arm soreness#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Chills/ Chills#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
		Pyrexia/ Fever#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1039 10391225	GENRL	Chills/ chills#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
		Fatigue/ fatigue#	4	27JAN2021	1/1	1	Yes		NA	R (27JAN2021)	N/N
		Pyrexia/ fever#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ injection site soreness#	4	28JAN2021	2/1	1	Yes		NA	RS (28JAN2021)	N/N
16-55/ C4591001 1039 10391233	GENRL	Chills/ chills	2	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1039 10391237	GENRL	Pain/ generalized aches	2	20NOV2020	1/2	1	Yes		NA/TC	R (21NOV2020)	N/N
		Fatigue/ fatigue#	3	04JAN2021	1/1	1	Yes		NA	R (04JAN2021)	N/N
16-55/ C4591001 1039 10391239	NERV	Headache/ headache#	4	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Injection site pain/ Injection Arm Soreness#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1039 10391240	GENRL	Injection site pain/ right arm injection soreness*		30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N
16-55/ C4591001 1039 10391243	GENRL	Injection site pain/ injection site soreness	2	23NOV2020	1/2	1	Yes		NA	R (24NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	24NOV2020	2/2	1	Yes		NA	R (25NOV2020)	N/N
	NERV	Headache/ headache	2	24NOV2020	2/2	1	Yes		NA	R (25NOV2020)	N/N
	RESP	Sinus congestion/ sinus congestion	2	24NOV2020	2/2	1	No	O	NA	R (25NOV2020)	N/N
	GENRL	Injection site pain/ Injection Arm Soreness#	3	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1039 10391254	GENRL	Injection site pain/ injection site pain#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1042 10421001	GENRL	Chills/ Chills#	4	24FEB2021	2/3	1	Yes		NA	R (26FEB2021)	N/N
		Pain/ Body Aches#	4	24FEB2021	2/3	1	Yes		NA	R (26FEB2021)	N/N
		Pyrexia/ Fever#	4	24FEB2021	2/3	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1042 10421028	INJ&P	Chest injury/ bruised ribs	1	22AUG2020	20/13	2	No	O	NA/TC	R (03SEP2020)	N/N
16-55/ C4591001 1042 10421034	SKIN	Acne/ Acne	2	NOV2020	69/C	2	No	O	NA/TC	N	N/N
	HEPAT	Cholecystitis/ cholecystitis#	2	07FEB2021	167/3	3	No	O	NA/TC/TCN	R (09FEB2021)	Y/N
16-55/ C4591001 1042 10421035	GASTR	Diarrhoea/ Diarrhea#	3	28FEB2021	4/C	2	Yes		NA	RG	N/N
	GENRL	Chills/ Chills#	3	28FEB2021	4/C	1	Yes		NA	RG	N/N
	MUSC	Myalgia/ Muscle Pain#	3	28FEB2021	4/C	1	Yes		NA	RG	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache#	3	28FEB2021	4/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1042 10421041	INFEC	Cystitis/ bladder infection	2	21SEP2020	27/15	2	No	O	NA/TC	R (05OCT2020)	N/N
16-55/ C4591001 1042 10421092	NERV	Headache/ headaches	2	15SEP2020	6/2	2	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1042 10421109	GENRL	Injection site pain/ INJECTION SITE PAIN	1	14AUG2020	1/1	1	Yes		NA	R (14AUG2020)	N/N
16-55/ C4591001 1042 10421115	INJ&P	Ankle fracture/ Fractured Left Ankle	2	04FEB2021	150/26	2	No	O	NA/TCN	R (01MAR2021)	N/N
16-55/ C4591001 1042 10421125	GENRL	Chills/ Chills	2	14SEP2020	6/3	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1042 10421128	GENRL	Fatigue/ Fatigue Chills/ Chills#	2 3	14SEP2020 03MAR2021	6/3 1/2	1 1	Yes Yes		NA NA	R (16SEP2020) R (04MAR2021)	N/N N/N
	GENRL	Chest discomfort/ Chest Tightness#	3	04MAR2021	2/2	1	Yes		NA	R (05MAR2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1042 10421129	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	1	19AUG2020	1/C		No	O	NA	UNK	N/N
16-55/ C4591001 1042 10421140	METAB	Hypercholesterolaemia/ Hyperchlesterolemia	2	18DEC2020	102/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1042 10421143	GENRL	Pyrexia/ fever	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
	NERV	Headache/ headache	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001 1042 10421158	GENRL	Pain/ Bodyache	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ Low Grade Fever	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1042 10421161	GENRL	Pain/ Bodyaches	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
		Pyrexia/ Low Grade Fever	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001	INV	Blood cholesterol increased/ High Cholesterol#	2	23FEB2021	162/C	1	No	O	NA/TC	RG	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1042 10421163 16-55/ C4591001	GENRL	Pain/ Body Aches#	4	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
1042 10421169		Pyrexia/ Fever 100.9#	4	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001	INFEC	Sinusitis/ Sinus Infection	2	22JAN2021	124/6	1	No	O	NA/TC	R (27JAN2021)	N/N
1042 10421175											
16-55/ C4591001	INJ&P	Ligament rupture/ Torn ACL Left Knee	2	04JAN2021	106/15	2	No	CND	NA/TCN	R (18JAN2021)	N/N
1042 10421177											
16-55/ C4591001	INJ&P	Meniscus injury/ Torn Meniscus	2	27JAN2021	122/1	2	No	O	NA/TC	R (27JAN2021)	N/N
1042 10421196											
16-55/ C4591001	MUSC	Arthralgia/ SHOULDER PAIN RIGHT SIDE	2	29SEP2020	2/4	1	Yes		NA	R (02OCT2020)	N/N
1042 10421198											
		Neck pain/ NECK PAIN RIGHT SIDE	2	29SEP2020	2/4	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
1042 10421206											

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1042 10421210	VASC	Pyrexia/ Fever	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N	
		Hypertension/ High Blood Pressure	2	10DEC2020	74/50	1	No	O	NA/TC	R (28JAN2021)	N/N	
	PSYCH	Attention deficit hyperactivity disorder/ Attention-Deficit/Hyperactivity Disorder#	4	25FEB2021	4/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1042 10421216	GENRL	Chills/ Chills	2	29SEP2020	1/1	1	Yes		NA	R (29SEP2020)	N/N	
16-55/ C4591001 1042 10421217	INJ&P	Pyrexia/ Fever	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N	
		Exposure during pregnancy/ Exposure During Pregnancy#	3	20JAN2021	3/C		No	O	NA	UNK	N/N	
16-55/ C4591001 1042 10421222	GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N	
16-55/ C4591001 1042 10421232	NERV	Headache/ Headache	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N	
	RESP	Oropharyngeal pain/ Sore Throat	1	13SEP2020	3/2	1	Yes		NA	R (14SEP2020)	N/N	
	RESP	Respiratory tract congestion/ Chest Congestion#	2	27JAN2021	120/8	2	Yes		NA/TC	R (03FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1042 10421238	VASC	Hypertension/ Hypertension	2	12OCT2020	13/C	1	No	CD	NA/TC	N	N/N	
16-55/ C4591001 1042 10421243	INFEC	Ear infection/ It ear infection	1	17SEP2020	7/C	1	No	O	NA/TC	N	N/N	
	INV	Blood cholesterol increased/ High Cholesterol	1	24SEP2020	14/C	2	No	O	NA/TC	N	N/N	
		Blood potassium decreased/ Low Potassium	1	24SEP2020	14/C	2	No	O	NA/TC	N	N/N	
	GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
		Fatigue/ Fatigue	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
	MUSC	Arthralgia/ Joint Pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
	NERV	Headache/ Headache	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
	GENRL	Pyrexia/ Fever	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N	
16-55/ C4591001 1042 10421259	BLOOD	Lymphadenopathy/ ENLARGED LYMPHNODES LEFT AXILLA	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N	
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N	
16-55/ C4591001	MUSC	Pain in extremity/ Medical Pain in Thigh (Left)	2	DEC2020	21/C	1	No	O	NA	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1042 10421265 16-55/ C4591001 1044 10441011	MUSC	Back pain/ low back pain	2	11SEP2020	2/1	1	No	O	NA	R (11SEP2020)	N/N	
16-55/ C4591001 1044 10441028	MUSC	Myalgia/ generalized Myalgias	2	16SEP2020	2/34	2	Yes		NA/TC	R (19OCT2020)	N/N	
16-55/ C4591001 1044 10441029	MUSC	Myalgia/ Myalgia	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N	
16-55/ C4591001 1044 10441037	MUSC	Myalgia/ generalized Myalgia	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001 1044 10441045	NERV	Sciatica/ Sciatica (Right side)	2	06JAN2021	114/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1044 10441048	GENRL	Chills/ chills	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	
		Fatigue/ fatigue	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	
	MUSC	Myalgia/ generalized Myalgias	2	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1044 10441053	RENAL	Urinary retention/ urinary retention	2	12JAN2021	119/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1044 10441054	GENRL	Chills/ chills	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	
		Fatigue/ FATIGUE	2	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N	
		Pyrexia/ fever	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N	
16-55/ C4591001 1044 10441057	GENRL	Injection site pain/ Injection site pain	1	29AUG2020	1/2	2	Yes		NA	R (30AUG2020)	N/Y	
	RENAL	Nephrolithiasis/ Renal Calculi	1	29AUG2020	1/36	2	No	O	NA	R (03OCT2020)	N/Y	
16-55/ C4591001 1044 10441058	GASTR	Diarrhoea/ diarrhea	1	13SEP2020	3/1	1	Yes		NA	R (13SEP2020)	N/N	
16-55/ C4591001 1044 10441060	SKIN	Alopecia/ hair loss	2	05OCT2020	15/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1044 10441069	SKIN	Dermatitis contact/ adhesive tape hypersensitivity extremities#	3	02JAN2021	16/1	1	No	O	NA/TC	R (02JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1044 10441071	GENRL	Injection site pain/ Injection Site Pain	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ fever	2	23SEP2020	2/1	3	Yes		NA/TC	R (23SEP2020)	N/N
	MUSC	Arthralgia/ joint pain	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
		Myalgia/ generalized Myalgia	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1044 10441076	GENRL	Chills/ chills	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ generalized myalgia	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1044 10441077	GASTR	Mouth ulceration/ ORAL ulcer	1	05SEP2020	3/2	1	No	O	NA/TC	R (06SEP2020)	N/N
16-55/ C4591001 1044 10441079	GENRL	Chills/ chills	2	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ generalized myalgia	2	25SEP2020	1/32	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C4591001 1044 10441086	GASTR	Diarrhoea/ diarrhea	1	05SEP2020	1/1	1	No	O	NA	R (05SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1044 10441088	GENRL	Fatigue/ fatigue	1	05SEP2020	1/1	1	Yes		NA	R (05SEP2020)	N/N	
	NERV	Headache/ headache	1	05SEP2020	1/1	1	Yes		NA	R (05SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	2	26SEP2020	2/5	1	Yes		NA	R (30SEP2020)	N/N	
			Injection site pain/ injection site pain	2	26SEP2020	2/5	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Myalgia/ generalized myalgia	2	26SEP2020	2/4	1	Yes		NA	R (29SEP2020)	N/N	
	NERV	Headache/ headache	2	26SEP2020	2/4	1	Yes		NA	R (29SEP2020)	N/N	
	INFEC	Sinusitis bacterial/ Bacterial sinusitis#	2	22FEB2021	151/10	1	No	O	NA/TC	R (03MAR2021)	N/N	
	16-55/ C4591001 1044 10441099	INFEC	Gastroenteritis/ gastroenteritis	2	05OCT2020	7/1	1	No	O	NA	R (05OCT2020)	N/N
	16-55/ C4591001 1044 10441101	INFEC	Furuncle/ boil inguinal area	1	22SEP2020	13/36	1	No	O	NA/TC	R (27OCT2020)	N/N
16-55/ C4591001 1044 10441102	INJ&P	Corneal abrasion/ Corneal abrasion (left)	1	27SEP2020	18/3	1	No	O	NA/TC	R (29SEP2020)	N/N	
16-55/ C4591001	GENRL	Chills/ chills	2	13OCT2020	1/1	1	Yes		NA	R (13OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1044 10441119		Fatigue/ fatigue	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N	
	NERV	Headache/ headache	2	13OCT2020	1/3	1	Yes		NA/TC/TCN	R (15OCT2020)	N/N	
16-55/ C4591001 1044 10441122	GENRL	Pyrexia/ fever#	4	26FEB2021	2/1	1	Yes		NA	R (26FEB2021)	N/N	
16-55/ C4591001 1044 10441123	GENRL	Injection site pain/ Injection site pain	1	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N	
		Pyrexia/ fever	1	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N	
	NERV	Headache/ headache	1	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1044 10441127	GENRL	Chills/ chills	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
		Fatigue/ General fatigue	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
		Pyrexia/ fever	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia (mild) generalized	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
	GENRL	Injection site pain/ injection site pain	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1044 10441129	MUSC	Myalgia/ Myalgia	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N	
	GENRL	Pyrexia/ FEVER	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 1044 10441133	MUSC	Myalgia/ Myalgia GENERALIZED	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	2	13OCT2020	1/1	1	Yes		NA	R (13OCT2020)	N/N	
16-55/ C4591001 1044 10441139	MUSC	Myalgia/ Myalgia	2	13OCT2020	1/1	1	Yes		NA/TC	R (13OCT2020)	N/N	
	GENRL	Pyrexia/ fever	2	14OCT2020	2/1	2	Yes		NA	R (14OCT2020)	N/N	
	GENRL	Fatigue/ fatigue	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N	
			Injection site pain/ injection site pain	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
	NERV	Headache/ headache	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N	
	GENRL	Chills/ chills	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N	
		Pyrexia/ fever	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N	
	SKIN	Angioedema/ Angioedema face	2	16OCT2020	3/2	1	Yes		NA	R (17OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1044 10441142	GENRL	Injection site pain/ Injection site pain	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
	GENRL	Chills/ chills	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
	NERV	Headache/ Headache	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1044 10441146	INFEC	Otitis externa/ otitis externa (left ear)	1	27SEP2020	4/8	1	No	O	NA/TC	R (04OCT2020)	N/N
16-55/ C4591001 1044 10441152†	GASTR	Mouth ulceration/ oral Ulcer	2	24OCT2020	6/3	1	No	O	NA	R (26OCT2020)	N/N
		Stomatitis/ Stomatitis	2	24OCT2020	6/3	1	No	O	NA	R (26OCT2020)	N/N
	NEOPL	Breast cancer/ breast cancer initial diagnosis	2	28DEC2020	71/C	2	No	O	NA/TC	N	Y/N
16-55/ C4591001 1044 10441153	GENRL	Injection site pain/ Injection site pain	1	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Injection site erythema/ redness to injection site	2	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
		Pyrexia/ fever	2	20OCT2020	2/1	1	Yes		NA/TC	R (20OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1044 10441157	MUSC	Myalgia/ mylalgia	2	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N	
	GENRL	Chills/ Chills	2	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N	
16-55/ C4591001 1044 10441163		Pyrexia/ Fever	2	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N	
	GENRL	Chills/ chills	2	27OCT2020	2/2	1	Yes		NA/TC	R (28OCT2020)	N/N	
		Fatigue/ fatigue	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N	
	MUSC	Myalgia/ generalized myalgia	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N	
	NERV	Headache/ headache	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N	
	MUSC	Intervertebral disc protrusion/ Worsening of herniated disc	2	05JAN2021	72/C	2	No	O	NA/TC	RG	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	04MAR2021	1/1	1	Yes		NA/TC/W	R (04MAR2021)	N/N	
16-55/ C4591001 1044 10441164	MUSC	Myalgia/ generalized myalgia	2	27OCT2020	2/2	1	Yes		NA/TC	R (28OCT2020)	N/N	
	NERV	Headache/ headache	2	27OCT2020	2/2	1	Yes		NA/TC	R (28OCT2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ injection site pain	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1044 10441165	GENRL	Pyrexia/ Fever	1	20OCT2020	2/1	1	Yes		NA/TC	R (20OCT2020)	N/N	
	MUSC	Myalgia/ myalgia	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N	
	GASTR	Nausea/ nausea	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N	
	GENRL	Chills/ chills	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N	
		Injection site pain/ injection site pain	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N	
		Pyrexia/ fever	2	09NOV2020	1/2	3	Yes		NA/TC	R (10NOV2020)	N/N	
	MUSC	Myalgia/ generalized myalgia	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N	
	INJ&P	Foreign body/ Foreign object in finger	2	20NOV2020	12/5	1	No	O	NA/TC	R (24NOV2020)	N/N	
16-55/ C4591001 1044 10441166	GENRL	Injection site pain/ Injection site pain	2	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N	
		Pyrexia/ fever	2	28OCT2020	2/1	1	Yes		NA/TC	R (28OCT2020)	N/N	
	NERV	Headache/ headache	2	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N	
16-55/ C4591001 1044 10441171	INFEC	Tooth abscess/ TOOTH ABSCESS	2	10NOV2020	14/9	1	No	O	NA/TC	R (18NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1044 10441177	GENRL	Fatigue/ Fatigue	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
		Injection site pain/ Injection site pain	2	27OCT2020	1/3	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	28OCT2020	2/1	1	Yes		NA/TC	R (28OCT2020)	N/N
	GASTR	Irritable bowel syndrome/ Worsening of IBS	2	23NOV2020	28/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1044 10441186	NERV	Headache/ headache	2	02DEC2020	27/1	1	No	O	NA/TC	R (02DEC2020)	N/N
	RESP	Nasal congestion/ nasal congestion	2	02DEC2020	27/1	1	No	O	NA/TC	R (02DEC2020)	N/N
		Sneezing/ sneezing	2	02DEC2020	27/1	1	No	O	NA	R (02DEC2020)	N/N
16-55/ C4591001 1044 10441190	GENRL	Fatigue/ worsening fatigue	2	08NOV2020	3/3	1	Yes		NA	R (10NOV2020)	N/N
		Pyrexia/ Fever	2	08NOV2020	3/3	1	Yes		NA	R (10NOV2020)	N/N
	NERV	Headache/ headache	2	08NOV2020	3/3	1	Yes		NA	R (10NOV2020)	N/N
16-55/ C4591001 1044 10441218	GASTR	Abdominal pain/ Abdominal pain	2	13NOV2020	2/1	1	Yes		NA	R (13NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Nausea/ nausea	2	13NOV2020	2/1	1	Yes		NA	R (13NOV2020)	N/N
		Chills/ chills	2	13NOV2020	2/1	1	Yes		NA	R (13NOV2020)	N/N
		Pyrexia/ fever	2	13NOV2020	2/1	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1044 10441234	RESP	Reflux laryngitis/ Laryngopharyngeal Reflux	2	DEC2020	1/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1044 10441237	GENRL	Injection site pain/ injection site pain#	3	25FEB2021	1/3	1	Yes		NA	R (27FEB2021)	N/N
	NERV	Headache/ headache#	3	25FEB2021	1/4	1	Yes		NA/TC	R (28FEB2021)	N/N
16-55/ C4591001 1044 10441240	GASTR	Nausea/ nausea	1	09DEC2020	17/1	1	No	O	NA/TC	R (09DEC2020)	N/N
16-55/ C4591001 1044 10441242	NERV	Dizziness/ dizziness	1	24NOV2020	1/1	1	Yes		NA	R (24NOV2020)	N/N
	SKIN	Eczema/ Worsening of eczema (face)#	2	26FEB2021	74/3	1	No	O	NA/TC	R (28FEB2021)	N/N
16-55/ C4591001 1044 10441244	GENRL	Injection site pain/ injection site pain	1	24NOV2020	1/4	1	Yes		NA	R (27NOV2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1044 10441246	INFEC	Otitis media/ otitis media (Left ear)	1	02JAN2021	6/6	1	No	O	NA/TC	R (07JAN2021)	N/N	
16-55/ C4591001 1046 10461030	GENRL	Injection site pain/ Sore Left Arm at Injection Site#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N	
		Injection site swelling/ Swollen Left Arm at Injection Site#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N	
16-55/ C4591001 1046 10461046	BLOOD	Lymphadenopathy/ Swollen Lymph Node on left side of Neck	2	14SEP2020	7/7	1	No	O	NA	R (20SEP2020)	N/N	
16-55/ C4591001 1046 10461091	NERV	Migraine/ Migraine	2	15SEP2020	2/3	2	No	O	NA	R (17SEP2020)	N/N	
	ENDO	Hyperthyroidism/ Hyperthyroidism#	2	02MAR2021	170/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1046 10461118	INJ&P	Exposure during pregnancy/ Pregnancy Exposure	2	09JAN2021	114/C		No	O	NA	UNK	N/N	
16-55/ C4591001 1046 10461131	INFEC	Urinary tract infection/ Urinary Tract Infection	2	01DEC2020	75/4	2	No	O	NA	R (04DEC2020)	N/N	
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1046 10461134		Pain/ Full Body Aches#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1046 10461145	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	05OCT2020	15/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1046 10461153	GENRL	Fatigue/ Fatigue	1	05SEP2020	5/4	3	No	O	NA	R (08SEP2020)	N/N
16-55/ C4591001 1046 10461168	GENRL	Pyrexia/ Fever	1	05SEP2020	5/4	3	No	O	NA	R (08SEP2020)	N/N
16-55/ C4591001 1046 10461174	GENRL	Pyrexia/ Low Fever#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1046 10461174	GENRL	Injection site pain/ Left Arm Muscle Aches at Injection Site#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1046 10461175	INFEC	COVID-19/ CoVid19	2	14JAN2021	115/12	3	No	O	NA/TC	R (25JAN2021)	Y/N
16-55/ C4591001 1046 10461209	GENRL	Injection site pain/ Sore Left Arm at Injection Site#	3	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1046 10461219	GENRL	Injection site pain/ Left Arm Soreness at Injection Site#	4	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
		Pain/ General Body Aches#	4	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1046 10461268	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Sore Left Arm at Injection Site#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1046 10461280	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1046 10461332	PSYCH	Anxiety/ Anxiety Attack	2	12DEC2020	24/3	1	No	O	NA	R (14DEC2020)	N/N
	IMMUN	Seasonal allergy/ Seasonal Allergies#	4	03MAR2021	37/2	1	No	O	NA	R (04MAR2021)	N/N
16-55/ C4591001 1047 10471010	GENRL	Injection site erythema/ Redness at injection site left deltoid	2	08SEP2020	1/8	1	Yes		NA	R (15SEP2020)	N/N
		Injection site pain/ soreness of injection site left deltoid	2	08SEP2020	1/8	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1047 10471017	GASTR	Diarrhoea/ diarrhea	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
16-55/ C4591001 1047 10471018	GENRL	Injection site pain/ Soreness Left arm post injection	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
	GENRL	Chills/ chills#	4	23FEB2021	1/2	2	Yes		NA	R (24FEB2021)	N/N	
		Pain/ bodyaches#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N	
16-55/ C4591001 1047 10471025	GENRL	Pain/ body aches	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	
	NERV	Headache/ headache	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	
16-55/ C4591001 1047 10471033	GENRL	Injection site pain/ injection site Soreness Left Deltoid	1	25AUG2020	4/1	1	Yes		NA	R (25AUG2020)	N/N	
	GENRL	Injection site pain/ injection site pain left arm	2	12SEP2020	1/3	2	Yes		NA	R (14SEP2020)	N/N	
		Injection site pruritus/ left arm itchiness at injection site	2	12SEP2020	1/3	2	Yes		NA	R (14SEP2020)	N/N	
		Injection site swelling/ left arm swollen at injection site	2	12SEP2020	1/3	2	Yes		NA	R (14SEP2020)	N/N	
16-55/ C4591001	MUSC	Back pain/ lower back pain	2	13OCT2020	30/C	1	No	O	NA	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1047 10471035	MUSC	Tendonitis/ elbow tendinitis#	2	29JAN2021	138/C	2	No	O	NA	N	N/N	
16-55/ C4591001 1047 10471040	GENRL	Pain/ body aches	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N	
		Pyrexia/ 100.4 fever	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001 1047 10471041	GENRL	Pyrexia/ 100.4 fever	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	
	MUSC	Myalgia/ generalized muscles aches	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001 1047 10471042	GENRL	Chills/ chills#	3	22DEC2020	1/2	2	Yes		NA	R (23DEC2020)	N/N	
		Pyrexia/ fever of 101.9#	3	22DEC2020	1/2	2	Yes		NA	R (23DEC2020)	N/N	
	NERV	Headache/ headaches#	3	22DEC2020	1/2	3	Yes		NA	R (23DEC2020)	N/N	
16-55/ C4591001 1047 10471049	GENRL	Chills/ chills#	4	02MAR2021	1/3	2	Yes		NA	R (04MAR2021)	N/N	
		Fatigue/ fatigue`#	4	02MAR2021	1/3	2	Yes		NA	R (04MAR2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1047 10471052	RESP	Pain/ body aches# Sleep apnoea syndrome/ sleep apnea	4	02MAR2021	1/3	2	Yes		NA	R (04MAR2021)	N/N
16-55/ C4591001 1047 10471057	GENRL	Pyrexia/ low grade temp post injection 99.9	2	19SEP2020	2/2	1	Yes	O	NA	R (20SEP2020)	N/N
16-55/ C4591001 1047 10471061	GENRL	Pain/ Body Aches generalized	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ Fever 102	2	17SEP2020	2/1	2	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ Fever 103.0	2	17SEP2020	2/1	3	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	18SEP2020	3/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1047 10471064	GENRL	Pain/ Body aches generalized	2	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ Temp 101	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1047 10471068		Injection site pain/ injection site pain#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1047 10471069	GENRL	Pain/ Body aches generalized	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1047 10471070	GENRL	Injection site pain/ Injection Site Soreness	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Pain/ Body aches generalized	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ Fever	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1047 10471081	GASTR	Nausea/ Nausea	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1047 10471088	EAR	Vertigo/ Vertigo	2	15NOV2020	56/3	1	No	O	NA/TC	R (17NOV2020)	N/N
	NERV	Tension headache/ Tension Headache	2	15NOV2020	56/3	1	No	O	NA	R (17NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1047 10471093	IMMUN	Seasonal allergy/ Seasonal Allergies	1	02SEP2020	3/2	1	No	O	NA	R (03SEP2020)	N/N	
	RESP	Oropharyngeal pain/ intermittent Sore throat	1	02SEP2020	3/2	1	No	O	NA	R (03SEP2020)	N/N	
	GENRL	Chills/ Chills	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
		Injection site pain/ left injection site shoulder pain.	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
	MUSC	Neck pain/ Neck Pain	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
	NERV	Headache/ Headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 1047 10471095	GENRL	Fatigue/ Fatigue	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N	
		Injection site swelling/ Injection site swelling	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N	
	EYE	Retinal tear/ retinal tear	2	20NOV2020	58/15	3	No	O	NA	R (04DEC2020)	N/N	
	SURG	Retinal operation/ Laser Surgery for Retinal tear repair	2	04DEC2020	72/1	3	No	O	NA/TCN	R (04DEC2020)	N/N	
	MUSC	Arthralgia/ bilateral shoulder pain#	2	01MAR2021	159/C	2	No	O	NA	N	N/N	
16-55/ C4591001 1047 10471106	GENRL	Chills/ Chills	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1047 10471128	NERV	Headache/ Headaches	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
	GENRL	Chills/ Chills	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N	
		Pain/ Bodyaches	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N	
16-55/ C4591001 1047 10471131		Pyrexia/ Fever 101.0	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N	
	NERV	Headache/ Headache	2	24SEP2020	2/8	1	Yes		NA	R (01OCT2020)	N/N	
	RESP	Paranasal sinus discomfort/ Sinus Pressure	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N	
16-55/ C4591001 1047 10471131	GENRL	Pyrexia/ fever (100.8)#	4	20FEB2021	2/1	2	Yes		NA	R (20FEB2021)	N/N	
16-55/ C4591001 1047 10471133	GENRL	Pain/ Bodyaches	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N	
16-55/ C4591001 1047 10471143	INV	Body temperature increased/ Increased body temperature 100.0	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N	
	MUSC	Arthralgia/ Elbow pain right arm	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N	
		Arthralgia/ wrist pain right arm	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1047 10471146	GENRL	Myalgia/ muscle pain right arm	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
		Chills/ Chills	1	25SEP2020	22/2	1	Yes		NA	R (26SEP2020)	N/N
		Fatigue/ Fatigue	1	25SEP2020	22/2	1	Yes		NA	R (26SEP2020)	N/N
		Injection site pain/ Injection site soreness	1	25SEP2020	22/2	1	Yes		NA	R (26SEP2020)	N/N
	Pyrexia/ fever (103.0 F)#	4	25JAN2021	1/2	3	Yes		NA	R (26JAN2021)	N/N	
16-55/ C4591001 1047 10471150	NERV	Migraine/ intermittent migraines#	4	09FEB2021	16/C	2	No	O	NA	N	N/N
	GENRL	Injection site pain/ injection site pain#	2	21DEC2020	85/3	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	11JAN2021	22/2	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1047 10471172	GENRL	Pain/ body aches#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
	RENAL	Nephrolithiasis/ Kidney Stone, Right Side	2	05NOV2020	37/4	2	No	O	NA	R (08NOV2020)	N/N
16-55/ C4591001 1047 10471174	GASTR	Diarrhoea/ Diarrhea	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1047 10471180	GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1047 10471186	EAR	Ear discomfort/ Ear pressure	2	05OCT2020	1/3	1	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1047 10471189	GENRL	Chills/ Chills	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
	RESP	Rhinitis allergic/ Allergic Rhinitis	1	05OCT2020	25/3	1	No	O	NA/TC	R (07OCT2020)	N/N
	EAR	Ear pain/ Bilateral Otagia	2	06OCT2020	2/3	1	No	O	NA/TC	R (08OCT2020)	N/N
	PSYCH	Cyclothymic disorder/ cyclothyma	2	01NOV2020	32/C	2	No	O	NA	N	N/N
	GENRL	Fatigue/ fatigue#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
16-55/ C4591001 1047 10471189		Pain/ body ache#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
	INJ&P	Procedural pain/ post injection pain#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
	NERV	Headache/ headache#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
	BLOOD	Lymphadenopathy/ swollen lymph node (left shoulder)#	4	21JAN2021	14/8	1	Yes		NA	R (28JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1047 10471198	GENRL	Injection site pain/ injection site pain#	2	22DEC2020	83/3	1	Yes		NA	R (24DEC2020)	N/N
16-55/ C4591001 1047 10471201	GENRL	Injection site pain/ Left Arm soreness post injection	1	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001 1047 10471203	GENRL	Fatigue/ Fatigue*		14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		Injection site pain/ Left arm pain at injection site*		14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	12OCT2020	29/2	1	Yes		NA	R (13OCT2020)	N/N
		Injection site pain/ Left arm pain at injection site	1	12OCT2020	29/2	1	Yes		NA	R (13OCT2020)	N/N
	INJ&P	Fall/ fall	2	09NOV2020	29/1	2	No	O	NA	R (09NOV2020)	N/N
		Ligament sprain/ Sprained Left Foot	2	09NOV2020	29/73	2	No	O	NA	R (20JAN2021)	N/N
		Ligament sprain/ Sprained Right Foot	2	09NOV2020	29/73	2	No	O	NA	R (20JAN2021)	N/N
16-55/ C4591001 1047 10471217	SKIN	Blister/ left torso blisters	2	12OCT2020	4/25	1	No	O	NA	R (05NOV2020)	N/N
		Rash/ left torso rash	2	12OCT2020	4/25	1	No	O	NA	R (05NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1047 10471223	GENRL	Chills/ Chills	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Pain/ body aches	1	08OCT2020	23/2	1	Yes		NA	R (09OCT2020)	N/N
	INV	Body temperature increased/ increased body temperture 99.1	1	08OCT2020	23/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1047 10471225	EYE	Photophobia/ Light sensitivity eyes	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Pain/ Bodyaches	2	06OCT2020	2/9	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Pyrexia/ Fever 102.6	2	07OCT2020	3/1	3	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1047 10471232	GENRL	Injection site pain/ Injection site soreness left arm*		17SEP2020	1/8	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1047 10471236	GENRL	Fatigue/ fatigue#	3	28JAN2021	2/3	2	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1047 10471238	GENRL	Injection site pain/ pain at injection site#	4	12FEB2021	1/1	1	Yes		NA	R (12FEB2021)	N/Y

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1047 10471241	GASTR	Injection site pruritus/ itching at injection site#	4	12FEB2021	1/1	1	Yes		NA	R (12FEB2021)	N/Y
		Diarrhoea/ Diarrhea	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
	GENRL	Nausea/ Nausea	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
		Injection site pain/ Injection Site Soreness	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
		Pain/ Bodyaches	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
		Pyrexia/ Low Grade Fever 100.4	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
		NERV	Headache/ Headaches	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)
16-55/ C4591001 1047 10471244	GENRL	Injection site pain/ Injection site soreness left arm*		18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1047 10471251	GASTR	Nausea/ nausea#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
		Pain/ body ache#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
		Pyrexia/ Fever#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1047 10471254	NERV	Headache/ headache#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N	
	GENRL	Pain/ body aches#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
	GASTR	Nausea/ Nausea	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N	
16-55/ C4591001 1047 10471255	NERV	Headache/ headache#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N	
	BLOOD	Lymphadenopathy/ swollen lymph node (left armpit)#	4	09JAN2021	2/28	1	Yes		NA	R (05FEB2021)	N/N	
	GENRL	Pain/ body aches#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N	
	GENRL	Injection site pain/ Soreness at injection site left arm*		21SEP2020	1/4	1	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 1047 10471258	GENRL	Injection site pain/ soreness at injection site	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N	
		Pyrexia/ fever 101.6	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N	
	INFEC	Localised infection/ right lower leg infection	1	26SEP2020	5/12	2	No	O	NA	R (07OCT2020)	N/N	
	INFEC	Vulvovaginal mycotic infection/ vaginal yeast infection	1	29SEP2020	8/4	2	No	O	NA	R (02OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1047 10471266	INFEC	Subcutaneous abscess/ cutaneous abscess under left arM#	4	02MAR2021	13/1	1	No	O	NA	R (02MAR2021)	N/N
	SKIN	Dermatitis contact/ poison ivy#	4	02MAR2021	13/C	2	No	O	NA	N	N/N
	GASTR	Diarrhoea/ diarrhea (mild)	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Chills/ chills	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	4	05FEB2021	1/2	2	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1047 10471267	GENRL	Pain/ body aches#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Injection site pain/ soreness at injection site*		22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Pyrexia/ low grade temperature (99.1)	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	MUSC	Myalgia/ muscle aches	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1047 10471275	GENRL	Chills/ chills	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Pain/ body aches	2	14OCT2020	1/5	2	Yes		NA	R (18OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1047 10471279	NERV	Headache/ headache#	4	19FEB2021	1/2	2	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1047 10471318	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	DEC2020	30/C		No	O	NA	UNK	N/N
16-55/ C4591001 1047 10471326	GENRL	Injection site pruritus/ Itchiness left arm, injection site*		21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Left arm soreness, injection site	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1047 10471331	INJ&P	Ligament sprain/ right lower leg sprain	1	02NOV2020	12/15	1	No	O	NA	R (16NOV2020)	N/N
16-55/ C4591001 1048 10481004	INJ&P	Muscle strain/ THORACIC MUSCLE STRAIN	2	24SEP2020	23/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1048 10481020	SKIN	Pruritus/ PRURITIS - LEFT FOOT	2	05OCT2020	26/2	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1048 10481025	GENRL	Fatigue/ fatigue	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1048 10481032	MUSC	Myalgia/ New muscle pain, generalized	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ Headache	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	26AUG2020	2/5	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
	MUSC	Intervertebral disc degeneration/ Worsening of degenerative disc disease	2	11JAN2021	119/C	1	No	O	NA/TC	N	N/N
	GASTR	Gastritis/ Worsening of gastritis	2	14FEB2021	153/4	3	No	O	NA/TC	R (17FEB2021)	Y/N
16-55/ C4591001 1048 10481040		Impaired gastric emptying/ Worsening of gastroparesis	2	14FEB2021	153/4	3	No	O	NA/TC	R (17FEB2021)	Y/N
	SKIN	Rash/ RASH LEFT ANTECUBITAL	1	27AUG2020	1/4	1	No	O	NA	R (30AUG2020)	N/N
16-55/ C4591001 1048 10481044	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Cyst/ CYST ON LEFT GROIN	2	05OCT2020	20/148	2	No	O	NA/TC	R (01MAR2021)	N/N
	GENRL	Fatigue/ fatigue	1	01SEP2020	2/2	2	Yes		NA/TC	R (02SEP2020)	N/N
16-55/ C4591001 1048 10481055											

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1048 10481056	GENRL	Injection site pain/ injection site pain	1	01SEP2020	2/2	2	Yes		NA/TC	R (02SEP2020)	N/N	
		Fatigue/ Fatigue#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N	
16-55/ C4591001 1048 10481065	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N	
16-55/ C4591001 1048 10481075	GENRL	Injection site pain/ pain at injection site	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N	
16-55/ C4591001 1048 10481079	GENRL	Chills/ Chills	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N	
	IN FEC	Pain/ body aches	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
		Nasopharyngitis/ common cold	2	18OCT2020	26/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1048 10481079	GENRL	Fatigue/ FATIGUE	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 1048 10481083	GENRL	Pyrexia/ Fever	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
		Chills/ chills	1	06SEP2020	4/7	1	Yes		NA	R (12SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1048 10481086	NERV	Fatigue/ Fatigue	1	06SEP2020	4/7	1	Yes		NA	R (12SEP2020)	N/N
		Dizziness/ dizziness	1	06SEP2020	4/7	1	Yes		NA	R (12SEP2020)	N/N
		Headache/ headaches	1	06SEP2020	4/7	1	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Injection site pain/ muscle pain at injection site	1	04SEP2020	2/2	2	Yes		NA	R (05SEP2020)	N/N
	SKIN	Night sweats/ Profuse night sweating	1	04SEP2020	2/2	2	Yes		NA	R (05SEP2020)	N/N
	GASTR	Nausea/ nausea	1	05SEP2020	3/3	1	Yes		NA	R (07SEP2020)	N/N
	NERV	Headache/ headache	1	05SEP2020	3/6	1	Yes		NA	R (10SEP2020)	N/N
GENRL	Pain/ body aches	2	23SEP2020	2/3	1	Yes		NA/TC	R (25SEP2020)	N/N	
16-55/ C4591001 1048 10481088	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	20SEP2020	17/C		No	O	NA	N	N/N
16-55/ C4591001 1048 10481095	GASTR	Gastroesophageal reflux disease/ Acid reflux	2	03FEB2021	128/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1048 10481101	GENRL	Injection site pain/ Pain at injection site#	3	03FEB2021	2/3	1	Yes		NA	R (05FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1048 10481103	GENRL	Injection site pain/ Left arm pain at injection site#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1048 10481106	GENRL	Fatigue/ FATIGUE	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
		Pyrexia/ FEVER	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1048 10481125	INJ&P	Tooth fracture/ CRACKED TOOTH	2	05OCT2020	5/5	2	No	O	NA	R (09OCT2020)	N/N
16-55/ C4591001 1048 10481132	GENRL	Fatigue/ FATIGUE	1	12SEP2020	2/11	1	Yes		NA/TCN	R (22SEP2020)	N/N
16-55/ C4591001 1052 10521160	NERV	Headache/ intermittent headaches	1	23SEP2020	1/C	1	No	O	NA	N	N/Y
16-55/ C4591001 1052 10521172	INFEC	Infection/ infection#	4	05FEB2021	11/C	2	No	O	NA/TC	R	N/N
	METAB	Lactic acidosis/ lactic acidosis#	4	05FEB2021	11/1	2	No	O	NA/TC	R (05FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Seizure/ Seizure#	4	05FEB2021	11/1	1	No	O	NA/TC	R (05FEB2021)	Y/N
16-55/ C4591001 1054 10541002	GENRL	Chills/ one episode of chills	1	19AUG2020	1/1	1	Yes		NA	R (19AUG2020)	N/N
16-55/ C4591001 1054 10541003	GENRL	Injection site pain/ soreness L arm injection site	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1054 10541005	NERV	Headache/ headache	2	09SEP2020	1/1	1	Yes		NA/TC	R (09SEP2020)	N/N
	MUSC	Arthralgia/ L shoulder pain	2	04OCT2020	26/7	2	No	O	NA/TC	R (10OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
	NERV	Headache/ headache#	3	28JAN2021	2/1	1	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Chills/ chills#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
		Pain/ generalized body ache#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Lethargy/ lethargy#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1054 10541008	GENRL	Injection site pain/ soreness at the injection site, L arm#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1054 10541011	GENRL	Fatigue/ fatigue#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N	
		Injection site pain/ injection site pain L arm#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N	
	GENRL	Fatigue/ fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N	
		Injection site erythema/ redness at L arm injection site	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N	
		Injection site pain/ soreness at L arm injection site	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N	
		Injection site swelling/ swelling at L arm injection site	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N	
		Diarrhoea/ diarrhea - 1 episode	2	17SEP2020	7/1	1	Yes		NA	R (17SEP2020)	N/N	
	16-55/ C4591001 1054 10541014	GASTR	Nausea/ nausea	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
			Chills/ chills	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
	16-55/ C4591001 1054 10541018	GENRL	Injection site pain/ muscle ache at injection site, L arm	2	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
Injection site pain/ pain at injection site L arm			2	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1054 10541028	METAB	Hypercholesterolaemia/ hypercholesterolemia	2	DEC2020	84/C	1	No	O	NA/TC	N	N/N	
	GENRL	Injection site pain/ pain at injection site L arm#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N	
	GENRL	Injection site pain/ L arm soreness site injection#	3	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N	
	GENRL	Chills/ chills#	4	04MAR2021	1/2	1	Yes		NA	R (05MAR2021)	N/N	
		Pyrexia/ fever#	4	04MAR2021	1/C	1	Yes		NA/TC	RG	N/N	
	GENRL	Pain/ generalized body ache#	4	05MAR2021	2/C	1	Yes		NA/TC	RG	N/N	
	16-55/ C4591001 1054 10541032	GENRL	Injection site pain/ pain L arm at injection site	1	23AUG2020	2/3	1	Yes		NA	R (25AUG2020)	N/N
	MUSC	Back pain/ low back pain	1	23AUG2020	2/4	1	Yes		NA/TC	R (26AUG2020)	N/N	
	GENRL	Injection site pain/ pain injection site	2	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N	
	GASTR	Nausea/ nausea	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N	
16-55/ C4591001 1054 10541034	GENRL	Fatigue/ fatigue	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N	
GENRL	Fatigue/ fatigue	1	23AUG2020	2/13	1	Yes		NA	R (04SEP2020)	N/N		



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541035	INFEC	Chronic sinusitis/ worsening of chronic sinusitis	2	24SEP2020	15/C	1	No	O	NA/TC/TCN	N	N/N
16-55/ C4591001 1054 10541037	GENRL	Injection site pain/ L arm soreness at injection site#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ chills#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
		Pyrexia/ fever 101 degrees Fahrenheit#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1054 10541038	GENRL	Fatigue/ fatigue#	3	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
	NERV	Headache/ headache#	3	13FEB2021	2/1	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1054 10541043	GENRL	Injection site pain/ soreness at injection site (LUE)	1	24AUG2020	1/5	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ chills	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		Pyrexia/ fever	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
	NERV	Headache/ headache	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ L arm pain at injection site#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1054 10541044	SKIN	Night sweats/ night sweats#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N	
	GENRL	Injection site pain/ L arm injection site pain#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N	
	GENRL	Chills/ intermittent chills#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N	
		Injection site pain/ L arm injection site pain#	4	23FEB2021	2/4	2	Yes		NA	R (26FEB2021)	N/N	
	MUSC	Arthralgia/ joint pain#	4	23FEB2021	2/2	2	Yes		NA	R (24FEB2021)	N/N	
		Myalgia/ muscle pain#	4	23FEB2021	2/2	2	Yes		NA	R (24FEB2021)	N/N	
	NERV	Headache/ headache#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N	
		Hyperaesthesia/ diffuse skin sensitivity#	4	23FEB2021	2/4	1	Yes		NA	R (26FEB2021)	N/N	
	SKIN	Hyperhidrosis/ intermittent sweats#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N	
16-55/ C4591001 1054 10541050	GENRL	Injection site pain/ pain at injection site, L deltoid	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N	
	MUSC	Myalgia/ muscle ache L upper arm	1	28AUG2020	3/2	1	Yes		NA	R (29AUG2020)	N/N	
	NERV	Headache/ headache	2	30SEP2020	15/1	1	Yes		NA	R (30SEP2020)	N/N	
16-55/ C4591001	NERV	Headache/ headache#	3	01FEB2021	1/1	1	Yes		NA/TC	R (01FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1054 10541051	GENRL	Chills/ chills#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
	NERV	Headache/ headache#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1054 10541054	GENRL	Pyrexia/ subjective fever	1	26AUG2020	1/2	1	Yes		NA/TC	R (27AUG2020)	N/N
	GENRL	Chest pain/ chest pain with deep inspiration	1	29AUG2020	4/2	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Fatigue/ tiredness#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
		Injection site pain/ L arm soreness at injection site#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	NERV	Headache/ mild headache#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1054 10541057	GENRL	Fatigue/ fatigue#	3	04FEB2021	1/1	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ L arm soreness site injection#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
	NERV	Headache/ headache#	3	04FEB2021	1/1	1	Yes		NA/TC	R (04FEB2021)	N/N
16-55/ C4591001 1054 10541058	GENRL	Injection site pain/ soreness L arm injection site	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1054 10541065	GASTR	Vomiting/ vomiting	1	03SEP2020	8/2	1	No	O	NA	R (04SEP2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	26JAN2021	1/3	2	Yes		NA	R (28JAN2021)	N/N	
16-55/ C4591001 1054 10541067	NERV	Headache/ Headache	1	28AUG2020	1/2	2	Yes		NA/TC/TCN	R (29AUG2020)	N/N	
	NERV	Headache/ headache	2	18SEP2020	1/2	2	Yes		NA/TC	R (19SEP2020)	N/N	
	EAR	Hypoacusis/ decreased hearing R ear	2	20SEP2020	3/C	2	No	O	NA/TC	RG	N/N	
		Tinnitus/ Tinnitus R ear	2	20SEP2020	3/C	2	No	O	NA/TC	N	N/N	
		Vertigo/ vertigo	2	20SEP2020	3/3	1	No	O	NA	R (22SEP2020)	N/N	
	EAR	Ear disorder/ fluid R ear	2	22SEP2020	5/145	1	No	O	NA/TC	R (13FEB2021)	N/N	
	MUSC	Temporomandibular joint syndrome/ worsening R TMJ dysfunction#	3	12FEB2021	10/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1054 10541068	GENRL	Pyrexia/ fever	1	17SEP2020	21/1	3	No	O	NA	R (17SEP2020)	N/N	
16-55/ C4591001 1054 10541069	GENRL	Chills/ intermittent chills	1	28AUG2020	1/8	1	Yes		NA	R (04SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541070	GENRL	Pain/ diffuse body aches	1	28AUG2020	1/4	1	Yes		NA	R (31AUG2020)	N/N
		Fatigue/ fatigue	1	29AUG2020	2/2	2	Yes		NA	R (30AUG2020)	N/N
		Hot flush/ hot flashes (worsening)	1	29AUG2020	2/8	1	Yes		NA	R (05SEP2020)	N/N
	INV	Blood testosterone decreased/ low testosterone	2	16OCT2020	8/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ pain L arm injection site	1	28AUG2020	1/4	1	Yes		NA	R (31AUG2020)	N/N
	GENRL	Chills/ chills	1	18SEP2020	22/1	1	Yes		NA/TC	R (18SEP2020)	N/N
	INFECTION	Fungal skin infection/ fungal skin infection L arm	1	11SEP2020	15/62	1	No	O	NA/TC	R (11NOV2020)	N/N
	GENRL	Injection site pain/ L arm site injection pain#	3	04FEB2021	1/4	1	Yes		NA/TC	R (07FEB2021)	N/N
	GENRL	Injection site pain/ L arm pain site injection#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Chills/ chills#	4	24FEB2021	2/2	1	Yes		NA	R (25FEB2021)	N/N
		Fatigue/ fatigue#	4	24FEB2021	2/3	1	Yes		NA	R (26FEB2021)	N/N
		Pyrexia/ subjective fever, 99.8 degrees Fahrenheit#	4	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541074	SKIN	Pruritus/ intermittent itching umbilical area	1	04SEP2020	8/16	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ chills	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1054 10541078	GENRL	Pain/ body ache	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Dizziness/ dizziness - intermittent	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Headache/ headache	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1054 10541080	INJ&P	Road traffic accident/ road accident	2	19OCT2020	29/1	1	No	O	NA	R (19OCT2020)	N/N
	MUSC	Coccydynia/ pain in tail bone	2	19OCT2020	29/C	1	No	O	NA	N	N/N
16-55/ C4591001 1054 10541081	GENRL	Injection site pain/ L arm soreness site injection#	3	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1054 10541084	GENRL	Injection site pain/ L arm soreness at injection site#	3	28JAN2021	1/1	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ soreness R arm injection site#	3	24DEC2020	1/2	1	Yes		NA	R (25DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1054 10541085	GENRL	Injection site pain/ injection site pain L arm#	3	04FEB2021	2/1	1	Yes	NA	NA	R (04FEB2021)	N/N
16-55/ C4591001 1054 10541086	GENRL	Injection site pain/ site injection pain	1	01SEP2020	1/4	1	Yes	NA	NA	R (04SEP2020)	N/N
16-55/ C4591001 1054 10541087	GENRL	Asthenia/ low energy	2	23SEP2020	2/2	2	Yes	NA	NA	R (24SEP2020)	N/N
16-55/ C4591001 1054 10541089	GENRL	Injection site pain/ soreness L arm injection site	2	23SEP2020	2/5	1	Yes	NA	NA	R (27SEP2020)	N/N
		Pain/ diffuse body aches	2	23SEP2020	2/2	2	Yes	NA/TC	NA/TC	R (24SEP2020)	N/N
		Pyrexia/ subjective fever	2	23SEP2020	2/2	1	Yes	NA	NA	R (24SEP2020)	N/N
	NERV	Headache/ headache	2	23SEP2020	2/2	1	Yes	NA	NA	R (24SEP2020)	N/N
16-55/ C4591001 1054 10541090	GENRL	Chills/ chills	1	01SEP2020	1/2	1	Yes	NA	NA	R (02SEP2020)	N/N
	MUSC	Pain in extremity/ soreness R arm	1	01SEP2020	1/2	1	Yes	NA	NA	R (02SEP2020)	N/N
	NERV	Headache/ headache	1	01SEP2020	1/2	1	Yes	NA	NA	R (02SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		Pain/ diffuse soreness	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1054 10541091	GENRL	Injection site pain/ soreness L arm injection site#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Chills/ chills#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1054 10541092	GENRL	Chills/ chills#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1054 10541094	GENRL	Fatigue/ fatigue#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
		Injection site pain/ injection site pain L arm#	3	03FEB2021	1/2	2	Yes		NA	R (04FEB2021)	N/N
	GASTR	Vomiting/ vomiting#	4	24FEB2021	1/1	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Chills/ chills#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
		Injection site pain/ soreness at L arm injection site#	4	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
		Pyrexia/ fever#	4	24FEB2021	1/3	1	Yes		NA/TC	R (26FEB2021)	N/N
16-55/ C4591001	GENRL	Chills/ intermittent chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1054 10541096		Fatigue/ fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ fever	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
	BLOOD	Iron deficiency anaemia/ anemia, iron deficiency	2	08OCT2020	16/C	1	No	CD	NA/TC	N	N/N
16-55/ C4591001 1054 10541097	GENRL	Fatigue/ fatigue	1	14SEP2020	13/34	1	Yes		NA	R (17OCT2020)	N/N
	NERV	Somnolence/ sleepiness	1	14SEP2020	13/34	1	Yes		NA	R (17OCT2020)	N/N
	VASC	Hot flush/ hot flashes	1	14SEP2020	13/23	1	Yes		NA	R (06OCT2020)	N/N
	NERV	Headache/ intermittent headache	1	18SEP2020	17/32	1	Yes		NA/TC	R (19OCT2020)	N/N
	ENDO	Hypothyroidism/ hypothyroidism	2	25SEP2020	3/28	1	No	O	NA	R (22OCT2020)	N/N
	METAB	Dyslipidaemia/ dyslipidemia	2	25SEP2020	3/C	1	No	O	NA	N	N/N
	INFEC	Urinary tract infection/ UTI	2	03OCT2020	11/3	1	No	O	NA/TC/TCN	R (05OCT2020)	N/N
	INFEC	Pyelonephritis/ pyelonephritis	2	05OCT2020	13/13	2	No	O	NA/TC	R (17OCT2020)	N/N
	GASTR	Diverticulum intestinal/ diverticulosis of the colon	2	06OCT2020	14/C	1	No	O	NA	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	RESP	Lung infiltration/ nodular interstitial infiltrate, RLL of lung	2	06OCT2020	14/C	1	No	O	NA	N	N/N	
	REPRO	Nipple pain/ bilateral nipple pain	2	15OCT2020	23/13	1	No	O	NA	R (27OCT2020)	N/N	
	GASTR	Constipation/ constipation#	3	10FEB2021	3/C	1	No	O	NA/TC	RG	N/N	
	GENRL	Injection site pain/ injection site pain L arm#	4	01MAR2021	1/2	1	Yes		NA	R (02MAR2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	03MAR2021	3/2	1	Yes		NA	R (04MAR2021)	N/N	
	NERV	Headache/ headache#	4	03MAR2021	3/2	1	Yes		NA	R (04MAR2021)	N/N	
16-55/ C4591001 1054 10541098	GENRL	Injection site pain/ pain R arm injection site	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N	
16-55/ C4591001 1054 10541100	GENRL	Injection site pain/ L arm injection site soreness#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
	GENRL	Injection site pain/ injection site pain L arm#	4	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N	
		Pyrexia/ fever 101 degrees Fahrenheit#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N	
16-55/ C4591001 1054 10541101	GENRL	Injection site pain/ pain L arm injection site	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N	
	GENRL	Chills/ chills	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541104	GENRL	Pyrexia/ low grade fever	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ fever - subjective	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1054 10541106	GENRL	Injection site pain/ injection site pain L arm#	3	04FEB2021	1/2	2	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1054 10541107	GENRL	Injection site pain/ injection site pain R arm#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ R arm injection site soreness#	4	24FEB2021	1/10	1	Yes		NA	R (05MAR2021)	N/N
	GENRL	Chills/ intermittent chills#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
		Fatigue/ fatigue#	4	25FEB2021	2/2	2	Yes		NA	R (26FEB2021)	N/N
		Injection site erythema/ redness R arm injection site#	4	25FEB2021	2/9	1	Yes		NA	R (05MAR2021)	N/N
		Injection site swelling/ swelling R arm injection site#	4	25FEB2021	2/9	1	Yes		NA	R (05MAR2021)	N/N
	MUSC	Arthralgia/ joint pain#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1054 10541108	GENRL	Injection site pain/ soreness R arm injection site	1	03SEP2020	1/5	1	Yes		NA	R (07SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1054 10541111	GASTR	Diarrhoea/ diarrhea	2	25SEP2020	2/3	2	Yes		NA	R (27SEP2020)	N/N	
		Nausea/ nausea	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
	GENRL	Pain/ diffuse body aches	2	25SEP2020	2/2	2	Yes		NA/TC	R (26SEP2020)	N/N	
	METAB	Decreased appetite/ decreased appetite	2	25SEP2020	2/2	2	Yes		NA	R (26SEP2020)	N/N	
	NERV	Dysgeusia/ metallic taste	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N	
		Migraine/ migraine headache	2	25SEP2020	2/3	2	Yes		NA/TC	R (27SEP2020)	N/N	
16-55/ C4591001 1054 10541113	GENRL	Injection site pain/ site injection pain	1	05SEP2020	3/6	1	Yes		NA	R (10SEP2020)	N/N	
16-55/ C4591001 1054 10541115	GENRL	Injection site pain/ tenderness L arm injection site	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N	
	MUSC	Injection site pruritus/ itching L arm injection site	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N	
Arthralgia/ joint aches		1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N		
GENRL	Injection site bruising/ bruising L arm injection site	1	06SEP2020	3/6	1	Yes		NA	R (11SEP2020)	N/N		
GENRL	Chills/ chills	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N		

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541119	MUSC	Fatigue/ fatigue	2	26SEP2020	2/1	2	Yes		NA	R (26SEP2020)	N/N
		Pain/ generalized body aches	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ subjective fever	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
		Arthralgia/ bilateral hip joint ache	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
		SKIN	Night sweats/ night sweats	2	27SEP2020	3/1	1	Yes		NA	R (27SEP2020)
	NERV	Headache/ headache	2	19OCT2020	25/1	1	No	O	NA/TC	R (19OCT2020)	N/N
	GENRL	Injection site pain/ L arm injection site pain#	3	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1054 10541121	NERV	Headache/ headache#	3	10FEB2021	1/1	1	Yes		NA/TC	R (10FEB2021)	N/N
	GASTR	Diarrhoea/ diarrhea, single episode	1	08SEP2020	5/1	1	No	O	NA	R (08SEP2020)	N/N
	GENRL	Chills/ chills	1	08SEP2020	5/1	1	No	O	NA	R (08SEP2020)	N/N
	GENRL	Injection site pain/ soreness L arm (injection site)#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain L arm#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
NERV	Headache/ headache#	4	17FEB2021	2/1	1	Yes		NA/TC	R (17FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541122	RESP	Nasal congestion/ nasal congestion	1	27SEP2020	20/2	1	No	O	NA/TC	R (28SEP2020)	N/N
	INFEC	Vulvovaginal mycotic infection/ yeast vaginitis	2	13JAN2021	108/21	1	No	O	NA/TC	R (02FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain L arm#	3	05FEB2021	1/3	2	Yes		NA/TC	R (07FEB2021)	N/N
	GENRL	Chills/ chills#	4	26FEB2021	1/2	1	Yes		NA	R (27FEB2021)	N/N
		Injection site pain/ pain L arm injection site#	4	26FEB2021	1/7	1	Yes		NA	R (04MAR2021)	N/N
	MUSC	Musculoskeletal stiffness/ generalized muscle stiffness#	4	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
	NERV	Lethargy/ lethargy#	4	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001 1054 10541135	MUSC	Back pain/ low back soreness	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Back pain/ low back soreness	2	30SEP2020	2/1	2	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1054 10541137	GENRL	Chills/ chills#	3	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1054 10541140	GENRL	Injection site bruising/ bruise L arm injection site	1	11SEP2020	2/21	1	Yes		NA	R (01OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541141	GENRL	Injection site pain/ L arm injection site soreness#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Injection site pain/ soreness injection site L arm#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
	GENRL	Injection site pain/ muscle pain at injection site, L arm	1	10SEP2020	1/4	1	Yes		NA/TC	R (13SEP2020)	N/N
	NERV	Headache/ headache*		10SEP2020	1/4	1	No	O	NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	30SEP2020	1/5	2	Yes		NA/TC	R (04OCT2020)	N/N
	GASTR	Nausea/ nausea	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Chills/ chills	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ fever	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
	MUSC	Back pain/ upper back ache	2	01OCT2020	2/1	2	Yes		NA/TC	R (01OCT2020)	N/N
	16-55/ C4591001 1054 10541144	GASTR	Abdominal pain upper/ epigastric pain	1	12SEP2020	2/5	1	Yes		NA/TC	R (16SEP2020)
16-55/ C4591001	GENRL	Fatigue/ fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	MUSC	Myalgia/ myalgia	1	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Injection site pain/ L arm soreness at injection site#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1054 10541145	GENRL	Injection site pain/ soreness L arm injection site	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1054 10541148	NERV	Headache/ headache	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GASTR	Nausea/ nausea	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Chills/ chills	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		Injection site pain/ soreness at injection site	2	02OCT2020	1/9	1	Yes		NA	R (10OCT2020)	N/N
		Pyrexia/ fever	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N
	NERV	Headache/ headache	2	02OCT2020	1/2	2	Yes		NA/TC	R (03OCT2020)	N/N
	SKIN	Rash/ rash upper abdomen	2	02OCT2020	1/5	1	Yes		NA	R (06OCT2020)	N/N
	GASTR	Nausea/ intermittent nausea	2	07OCT2020	6/4	1	Yes		NA	R (10OCT2020)	N/N
		Retching/ dry heaves	2	07OCT2020	6/1	1	Yes		NA	R (07OCT2020)	N/N
	MUSC	Musculoskeletal stiffness/ neck stiffness	2	07OCT2020	6/1	1	Yes		NA	R (07OCT2020)	N/N
			2	07OCT2020	6/10	2	Yes		NA	R (16OCT2020)	N/N
	NERV	Headache/ headache	2	07OCT2020	6/3	1	Yes		NA	R (09OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541152	GENRL	Feeling abnormal/ brain fog	2	11OCT2020	10/1	1	No	O	NA	R (11OCT2020)	N/N
	GENRL	Feeling abnormal/ brain fog	2	13OCT2020	12/1	1	No	O	NA	R (13OCT2020)	N/N
	GENRL	Pyrexia/ fever	1	19SEP2020	6/1	1	Yes		NA	R (19SEP2020)	N/N
	NERV	Motor dysfunction/ L C7 motor dysfunction	2	OCT2020	1/C	1	No	O	NA/TCN	N	N/N
		Radiculopathy/ worsening of radiculopathy, both upper extremities	2	OCT2020	1/C	2	No	O	NA/TC/TCN	N	N/N
	EYE	Eye irritation/ burning sensation in eyes	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
	GENRL	Chills/ chills	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N
		Pyrexia/ fever	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		Pyrexia/ subjective fever	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
	MUSC	Myalgia/ diffuse muscle aches	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
NERV	Headache/ headache	2	06OCT2020	2/2	2	Yes		NA/TC	R (07OCT2020)	N/N	
16-55/ C4591001 1054 10541153	GENRL	Injection site pain/ L arm soreness at injection site#	3	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541155	GENRL	Injection site pain/ L arm injection site pain#	4	17FEB2021	1/5	1	Yes		NA	R (21FEB2021)	N/N
	GENRL	Injection site pain/ soreness L arm injection site#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1054 10541157	GENRL	Fatigue/ fatigue#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Injection site pain/ site injection pain, L arm	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1054 10541158	GENRL	Injection site pain/ soreness L arm injection site#	3	26JAN2021	1/5	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Pyrexia/ fever#	3	28JAN2021	3/1	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1054 10541160	GENRL	Injection site pain/ soreness at R arm injection site	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	GASTR	Nausea/ nausea	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Chills/ chills	2	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N
		Fatigue/ fatigue	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
		Injection site pain/ muscle ache at R arm injection site	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1054 10541170	INJ&P	Contusion/ contusion - multiple areas#	3	26FEB2021	11/5	2	No	O	NA	R (02MAR2021)	N/N	
		Skin abrasion/ abrasion - multiple areas#	3	26FEB2021	11/C	2	No	O	NA/TC	RG	N/N	
	MUSC	Pain in extremity/ sore L arm#	4	09MAR2021	1/5	1	Yes		NA	R (13MAR2021)	N/N	
16-55/ C4591001 1054 10541171	MUSC	Pain in extremity/ L arm soreness#	3	02FEB2021	1/6	1	Yes		NA	R (07FEB2021)	N/N	
	GENRL	Injection site pain/ R arm injection site pain#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N	
	NERV	Headache/ headache#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N	
16-55/ C4591001 1054 10541174	GENRL	Injection site pain/ soreness R arm injection site	1	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N	
	NERV	Headache/ headache	1	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N	
		Somnolence/ drowsiness	1	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N	
	GENRL	Injection site pain/ soreness R arm injection site	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N	
			2	08OCT2020	1/6	2	Yes		NA	R (13OCT2020)	N/N	
	GENRL	Fatigue/ fatigue	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541178	GENRL	Pain/ generalized body aches	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		Pyrexia/ intermittent low grade feverw	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		Injection site pain/ L arm site injection pain#	3	29JAN2021	1/2	1	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1054 10541182	BLOOD	Anaemia/ anemia	1	06OCT2020	14/C	1	No	O	NA	N	N/N
16-55/ C4591001 1054 10541184	GASTR	Dry mouth/ dry mouth	2	19OCT2020	5/6	1	Yes		NA/TCN	R (24OCT2020)	N/N
	GENRL	Thirst/ increased thirst	2	19OCT2020	5/6	1	Yes		NA/TCN	R (24OCT2020)	N/N
	GENRL	Injection site pain/ soreness R arm site injection#	3	26FEB2021	1/3	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001 1054 10541184	RESP	Epistaxis/ epistaxis R nostril	1	14OCT2020	22/1	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C4591001 1054 10541190	GENRL	Injection site pain/ L arm injection site pain	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1054 10541191	GENRL	Injection site pain/ pain at injection site, L arm	1	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541197	GENRL	Fatigue/ tiredness	1	19OCT2020	1/26	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Injection site pain/ soreness L arm injection site	1	20OCT2020	2/23	1	Yes		NA	R (11NOV2020)	N/N
	GENRL	Injection site pain/ soreness L arm injection site#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1054 10541200	GENRL	Chills/ intermittent chills	1	22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N
		Pain/ diffuse body aches	1	22OCT2020	1/6	1	Yes		NA/TC	R (27OCT2020)	N/N
	NERV	Headache/ headache	1	22OCT2020	1/6	1	Yes		NA/TC	R (27OCT2020)	N/N
	GENRL	Injection site swelling/ injection site swelling L arm	1	31OCT2020	10/2	1	Yes		NA/TC	R (01NOV2020)	N/N
16-55/ C4591001 1054 10541201	GENRL	Fatigue/ tiredness	1	22OCT2020	1/20	1	Yes		NA	R (10NOV2020)	N/N
		Pain/ body aches	1	22OCT2020	1/20	1	Yes		NA	R (10NOV2020)	N/N
	NERV	Headache/ intermittent headache	1	22OCT2020	1/20	1	Yes		NA/TC	R (10NOV2020)	N/N
	NERV	Cervical radiculopathy/ L upper extremity pain - cervicular radiculopathy	2	16DEC2020	27/9	2	No	O	NA/TC	R (24DEC2020)	N/N
	GENRL	Injection site pain/ pain at injection site, R arm#	4	26FEB2021	1/3	1	Yes		NA	R (28FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541203	EYE	Lacrimation increased/ watery eyes#	4	27FEB2021	2/2	1	No	O	NA	R (28FEB2021)	N/N
	GENRL	Chills/ chills#	4	27FEB2021	2/11	1	Yes		NA	R (09MAR2021)	N/N
		Pain/ body aches#	4	27FEB2021	2/12	1	Yes		NA/TC	R (10MAR2021)	N/N
	NERV	Headache/ headache#	4	27FEB2021	2/11	1	Yes		NA	R (09MAR2021)	N/N
	GENRL	Injection site pain/ injection site pain	1	24OCT2020	2/5	1	Yes		NA	R (28OCT2020)	N/N
		Pyrexia/ fever (subjective)	1	24OCT2020	2/1	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site erythema/ injection site erythema	1	25OCT2020	3/4	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1054 10541206		Injection site pruritus/ injection site pruritus	1	25OCT2020	3/4	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain L deltoid	2	13NOV2020	1/1	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Chills/ chills	1	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
		Injection site pain/ L arm - site injection pain	1	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Fatigue/ tiredness	2	16NOV2020	1/2	1	Yes		NA	R (17NOV2020)	N/N
	Feeling cold/ cold feeling	2	16NOV2020	1/1	1	Yes		NA	R (16NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541208	GENRL	Injection site pain/ pain L arm injection site	2	16NOV2020	1/4	1	Yes		NA	R (19NOV2020)	N/N
		Injection site pain/ soreness L arm injection site#	3	05FEB2021	2/2	2	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1054 10541215	GENRL	Injection site pain/ L arm soreness at the injection site#	2	28JAN2021	73/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1055 10551001	GENRL	Fatigue/ fatigue#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Injection site pain/ injection site soreness#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/Y
16-55/ C4591001 1055 10551007	GENRL	Injection site pain/ injection site pain#	4	10FEB2021	1/2	2	Yes		NA/TC	R (11FEB2021)	N/N
	NERV	Headache/ headache#	4	11FEB2021	2/3	2	Yes		NA/TC	R (13FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	12FEB2021	3/3	1	Yes		NA	R (14FEB2021)	N/N
	GENRL	Injection site pruritus/ Itching at injection site	2	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/Y
	GENRL	Injection site pain/ injection site pain#	3	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551012	EAR	Injection site pruritus/ Injection site itching#	4	29JAN2021	1/1	1	Yes		NA	R (29JAN2021)	N/Y
		Vertigo/ Vertigo#	4	30JAN2021	2/3	1	Yes		NA	R (01FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Left supraclavicular adenopathy	2	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C4591001 1055 10551013	INFEC	Herpes zoster/ Shingles#	2	08FEB2021	161/30	2	No	O	NA/TC	R (09MAR2021)	N/N
	GENRL	Injection site pain/ injection site soreness#	3	27JAN2021	1/5	1	Yes		NA	R (31JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	18FEB2021	1/1	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	18FEB2021	1/3	2	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	1/1	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1055 10551026	GENRL	Injection site pain/ Injection Site Pain#	3	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	13JAN2021	1/4	2	Yes		NA/TC	R (16JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1055 10551028	GENRL	Injection site pain/ Injection Site Pain#	4	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1055 10551032	GENRL	Injection site pain/ injection site pain#	3	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N
16-55/ C4591001 1055 10551034	RESP	Oropharyngeal pain/ Sore throat	2	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pruritus/ Itching at injection site	2	03SEP2020	3/5	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1055 10551037	GENRL	Chills/ Chills#	3	13JAN2021	2/1	2	Yes		NA	R (13JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	14JAN2021	3/1	2	Yes		NA	R (14JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	3	14JAN2021	3/1	2	Yes		NA/TC	R (14JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551040	GENRL	Injection site pain/ Injection Site Pain#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1055 10551045	GENRL	Injection site pain/ Injection Site Pain#	3	09FEB2021	1/1	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1055 10551046	GENRL	Injection site pain/ Injection Site Pain#	3	13JAN2021	2/2	2	Yes		NA/TC	R (14JAN2021)	N/N
16-55/ C4591001 1055 10551051	GENRL	Injection site pain/ Injection Site Pain#	4	02FEB2021	1/2	2	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
		Pyrexia/ Fever#	4	03FEB2021	2/1	1	Yes		NA/TC	R (03FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	03FEB2021	2/1	2	Yes		NA/TC	R (03FEB2021)	N/N
	GENRL	Chills/ Chills	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N
		Injection site pain/ Injection site pain, left	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N
	GENRL	Chills/ Chills	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551054	MUSC	Injection site pain/ Injection Site Pain	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
		Myalgia/ Myalgia	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N
	NERV	Headache/ Headache	1	17AUG2020	1/2	1	Yes		NA/TC	R (18AUG2020)	N/N
	GENRL	Fatigue/ fatigue#	3	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	3	09JAN2021	2/3	1	Yes		NA/TC	R (11JAN2021)	N/N
	GENRL	Chills/ Chills#	4	29JAN2021	1/1	1	Yes		NA	R (29JAN2021)	N/N
		Fatigue/ Fatigue#	4	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
	NERV	Headache/ Headache#	4	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N
	16-55/ C4591001 1055 10551056	GENRL	Injection site pain/ injection site pain#	3	18JAN2021	1/4	1	Yes		NA	R (21JAN2021)
GENRL	Chills/ Chills#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	
	Fatigue/ Fatigue#	4	08FEB2021	1/3	2	Yes		NA	R (10FEB2021)	N/N	
	Injection site pain/ Injection Site Pain#	4	08FEB2021	1/3	2	Yes		NA/TC	R (10FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551057	GENRL	Injection site pain/ Injection Site Pain	1	17AUG2020	1/7	2	Yes		NA	R (23AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N
	GENRL	Chills/ Chills	2	08SEP2020	1/2	2	Yes		NA	R (09SEP2020)	N/N
		Fatigue/ Fatigue	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	08SEP2020	1/7	1	Yes		NA/TC	R (14SEP2020)	N/N
	SKIN	Dermatitis contact/ Poison Oak Rash#	2	20FEB2021	166/15	1	No	O	NA/TC	R (06MAR2021)	N/N
16-55/ C4591001 1055 10551058	GENRL	Injection site pain/ Injection Site Pain	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Injection site pain/ Injection site pain	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1055 10551061	INJ&P	Back injury/ Back pain (post-traumatic)	2	03DEC2020	87/C	2	No	O	NA/TC	N	N/N
		Road traffic accident/ Car/pedestrian accident	2	03DEC2020	87/1	2	No	O	NA/TC	R (03DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1055 10551063	GENRL	Fatigue/ Fatigue#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N	
		Malaise/ Malaise#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N	
	MUSC	Myalgia/ Myalgias#	4	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain	1	18AUG2020	1/3	1	Yes		NA	R (20AUG2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	08SEP2020	1/3	1	Yes		NA/TC	R (10SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/N	
	16-55/ C4591001 1055 10551071	INFEC	Urinary tract infection/ Urinary tract infection	1	07SEP2020	20/6	2	No	O	NA/TC	R (12SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N	
		Injection site pain/ Injection Site Pain	2	14SEP2020	1/2	2	Yes		NA/TC	R (15SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1055 10551072	MUSC	Myalgia/ Myalgias	2	14SEP2020	1/4	1	Yes		NA/TC	R (17SEP2020)	N/N	
	MUSC	Arthralgia/ Joint Pains	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N	
	NERV	Headache/ Headache	2	15SEP2020	2/4	1	Yes		NA/TC	R (18SEP2020)	N/N	
	NERV	Headache/ Headache	1	20AUG2020	2/3	1	Yes		NA/TC	R (22AUG2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	17FEB2021	1/1	1	Yes		NA	R (17FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	3	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N	
	GENRL	Injection site pain/ Injection Site Pain#	3	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/5	1	Yes		NA	R (23AUG2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	2	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N	
GENRL	Chills/ Chills	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N		

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551076	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/4	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Chills/ Chills	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1055 10551077	GENRL	Injection site bruising/ bruising at injection site#	3	02FEB2021	2/4	1	Yes		NA	R (05FEB2021)	N/N
		Injection site pain/ injection site pain#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	23FEB2021	1/5	1	Yes		NA	R (27FEB2021)	N/N
	NERV	Headache/ Headache#	4	24FEB2021	2/1	1	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1055 10551078	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	2/3	1	Yes		NA	R (22AUG2020)	N/N
16-55/ C4591001 1055 10551080	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Pyrexia/ Fever	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
	RESP	Productive cough/ Productive cough	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551082	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ Fever	2	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N
	RESP	Productive cough/ Productive cough	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ fatigue#	3	22JAN2021	1/3	2	Yes		NA	R (24JAN2021)	N/N
		Injection site pain/ injection site pain#	3	22JAN2021	1/4	1	Yes		NA	R (25JAN2021)	N/N
	NERV	Headache/ headache#	3	22JAN2021	1/3	1	Yes		NA/TC	R (24JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	12FEB2021	1/5	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1055 10551084	GENRL	Fatigue/ Fatigue#	4	13FEB2021	2/3	1	Yes		NA	R (15FEB2021)	N/N
	NERV	Headache/ Headache#	4	13FEB2021	2/4	2	Yes		NA/TC	R (16FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
		Feeling hot/ Warm feeling of neck and head	1	20AUG2020	1/2	1	Yes		NA/TC	R (21AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Pyrexia/ Low grade fever	2	08SEP2020	1/2	1	Yes		NA/TC	R (09SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INJ&P	Exposure during pregnancy/ Exposure during Partner pregnancy#	2	04FEB2021	150/C		No	O	NA	UNK	N/N
16-55/ C4591001 1055 10551085	GENRL	Fatigue/ fatigue#	3	17DEC2020	1/4	1	Yes		NA	R (20DEC2020)	N/N
		Injection site pain/ injection site pain#	3	17DEC2020	1/4	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
		Injection site pain/ injection site pain#	4	07JAN2021	1/4	1	Yes		NA	R (10JAN2021)	N/N
		Pyrexia/ fever#	4	07JAN2021	1/1	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1055 10551086	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
	INFEC	Bacterial blepharitis/ Bacterial blepharitis	2	20SEP2020	12/51	1	No	O	NA/TC	R (09NOV2020)	N/N
16-55/ C4591001 1055 10551087	GENRL	Injection site pain/ Pain at injection site#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1055 10551089	GENRL	Injection site pain/ injection site pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
	GENRL	Injection site pain/ Pain at injection site, left	1	21AUG2020	1/5	1	Yes		NA	R (25AUG2020)	N/N	
	GENRL	Injection site erythema/ Erythema at injection site	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N	
	GENRL	Injection site erythema/ Erythema at injection site	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N	
			Injection site pain/ Pain at injection site	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Chills/ Chills	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N	
			Fatigue/ Fatigue	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N	
	16-55/ C4591001 1055 10551092	GENRL	Injection site pain/ Injection Site Pain	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N	
	INJ&P	Exposure during pregnancy/ Exposure during partner pregnancy	2	03FEB2021	142/C		No	O	NA	UNK	N/N	
16-55/ C4591001	GENRL	Chills/ chills#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1055 10551099		Pain/ body aches#	3	28JAN2021	2/2	1	Yes		NA/TC	R (29JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N	
		Fatigue/ Fatigue#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N	
		Injection site pain/ Injection site pain#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N	
16-55/ C4591001 1055 10551103	GENRL	Pyrexia/ Fever	1	25AUG2020	1/3	2	Yes		NA/TC	R (27AUG2020)	N/N	
	NERV	Headache/ Headache	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N	
	GENRL	Chills/ Chills	2	15SEP2020	1/3	1	Yes		NA/TC	R (17SEP2020)	N/N	
		Injection site pain/ Injection Site Pain	2	15SEP2020	1/8	2	Yes		NA/TC	R (22SEP2020)	N/N	
		Pyrexia/ Fever	2	15SEP2020	1/3	1	Yes		NA/TC	R (17SEP2020)	N/N	
	NERV	Headache/ Headache	2	15SEP2020	1/4	1	Yes		NA/TC	R (18SEP2020)	N/N	
16-55/ C4591001 1055 10551104	GENRL	Fatigue/ Fatigue	1	25AUG2020	1/4	2	Yes		NA	R (28AUG2020)	N/N	
	SKIN	Hyperhidrosis/ Diaphoresis	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551105	GENRL	Fatigue/ Fatigue	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Dizziness/ Dizzy	2	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	18SEP2020	3/3	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1055 10551115		Pyrexia/ Fever	2	15SEP2020	1/3	1	Yes		NA/TC	R (17SEP2020)	N/N
	NERV	Disturbance in attention/ Difficulty concentrating	2	16SEP2020	2/11	2	Yes		NA	R (26SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
		Injection site pain/ Pain at injection site	1	26AUG2020	1/6	2	Yes		NA/TC	R (31AUG2020)	N/N
GENRL	NERV	Dizziness/ Dizzy	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/Y
		Headache/ Headache	1	26AUG2020	1/2	1	Yes		NA/TC	R (27AUG2020)	N/Y
		Fatigue/ Fatigue	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ Injection site pain	2	16SEP2020	1/5	2	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	1/1	1	Yes		NA/TC	R (16SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1055 10551116	GENRL	Chills/ Chills	2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N	
		Injection site erythema/ Injection site redness	2	17SEP2020	2/4	1	Yes		NA	R (20SEP2020)	N/N	
		Injection site pruritus/ Injection site itching	2	17SEP2020	2/4	1	Yes		NA	R (20SEP2020)	N/N	
		Chills/ Chills	1	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/N	
		SKIN	Hyperhidrosis/ Diaphoresis	1	27AUG2020	2/1	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Chills/ Chills	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
			Pyrexia/ Fever	2	14SEP2020	1/2	3	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1055 10551117	MUSC	Myalgia/ Myalgias	2	14SEP2020	1/2	2	Yes		NA/TC	R (15SEP2020)	N/N	
	NERV	Headache/ Headache	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	02FEB2021	2/3	1	Yes		NA/TC	R (04FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N	
	GENRL	Injection site pain/ Injection Site Pain#	4	23FEB2021	2/2	2	Yes		NA/TC	R (24FEB2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ injection site soreness#	3	02FEB2021	2/3	1	Yes		NA	R (04FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1055 10551118	GENRL	Injection site pain/ Injection Site Pain#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N	
16-55/ C4591001 1055 10551121	GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/4	1	Yes		NA	R (20DEC2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N	
	GASTR	Nausea/ nausea#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	07JAN2021	2/4	2	Yes		NA	R (10JAN2021)	N/N	
		Pyrexia/ fever#	4	07JAN2021	2/2	1	Yes		NA/TC	R (08JAN2021)	N/N	
	NERV	Dizziness/ dizziness#	4	07JAN2021	2/1	2	Yes		NA	R (07JAN2021)	N/N	
		Headache/ headache#	4	07JAN2021	2/1	2	Yes		NA/TC	R (07JAN2021)	N/N	
16-55/ C4591001 1055 10551125	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551128	SKIN	Rash/ Rash on left thigh, left calf, left forearm, right foot	1	30AUG2020	4/22	2	Yes		NA/TC	R (20SEP2020)	N/N
	GENRL	Chills/ Chills	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
	SKIN	Pruritus/ Itching on left anterior thigh	2	28SEP2020	1/1	1	Yes		NA	R (28SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	18JAN2021	1/4	1	Yes		NA	R (21JAN2021)	N/Y
	BLOOD	Lymphadenopathy/ Left Axillary Lymphadenopathy#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	09FEB2021	2/1	3	Yes		NA/TC	R (09FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	09FEB2021	2/1	2	Yes		NA	R (09FEB2021)	N/N
	NERV	Headache/ Headache#	4	09FEB2021	2/1	2	Yes		NA	R (09FEB2021)	N/N
	GENRL	Pyrexia/ Fever	2	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001 1055 10551131	GENRL	Chills/ chills#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551134	GENRL	Injection site pain/ injection site pain#	4	11JAN2021	1/5	1	Yes		NA	R (15JAN2021)	N/N
		Injection site pain/ Injection Site Pain	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
		Chills/ Chills	2	16SEP2020	2/1	2	Yes		NA	R (16SEP2020)	N/N
	MUSC	Injection site pain/ Injection Site Pain	2	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ Fever	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N
		Myalgia/ Muscle Aches	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
		Headache/ Headache	2	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1055 10551135	GASTR	Nausea/ Nausea#	3	18DEC2020	1/1	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	19DEC2020	2/1	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	4	06JAN2021	1/8	2	Yes		NA/TC	R (13JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	07JAN2021	2/4	2	Yes		NA	R (10JAN2021)	N/N
	NERV	Cognitive disorder/ cognitive impairment#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	28AUG2020	1/4	1	Yes		NA	R (31AUG2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1055 10551136	GASTR	Oral pain/ Oral Pain	1	14SEP2020	18/9	1	No	O	NA/TC	R (22SEP2020)	N/N
	INFEC	Tooth abscess/ Dental Abscess	1	14SEP2020	18/1	1	No	O	NA/TC	R (14SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	16SEP2020	1/4	1	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	1/1	1	Yes		NA/TC	R (16SEP2020)	N/N
	INFEC	Tooth abscess/ Dental abscess	2	01OCT2020	16/14	2	No	O	NA/TC	R (14OCT2020)	N/N
	MUSC	Periarthritis/ frozen left shoulder	2	NOV2020	47/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1055 10551138	GENRL	Injection site pain/ injection site soreness#	3	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Chills/ Chills#	4	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
		Pyrexia/ Fever#	4	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1055 10551139	GENRL	Injection site pain/ injection site soreness#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551143	GENRL	Chills/ chills#	3	21JAN2021	2/2	1	Yes		NA/TC	R (22JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Chills/ Chills#	4	10FEB2021	1/2	1	Yes		NA/TC	R (11FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Right Axillary Adenopathy#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	1/3	2	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	18SEP2020	1/4	2	Yes		NA/TC	R (21SEP2020)	N/N
	NERV	Headache/ Headache	2	18SEP2020	1/1	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Chills/ Chills	1	29AUG2020	2/3	1	Yes		NA	R (31AUG2020)	N/N
	16-55/ C4591001 1055 10551144		Fatigue/ Fatigue	1	29AUG2020	2/3	1	Yes		NA	R (31AUG2020)
		Injection site pain/ Injection Site Pain	1	29AUG2020	2/3	1	Yes		NA	R (31AUG2020)	N/N
MUSC		Myalgia/ Generalized Muscle Pain	1	29AUG2020	2/3	1	Yes		NA	R (31AUG2020)	N/N
GENRL		Chills/ Chills	2	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1055 10551145	MUSC	Fatigue/ Fatigue	2	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N	
		Myalgia/ Myalgias	2	18SEP2020	1/3	2	Yes		NA/TC	R (20SEP2020)	N/N	
		Headache/ Headaches	2	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N	
	GASTR	Dysphagia/ Dysphagia	1	AUG2020	1/C	1	No	O	P	N	N/N	
	NERV	Cerebral capillary telangiectasia/ Cerebral Capillary telangiectasia	1	26SEP2020	30/C	1	No	O	NA	N	N/N	
	MUSC	Pain in extremity/ Bilateral upper extremity pain	1	10OCT2020	44/C	1	No	O	NA/TC	N	N/N	
	GENRL	Chronic fatigue syndrome/ Chronic Fatigue Syndrome	1	05JAN2021	131/C	2	No	O	NA	N	N/N	
16-55/ C4591001 1055 10551146	MUSC	Fibromyalgia/ Fibromyalgia	1	05JAN2021	131/C	2	No	O	NA/TC	N	N/N	
	GASTR	Diarrhoea/ Diarrhea	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N	
		Injection site pain/ Injection Site Pain	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N	
	MUSC	Myalgia/ Myalgias	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551151	MUSC	Myalgia/ Myalgias	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/5	2	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1055 10551157	NEOPL	Lipoma/ Lipoma	1	14SEP2020	15/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1055 10551161	GENRL	Injection site pain/ Injection site pain#	3	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	2/3	2	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1055 10551162	GASTR	Nausea/ Nausea	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/4	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1055 10551162	MUSC	Myalgia/ Myalgias	2	22SEP2020	1/2	2	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	28SEP2020	5/2	2	Yes		NA	R (29SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551165	GENRL	Injection site pain/ injection site soreness#	3	18JAN2021	1/2	2	Yes		NA	R (19JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	09FEB2021	2/1	1	Yes		NA/TC	R (09FEB2021)	N/N
	GENRL	Pyrexia/ Fever	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	03SEP2020	2/1	2	Yes		NA	R (03SEP2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	1	03SEP2020	2/1	2	Yes		NA	R (03SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1055 10551168	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	1/3	1	Yes		NA/TC	R (04SEP2020)	N/N
	GENRL	Chills/ Chills	1	03SEP2020	2/2	1	Yes		NA/TC	R (04SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	1	03SEP2020	2/2	1	Yes		NA/TC	R (04SEP2020)	N/N
	GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1055 10551169	MUSC	Myalgia/ Myalgias	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N	
		Injection site pain/ Injection Site Pain#	4	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N	
	NERV	Dizziness/ Dizziness#	4	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N	
	NERV	Headache/ Headache#	4	18FEB2021	3/1	1	Yes		NA/TC	R (18FEB2021)	N/N	
	16-55/ C4591001 1055 10551171	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/4	2	Yes		NA/TC	R (05SEP2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N	
	GASTR	Nausea/ Nausea	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N	
GENRL	Chills/ Chills	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N		
	Pyrexia/ Fever	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N		
NERV	Headache/ Headache	2	25SEP2020	2/1	1	Yes		NA/TC	R (25SEP2020)	N/N		

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551173	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	1/1	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	NERV	Dizziness/ Lightheaded	1	04SEP2020	2/2	2	Yes		NA	R (05SEP2020)	N/N
		Headache/ Headache	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	NERV	Headache/ headache#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Chills/ chills#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ injection site pain#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
	NERV	Dizziness/ Dizziness#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
		Headache/ headache#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1055 10551174	GENRL	Fatigue/ Fatigue#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	13FEB2021	2/2	1	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	2/3	2	Yes		NA	R (06SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1055 10551175	GENRL	Pyrexia/ Fever	1	04SEP2020	2/2	1	Yes		NA/TC	R (05SEP2020)	N/N
		Fatigue/ Fatigue	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ Injection site pain	2	23SEP2020	1/2	2	Yes		NA/TC	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1055 10551176	CARD	Arteriospasm coronary/ Coronary vasospasm	2	25SEP2020	3/2	3	No	O	NA	R (26SEP2020)	Y/N
16-55/ C4591001 1055 10551177	GENRL	Injection site pain/ Injection Site Tenderness	1	03SEP2020	1/5	2	Yes		NA/TC	R (07SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	24SEP2020	1/8	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1055 10551179	MUSC	Myalgia/ Generalized Muscle Aches	1	04SEP2020	2/2	1	Yes		NA/TC	R (05SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1055 10551181	EAR	Vertigo/ Vertigo	2	23FEB2021	155/C	1	No	O	NA/TC	N	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551184	NERV	Headache/ Headache	2	24SEP2020	1/1	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1055 10551186	GENRL	Fatigue/ Fatigue	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	12FEB2021	2/3	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1055 10551190	GENRL	Injection site pain/ Injection Site Pain	1	04SEP2020	1/3	2	Yes		NA/TC	R (06SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1055 10551193	GENRL	Fatigue/ Fatigue#	3	25FEB2021	1/2	1	Yes		NA/TC	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	3	25FEB2021	1/2	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1055 10551195	NERV	Dizziness/ Lightheaded	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/Y	
	GENRL	Fatigue/ fatigue#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N	
		Injection site pain/ injection site pain#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	18FEB2021	2/1	2	Yes		NA	R (18FEB2021)	N/N	
		Fatigue/ Fatigue#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N	
16-55/ C4591001 1055 10551198	GENRL	Injection site pain/ Pain at injection site	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N	
16-55/ C4591001 1055 10551200	GENRL	Chest discomfort/ Chest tightness	1	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N	
		Fatigue/ Fatigue	1	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N	
	MUSC	Myalgia/ Myalgias	1	09SEP2020	2/3	1	Yes		NA/TC	R (11SEP2020)	N/N	
	GENRL	Chills/ Chills	2	30SEP2020	2/3	1	Yes		NA/TC	R (02OCT2020)	N/N	
	MUSC	Myalgia/ Myalgias	2	30SEP2020	2/3	1	Yes		NA/TC	R (02OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551202	GENRL	Chest discomfort/ Chest tightness	2	01OCT2020	3/2	1	Yes		NA	R (02OCT2020)	N/N
	EAR	Vertigo/ Vertigo	2	23OCT2020	25/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ injection site pain#	3	30DEC2020	1/3	1	Yes		NA	R (01JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/2	2	Yes		NA	R (18DEC2020)	N/N
	MUSC	Myalgia/ Myalgias#	3	18DEC2020	2/2	2	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	09SEP2020	1/6	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Chills/ Chills	1	13SEP2020	5/1	2	Yes		NA	R (13SEP2020)	N/N
	GENRL	Pyrexia/ Fever	1	13SEP2020	5/1	2	Yes		NA/TC	R (13SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	1	13SEP2020	5/1	2	Yes		NA	R (13SEP2020)	N/N
MUSC	Costochondritis/ costochondritis	2	02OCT2020	3/4	2	Yes		NA/TC	R (05OCT2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ injection site soreness#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1055 10551206	SKIN	Rash maculo-papular/ Maculopapular rash	1	20SEP2020	12/48	1	No	CD	NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1055 10551207	GENRL	Pyrexia/ Fever	2	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	2	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
16-55/ C4591001 1055 10551208	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
	MUSC	Arthralgia/ Arthralgias	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1055 10551211	GENRL	Fatigue/ fatigue#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Pyrexia/ fever#	4	07JAN2021	1/3	1	Yes		NA/TC	R (09JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001	NERV	Headache/ Headache	1	11SEP2020	2/4	2	Yes		NA/TC	R (14SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1055 10551215	GENRL	Chills/ chills#	3	31DEC2020	2/1	1	Yes		NA	R (31DEC2020)	N/N	
		Injection site pain/ injection site pain#	3	31DEC2020	2/3	1	Yes		NA	R (02JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	3	01JAN2021	3/3	1	Yes		NA	R (03JAN2021)	N/N	
	NERV	Headache/ headache#	3	01JAN2021	3/3	1	Yes		NA/TC	R (03JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N	
		Pyrexia/ fever#	4	20JAN2021	2/1	1	Yes		NA/TC	R (20JAN2021)	N/N	
	NERV	Headache/ headache#	4	20JAN2021	2/1	1	Yes		NA/TC	R (20JAN2021)	N/N	
16-55/ C4591001 1055 10551219	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	
	MUSC	Myalgia/ Myalgias	2	01OCT2020	1/3	2	Yes		NA/TC	R (03OCT2020)	N/N	
	GENRL	Chills/ Chills	2	02OCT2020	2/1	2	Yes		NA	R (02OCT2020)	N/N	
		Fatigue/ Fatigue	2	02OCT2020	2/4	2	Yes		NA	R (05OCT2020)	N/N	
		Pyrexia/ Fever	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551220	MUSC	Arthralgia/ Generalized Joint aches	2	02OCT2020	2/2	2	Yes		NA/TC	R (03OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	3	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N
		Injection site bruising/ bruising at injection site#	3	16JAN2021	2/C	1	Yes		NA	N	N/N
		Injection site pain/ injection site soreness#	3	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N
16-55/ C4591001 1055 10551221	GENRL	Fatigue/ Fatigue#	4	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1055 10551221	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1055 10551222	NERV	Headache/ Headache	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ injection site soreness#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	22FEB2021	1/2	2	Yes		NA	R (23FEB2021)	N/N
		Fatigue/ Fatigue#	4	22FEB2021	1/2	2	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1055 10551223	MUSC	Muscle fatigue/ Muscle fatigue	1	12SEP2020	2/11	1	Yes		NA	R (22SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551224	GASTR	Gastrointestinal disorder/ Gastrointestinal frequency	1	13SEP2020	3/11	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1055 10551225		Injection site pain/ Injection Site Pain#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	NERV	Hyperaesthesia/ Hyperaesthesia	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1055 10551226	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	02OCT2020	1/2	2	Yes		NA	R (03OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	02OCT2020	1/2	2	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	02OCT2020	1/2	2	Yes		NA	R (03OCT2020)	N/N
	INJ&P	Facial bones fracture/ Fractured nose	2	26OCT2020	25/C	2	No	O	NA/TC	N	N/N
	GENRL	Pyrexia/ fever#	3	31DEC2020	2/2	1	Yes		NA/TC	R (01JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551228	NERV	Headache/ headache#	3	31DEC2020	2/2	1	Yes		NA/TC	R (01JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
		Injection site pain/ injection site pain#	4	20JAN2021	1/4	1	Yes		NA	R (23JAN2021)	N/N
		Pyrexia/ fever#	4	20JAN2021	1/3	1	Yes		NA/TC	R (22JAN2021)	N/N
	INFEC	Infected cyst/ infected right leg cyst#	4	02FEB2021	14/16	2	No	O	NA/TC	R (17FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain#	3	24DEC2020	4/3	1	Yes		NA	R (26DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	4	11JAN2021	1/6	1	Yes		NA	R (16JAN2021)	N/N
	MUSC	Arthralgia/ generalized joint pain#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	14SEP2020	1/5	2	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Malaise/ Malaise	1	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1055 10551229	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	2/3	2	Yes		NA/TC	R (08OCT2020)	N/N
		Malaise/ Malaise	2	06OCT2020	2/3	2	Yes		NA	R (08OCT2020)	N/N
	MUSC	Arthralgia/ Generalized joint pain	2	06OCT2020	2/3	2	Yes		NA/TC	R (08OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551230	GENRL	Injection site pain/ Injection site pain	1	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
	GENRL	Chills/ Chills	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		Fatigue/ Fatigue	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1055 10551231	GENRL	Injection site pain/ injection site soreness#	3	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1055 10551232	GENRL	Injection site pain/ Injection site pain	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Chills/ Chills	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Injection site pain/ Injection site pain	2	06OCT2020	1/4	2	Yes		NA	R (09OCT2020)	N/N
		Pyrexia/ Fever	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	MUSC	Myalgia/ Generalized myalgias	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1055 10551233	MUSC	Myalgia/ Generalized myalgias	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	3	22DEC2020	2/2	2	Yes		NA	R (23DEC2020)	N/N
	MUSC	Myalgia/ myalgias#	3	22DEC2020	2/2	2	Yes		NA	R (23DEC2020)	N/N
	PSYCH	Insomnia/ insomnia#	4	11JAN2021	1/7	1	Yes		NA	R (17JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	12JAN2021	2/3	1	Yes		NA	R (14JAN2021)	N/N
		Pyrexia/ fever#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1055 10551235	GENRL	Pyrexia/ Fever	1	15SEP2020	1/3	1	Yes		NA/TC	R (17SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	1	15SEP2020	1/6	2	Yes		NA	R (20SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	05OCT2020	1/3	2	Yes		NA	R (07OCT2020)	N/N
		Pyrexia/ Fever	2	05OCT2020	1/3	1	Yes		NA/TC	R (07OCT2020)	N/N
	MUSC	Myalgia/ Generalized myalgias	2	05OCT2020	1/3	1	Yes		NA/TC	R (07OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551237	GENRL	Chills/ Chills	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		Fatigue/ Fatigue	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ Injection site pain	1	16SEP2020	1/5	1	Yes		NA	R (20SEP2020)	N/N
		Pyrexia/ Fever	1	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N
		Fatigue/ Fatigue	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
		Injection site pain/ Injection site pain	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1055 10551238	GENRL	Injection site pain/ Injection Site Pain	1	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/Y
	GENRL	Injection site pain/ injection site pain#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1055 10551239	GENRL	Pyrexia/ Fever	1	18SEP2020	2/3	1	Yes		NA/TC	R (20SEP2020)	N/N
	METAB	Vitamin D deficiency/ Vitamin D deficiency	2	NOV2020	25/C	1	No	O	NA/TC	N	N/N
	GENRL	Injection site pain/ injection site soreness#	3	28JAN2021	1/5	1	Yes		NA	R (01FEB2021)	N/N
	GENRL	Pyrexia/ low grade fever#	3	29JAN2021	2/2	1	Yes		NA/TC	R (30JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue#	3	30JAN2021	3/2	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	17FEB2021	1/4	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1055 10551240	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	09OCT2020	1/2	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1055 10551243	GENRL	Injection site pain/ Pain at injection site	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	3	19JAN2021	2/1	1	Yes		NA	R (19JAN2021)	N/N
		Injection site pain/ injection site soreness#	3	19JAN2021	2/1	1	Yes		NA	R (19JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	3	19JAN2021	2/1	1	Yes		NA/TC	R (19JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	09FEB2021	2/3	1	Yes		NA	R (11FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	09FEB2021	2/2	2	Yes		NA/TC	R (10FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1055 10551244	GENRL	Fatigue/ Fatigue	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
	MUSC	Arthralgia/ Generalized joint pains	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
	NERV	Headache/ Headache	1	20OCT2020	2/1	1	Yes		NA/TC	R (20OCT2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1055 10551245	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	1/2	2	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	13NOV2020	1/4	1	Yes		NA/TC	R (16NOV2020)	N/N
	MUSC	Myalgia/ Generalized myalgias	2	13NOV2020	1/2	1	Yes		NA/TC	R (14NOV2020)	N/N
16-55/ C4591001 1055 10551246	GENRL	Injection site pain/ injection site pain#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
	PSYCH	Sleep disorder/ Disturbed sleep#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1055 10551247	MUSC	Myalgia/ Myalgias#	4	18FEB2021	2/1	2	Yes		NA/TC	R (18FEB2021)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	18FEB2021	2/1	2	Yes		NA/TC	R (18FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N	
16-55/ C4591001 1055 10551249	MUSC	Myalgia/ Myalgias#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/4	1	Yes		NA	R (14NOV2020)	N/N	
16-55/ C4591001 1056 10561013	GENRL	Pyrexia/ Fever	2	12NOV2020	2/2	1	Yes		NA/TC	R (13NOV2020)	N/N	
	GENRL	Chills/ CHILLS	2	05SEP2020	2/1	1	Yes		NA/TC	R (05SEP2020)	N/N	
	GENRL	Chills/ CHILLS	2	05SEP2020	2/1	1	Yes		NA/TC	R (05SEP2020)	N/N	
16-55/ C4591001 1056 10561016	INJ&P	Contusion/ MULTIPLE CONTUSION	2	26SEP2020	18/34	2	No	O	NA/TC	R (29OCT2020)	N/N	
		Road traffic accident/ CAR ACCIDENT	2	26SEP2020	18/1	2	No	O	NA/TC	R (26SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1056 10561022	BLOOD	Lymphadenopathy/ SWOLLEN LEFT AXILLARY LYMPH NODES	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N	
	GENRL	Injection site erythema/ INJECTION SITE ERYTHEMA	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N	
		Injection site pain/ PAIN AT INJECTION SITE	2	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N	
16-55/ C4591001 1056 10561039	GENRL	Pyrexia/ FEVER	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
16-55/ C4591001 1056 10561058	GENRL	Pyrexia/ FEVER	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
16-55/ C4591001 1056 10561059	GASTR	Diarrhoea/ DIARRHEA	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N	
	GENRL	Injection site pain/ LEFT ARM INJECTION SITE MUSCLE PAIN	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N	
		Pyrexia/ FEVER	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
16-55/ C4591001 1056 10561071	GENRL	Chills/ CHILLS#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N	
		Pyrexia/ FEVER#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1056 10561089	GENRL	Injection site pain/ LEFT ARM INJECTION SITE MUSCLE PAIN	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ FEVER	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1056 10561108	GENRL	Injection site swelling/ INJECTION SITE SWELLING	1	04SEP2020	4/2	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1056 10561121	GENRL	Chills/ CHILLS#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1056 10561146	GENRL	Pyrexia/ FEVER	2	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1056 10561177	GENRL	Chills/ CHILLS	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
		Fatigue/ FATIGUE	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
		Injection site pain/ INJECTION SITE MUSCLE PAIN	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
		Pyrexia/ FEVER	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ HEADACHE	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1056 10561187	GENRL	Injection site pain/ RIGHT ARM INJECTION SITE MUSCLE PAIN	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1056 10561213	GENRL	Fatigue/ TIREDNESS	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1056 10561219	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1056 10561251	GENRL	Fatigue/ TIREDNESS	1	16SEP2020	1/4	1	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ FEVER	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1056 10561252	GENRL	Injection site pain/ PAIN AR THE INJECTION SITE	1	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ CHILLS	1	01OCT2020	16/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1056 10561262	GENRL	Pyrexia/ FEVER	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1056 10561263	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN#	4	01MAR2021	1/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1056 10561277	GENRL	Injection site pain/ MUSCLE PAIN (INJECTION SITE LEFT)	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
		Pyrexia/ FEVER	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1056 10561315	RESP	Nasal congestion/ NASAL CONGESTION	1	30SEP2020	9/4	1	No	O	NA	R (03OCT2020)	N/N
	GENRL	Pyrexia/ FEVER	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1056 10561327	GENRL	Chills/ CHILLS	1	27SEP2020	4/4	1	Yes		NA/TC	R (30SEP2020)	N/N
	MUSC	Arthralgia/ GENERALIZED JOINT PAIN	1	27SEP2020	4/4	1	Yes		NA/TC	R (30SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	27SEP2020	4/4	1	Yes		NA/TC	R (30SEP2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE (LEFT)#	3	10FEB2021	3/7	1	Yes		NA	R (16FEB2021)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN#	3	10FEB2021	3/8	1	Yes		NA	R (17FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1056 10561330	GENRL	Chills/ Chills#	4	12MAR2021	1/C	1	Yes		NA	N	N/N
16-55/ C4591001 1056 10561360	GENRL	Pyrexia/ FEVER	2	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Pyrexia/ FEVER	2	21OCT2020	3/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1056 10561375	GENRL	Chills/ CHILLS	1	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	1	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
	NERV	Headache/ HEADACHE	1	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
	GENRL	Chills/ CHILLS	2	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1056 10561396	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ HEADACHE	1	11OCT2020	7/2	1	Yes		NA	R (12OCT2020)	N/N
	GENRL	Chills/ CHILLS	1	12OCT2020	8/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ FEVER#	3	06FEB2021	2/5	1	Yes		NA/TC	R (10FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1056 10561400	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN#	3	06FEB2021	2/5	1	Yes		NA/TC	R (10FEB2021)	N/N
16-55/ C4591001 1056 10561401	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN#	3	06FEB2021	2/13	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1056 10561442	GENRL	Pyrexia/ FEVER	2	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1056 10561444	GENRL	Pyrexia/ FEVER	1	09OCT2020	2/7	1	Yes		NA	R (15OCT2020)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	1	09OCT2020	2/8	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Pyrexia/ FEVER	2	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1056 10561453	GENRL	Chills/ CHILLS	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N
		Pyrexia/ FEVER	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	2	29OCT2020	2/9	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1056 10561484	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	1	13OCT2020	2/11	1	Yes		NA	R (23OCT2020)	N/N	
16-55/ C4591001 1056 10561540	GENRL	Pyrexia/ FEVER	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N	
16-55/ C4591001 1056 10561547	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N	
16-55/ C4591001 1056 10561555	GENRL	Pyrexia/ FEVER	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N	
16-55/ C4591001 1056 10561558	MUSC	Arthralgia/ GENERALIZED JOINT PAIN	1	13NOV2020	25/2	1	Yes		NA	R (14NOV2020)	N/N	
16-55/ C4591001 1056 10561558	GENRL	Injection site pain/ Pain At Site Of Injection (Left)#	4	23FEB2021	1/C	1	Yes		NA	RG	N/N	
16-55/ C4591001 1056 10561594	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N	
16-55/ C4591001 1056 10561600	GASTR	Diarrhoea/ DIARRHEA	1	29OCT2020	3/4	1	Yes		NA	R (01NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pyrexia/ FEVER	1	29OCT2020	3/4	1	Yes		NA	R (01NOV2020)	N/N
	NERV	Headache/ HEADACHE	1	29OCT2020	3/4	1	Yes		NA	R (01NOV2020)	N/N
16-55/ C4591001 1056 10561622	GENRL	Chills/ CHILLS	1	31OCT2020	4/2	1	Yes		NA	R (01NOV2020)	N/N
16-55/ C4591001 1056 10561635	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE LEFT	2	19NOV2020	1/3	1	Yes		NA	R (21NOV2020)	N/N
	MUSC	Arthralgia/ GENERALIZED JOINT PAIN	2	19NOV2020	1/3	1	Yes		NA	R (21NOV2020)	N/N
16-55/ C4591001 1056 10561642	GENRL	Chills/ CHILLS#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
		Pyrexia/ FEVER#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1057 10571002	GENRL	Injection site pain/ PAIN AT INJECTION SITE ON LEFT ARM#	3	27JAN2021	1/4	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1057 10571018	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001	GENRL	Chills/ CHILLS#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1057 10571032	HEPAT	Cholecystitis acute/ ACUTE CHOLECYSTITIS#	2	05FEB2021	150/4	3	No	O	NA/TCN	R (08FEB2021)	Y/N
1057 10571065	HEPAT	Steatohepatitis/ STEATOHEPATITIS#	2	07FEB2021	152/C	2	No	O	NA/TCN	N	N/N
1057 10571065	INFEC	Postoperative abscess/ POST CHOLECYSTECTOMY ABSCESS#	2	12FEB2021	157/C	3	No	O	NA/TC	N	Y/N
16-55/ C4591001 1057 10571074	GENRL	Fatigue/ FATIGUE#	3	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N
		Injection site pain/ INJECTION SITE PAIN LEFT ARM#	3	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N
		Pain/ BODY ACHES#	3	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1057 10571083	GASTR	Nausea/ NAUSEA	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
		Vomiting/ VOMITTING	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
	INV	Blood pressure increased/ INCREASED BLOOD PRESSURE	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
	NERV	Headache/ HEADACHE	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1057 10571100	GASTR	Vomiting/ VOMITING	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	INV	Blood pressure increased/ INCREASED BLOOD PRESSURE	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	GASTR	Nausea/ NAUSEA#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
		Pain/ BODY ACHES#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ HEADACHES#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN RIGHT ARM#	3	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1057 10571122	RESP	Throat irritation/ THROAT IRRITATION	2	19SEP2020	4/1	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001	GASTR	Vomiting/ Vomiting	1	08SEP2020	8/2	1	No	O	NA	R (09SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1057 10571132	GENRL	Injection site pain/ INJECTIONS SITE PAIN LEFT ARM#	3	15FEB2021	1/3	2	Yes		NA	R (17FEB2021)	N/N
1057 10571136	NEOPL	Uterine leiomyoma/ WORSENING OF UTERINE FIBROIDS	1	14SEP2020	14/6	2	No	O	NA/TCN	R (19SEP2020)	Y/N
1057 10571137	GENRL	Fatigue/ FATIGUE#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
1057 10571144	MUSC	Pyrexia/ FEVER#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
	MUSC	Myalgia/ MUSCLE SORENESS#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
	NERV	Headache/ HEADACHE#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
1057 10571152	GENRL	Injection site pain/ PAIN AT INJECTION SITE LEFT ARM#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
1057 10571165	GENRL	Injection site pain/ INJECTION SITE PAIN	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
1057 10571165	GASTR	Diarrhoea/ DIARRHEA	1	12SEP2020	3/2	1	Yes		NA	R (13SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1057 10571173	GENRL	Injection site pain/ PAIN AT INJECTIONS SITE ON LEFT ARM#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1057 10571182	NERV	Dizziness/ DIZZINESS	2	07OCT2020	1/C	2	Yes		NA	N	N/N
1057 10571188	EAR	Deafness unilateral/ HEARING LOSS IN RIGHT EAR	2	08OCT2020	2/C	1	Yes		NA	N	N/N
	INJ&P	Fall/ FALL	2	24NOV2020	49/1	2	Yes		NA	R (24NOV2020)	N/N
		Upper limb fracture/ BROKEN RIGHT ARM	2	24NOV2020	49/C	1	Yes		NA/TCN	N	N/N
16-55/ C4591001 1057 10571238	GENRL	Fatigue/ FATIGUE#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ INJECTION SITE PAIN#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
		Pain/ BODY ACHES#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ HEADACHES#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Pain/ BODY ACHES#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001	INFEC	Urinary tract infection/ Urinary Tract Infection	2	15OCT2020	2/8	2	No	O	NA	R (22OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1057 10571239	GENRL	Injection site pain/ SORENESS INJECTION SITE LEFT ARM	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
1057 10571241		Pain/ BODY ACHES	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1057 10571246	GENRL	Injection site pain/ LEFT ARM PAIN AT INJECTION SITE	1	25SEP2020	1/6	2	Yes		NA	R (30SEP2020)	N/N
1057 10571246		Pain/ BODY ACHES	1	25SEP2020	1/6	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1057 10571263	RESP	Nasal congestion/ Nasal Congestion	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1057 10571265	METAB	Type 2 diabetes mellitus/ Type 2 Diabetes mellitus	2	29DEC2020	61/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1057 10571273	GENRL	Injection site pruritus/ Itchiness on Left Arm at Injection Site	1	08OCT2020	2/5	1	Yes		NA	R (12OCT2020)	N/N
16-55/ C4591001 1057 10571278	GENRL	Injection site pain/ Pain at Injection Site	1	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Diarrhoea/ Diarrhea	1	09OCT2020	2/3	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1057 10571294	GENRL	Injection site pain/ INJECTION SITE PAIN LEFT ARM#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1057 10571295	GASTR	Nausea/ NAUSEA	2	25NOV2020	23/4	1	No	O	NA	R (28NOV2020)	N/N
16-55/ C4591001 1057 10571312	NERV	Dizziness/ Dizziness	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1057 10571316	INV	Body temperature increased/ ELEVATED TEMPERATURE	2	04NOV2020	2/2	2	Yes		NA	R (05NOV2020)	N/N
16-55/ C4591001 1057 10571319	GENRL	Pain/ BODY ACHES	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
	MUSC	Neck pain/ NECK PAIN	2	14NOV2020	3/C	1	No	O	NA	N	N/N
16-55/ C4591001 1057 10571320	GENRL	Chills/ CHills	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
		Fatigue/ Fatigue	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1057 10571331	MUSC	Injection site pain/ Injection site pain	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N	
		Myalgia/ Muscle Aches	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N	
	GENRL	Chills/ CHILLS	2	06NOV2020	1/3	1	Yes		NA	R (08NOV2020)	N/N	
		Fatigue/ FATIGUE	2	06NOV2020	1/5	1	Yes		NA	R (10NOV2020)	N/N	
		Pyrexia/ FEVER	2	06NOV2020	1/3	1	Yes		NA	R (08NOV2020)	N/N	
16-55/ C4591001 1057 10571332†	GENRL	Injection site pain/ LEFT ARM PAIN AT INJECTION SITE	1	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N	
16-55/ C4591001 1057 10571333	GENRL	Injection site pain/ INJECTION SITE PAIN LEFT ARM#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N	
16-55/ C4591001 1057 10571339	GASTR	Nausea/ NAUSEA	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N	
	GENRL	Fatigue/ FATIGUE	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N	
		Injection site pain/ INJECTION SITE PAIN	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N	
	NERV	Headache/ HEADACHE	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1057 10571373	GENRL	Injection site pain/ INJECTION SITE PAIN ON LEFT ARM#	3	26JAN2021	1/3	2	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1066 10661019	GENRL	Fatigue/ fatigue	1	18AUG2020	7/2	1	Yes		NA	R (19AUG2020)	N/N
16-55/ C4591001 1066 10661020	GENRL	Fatigue/ fatigue	1	13AUG2020	2/2	1	Yes		NA	R (14AUG2020)	N/N
		Injection site pain/ pain at injection site	1	13AUG2020	2/3	1	Yes		NA	R (15AUG2020)	N/N
16-55/ C4591001 1066 10661026	GENRL	Fatigue/ fatigue	1	16AUG2020	4/2	1	Yes		NA	R (17AUG2020)	N/N
	NERV	Headache/ headache	1	16AUG2020	4/2	1	Yes		NA	R (17AUG2020)	N/N
	GENRL	Fatigue/ fatigue	1	18AUG2020	6/2	1	Yes		NA	R (19AUG2020)	N/N
16-55/ C4591001 1066 10661027	GENRL	Fatigue/ fatigue	1	16AUG2020	4/5	2	Yes		NA	R (20AUG2020)	N/N
	GENRL	Chills/ chills	1	17AUG2020	5/4	2	Yes		NA	R (20AUG2020)	N/N
	NERV	Headache/ headache	1	17AUG2020	5/4	2	Yes		NA/TC	R (20AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1066 10661037	GENRL	Pain/ body aches#	4	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ soreness at injection site#	4	30JAN2021	2/3	1	Yes		NA	R (01FEB2021)	N/N
16-55/ C4591001 1066 10661059	GENRL	Fatigue/ fatigue#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ soreness at injection site#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
		Pain/ body aches#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1066 10661081	GENRL	Chills/ Chills#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
		Pain/ Body aches#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
		Pyrexia/ Fever#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	NERV	Headache/ Headache#	4	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
16-55/ C4591001 1066 10661086	GASTR	Diarrhoea/ diarrhea#	4	11JAN2021	1/8	1	Yes		NA	R (18JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache#	4	11JAN2021	1/8	1	Yes		NA	R (18JAN2021)	N/N
16-55/ C4591001 1066 10661095	MUSC	Back pain/ lower back pain	2	06OCT2020	23/3	2	No	O	NA	R (08OCT2020)	N/N
16-55/ C4591001 1066 10661106	GENRL	Pain/ body aches	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1066 10661116	GENRL	Pain/ body aches#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
		Pyrexia/ fever#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1066 10661129	GENRL	Injection site pain/ pain at injection site#	3	16JAN2021	2/3	1	Yes		NA	R (18JAN2021)	N/N
16-55/ C4591001 1066 10661138	GENRL	Injection site pain/ pain at injection site#	3	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
		Pain/ body aches#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	METAB	Decreased appetite/ lack of appetite#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1066 10661182	GENRL	Fatigue/ fatigue	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		Pain/ body aches	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1066 10661192	INFEC	Diverticulitis/ diverticulitis	2	07NOV2020	44/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1066 10661202	BLOOD	Lymphadenopathy/ L side axillary lymph node swelling#	4	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
		Pyrexia/ fever#	4	08JAN2021	1/2	2	Yes		NA/TC	R (09JAN2021)	N/N
16-55/ C4591001 1066 10661203	GENRL	Pain/ body aches	1	07SEP2020	1/3	1	Yes		NA	R (09SEP2020)	N/N
		Pyrexia/ fever	1	07SEP2020	1/2	1	Yes		NA	R (08SEP2020)	N/N
	GENRL	Chills/ chills	2	18NOV2020	1/2	1	Yes		NA	R (19NOV2020)	N/N
		Pain/ body aches	2	18NOV2020	1/2	1	Yes		NA	R (19NOV2020)	N/N
		Pyrexia/ fever	2	18NOV2020	1/2	1	Yes		NA	R (19NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1066 10661226	VASC	Hot flush/ hot flashes	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	10FEB2021	2/4	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1066 10661235	GASTR	Diarrhoea/ diarrhea	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Pain/ body aches	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		Pyrexia/ fever	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1066 10661242	RESP	Pleuritic pain/ pleuritic chest pain#	4	15FEB2021	6/8	2	No	O	NA/TC	R (22FEB2021)	N/N
		Pulmonary embolism/ Pulmonary Embolism with bilateral lower lobe Pulmonary embolisms#	4	15FEB2021	6/2	3	No	O	NA/TC	RS (16FEB2021)	Y/N
16-55/ C4591001 1066 10661253	GENRL	Pain/ body aches#	4	12JAN2021	1/3	1	Yes		NA/TC	R (14JAN2021)	N/N
		Pyrexia/ fever#	4	12JAN2021	1/2	1	Yes		NA/TC	R (13JAN2021)	N/N
16-55/ C4591001	GENRL	Chills/ chills#	3	17DEC2020	2/2	1	Yes		NA	R (18DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1066 10661261		Pain/ body aches#	3	17DEC2020	2/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Pyrexia/ fever#	4	04JAN2021	1/3	1	Yes		NA/TC	R (06JAN2021)	N/N
16-55/ C4591001 1066 10661264	GENRL	Chills/ chills	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1066 10661265	GENRL	Chills/ chills#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Pain/ body aches#	4	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
		Pyrexia/ fever#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1066 10661275	INFEC	Herpes zoster/ Herpes zoster	2	24OCT2020	16/14	2	No	O	NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1066 10661279	GASTR	Nausea/ nausea	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1066 10661282	GENRL	Pain/ body aches	2	13OCT2020	1/4	1	Yes		NA	R (16OCT2020)	N/N
		Injection site pain/ pain at injection site	2	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	4	26JAN2021	2/2	2	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1066 10661294	NERV	Headache/ headache#	4	26JAN2021	2/2	2	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Pain/ body aches	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1066 10661308	GENRL	Injection site pain/ pain at injection site	1	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1066 10661315	GENRL	Injection site pain/ pain at injection site	1	06OCT2020	2/4	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001	GENRL	Chills/ chills	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
	SKIN	Hyperhidrosis/ sweating	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Fatigue/ fatigue	1	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1066 10661323	NERV	Headache/ headache	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N	
	GENRL	Chills/ chills	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N	
	SKIN	Hyperhidrosis/ sweating	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N	
16-55/ C4591001 1066 10661324	INFEC	Localised infection/ infection left middle finger	2	29NOV2020	28/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1066 10661331	GENRL	Chills/ chills	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N	
		Pain/ body aches	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N	
16-55/ C4591001 1066 10661337	GENRL	Injection site pain/ pain at injection site	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N	
	GENRL	Injection site pain/ pain at injection site	2	10NOV2020	2/3	1	Yes		NA	R (12NOV2020)	N/N	
16-55/ C4591001 1066 10661342	GENRL	Pyrexia/ Fever#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	
16-55/ C4591001	GENRL	Fatigue/ fatigue	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1066 10661345	GENRL	Fatigue/ fatigue	2	07NOV2020	2/2	1	Yes		NA	R (08NOV2020)	N/N
		Injection site pain/ pain at injection site	2	07NOV2020	2/4	1	Yes		NA	R (10NOV2020)	N/N
16-55/ C4591001 1066 10661379	GENRL	Fatigue/ fatigue	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
		Pain/ body aches	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1066 10661388	GENRL	Injection site pain/ pain at injection site	1	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1066 10661396	GENRL	Injection site pain/ pain at injection site#	3	22DEC2020	1/3	1	Yes		NA	R (24DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
	MUSC	Myalgia/ muscle pain#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
	NERV	Headache/ headache#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
16-55/ C4591001 1068 10681002	GENRL	Injection site pain/ pain at injection site	1	19AUG2020	2/4	2	Yes		NA/TC/TCN	R (22AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1068 10681013	NERV	Dizziness/ lightheadedness	1	19AUG2020	2/4	1	Yes	NA/TC/TCN	R (22AUG2020)	N/N		
		Headache/ Headache	1	19AUG2020	2/4	2	Yes	NA/TC/TCN	R (22AUG2020)	N/N		
	GASTR	Nausea/ Nausea	2	10SEP2020	2/1	1	Yes	NA	R (10SEP2020)	N/N		
	GENRL	Chills/ Chills	2	10SEP2020	2/2	2	Yes	NA	R (11SEP2020)	N/N		
	MUSC	Arthralgia/ Joint Aches	2	10SEP2020	2/2	2	Yes	NA/TC/TCN	R (11SEP2020)	N/N		
		Myalgia/ Muscle Aches	2	10SEP2020	2/2	2	Yes	NA/TC	R (11SEP2020)	N/N		
	NERV	Headache/ Headache	2	10SEP2020	2/2	2	Yes	NA/TC	R (11SEP2020)	N/N		
	NERV	Headache/ headache#	3	25FEB2021	1/2	1	Yes	NA	R (26FEB2021)	N/Y		
	16-55/ C4591001 1068 10681021	GENRL	Fatigue/ Fatigue	1	22AUG2020	2/2	1	Yes	NA	R (23AUG2020)	N/N	
			Pyrexia/ Fever	1	22AUG2020	2/2	1	Yes	NA	R (23AUG2020)	N/N	
GENRL		Chills/ chills	2	11SEP2020	1/2	1	Yes	NA	R (12SEP2020)	N/N		
		Injection site pain/ pain at injection site	2	11SEP2020	1/2	1	Yes	NA	R (12SEP2020)	N/N		
		Pyrexia/ fever	2	11SEP2020	1/2	1	Yes	NA	R (12SEP2020)	N/N		

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1068 10681024	GENRL	Pyrexia/ Fever	2	10SEP2020	2/2	1	Yes		NA/TC/TCN	R (11SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	NERV	Headache/ Headache	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1068 10681025	GENRL	Chills/ chills#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
		Pain/ body aches#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ headache#	4	09JAN2021	2/2	1	Yes		NA/TC	R (10JAN2021)	N/N
16-55/ C4591001 1068 10681026	GENRL	Injection site pain/ Injection Site pain	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
	MUSC	Myalgia/ Generalized myalgia	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
16-55/ C4591001 1068 10681027	GENRL	Injection site pain/ Pain at the injection site	1	21AUG2020	1/2	1	Yes		NA/TC	R (22AUG2020)	N/N
	NERV	Headache/ Headache	1	22AUG2020	2/1	1	Yes		NA/TC	R (22AUG2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1068 10681031	GENRL	Injection site pain/ pain at injection site	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N	
	GASTR	Nausea/ nausea#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N	
	GENRL	Chills/ chills#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N	
	GENRL	Pyrexia/ fever#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	1	14SEP2020	22/4	1	Yes		NA	R (17SEP2020)	N/N	
	MUSC	Arthralgia/ Joint Aches	2	15SEP2020	2/3	2	Yes		NA	R (17SEP2020)	N/N	
	MUSC	Myalgia/ Muscle Aches	2	15SEP2020	2/3	2	Yes		NA	R (17SEP2020)	N/N	
	GENRL	Fatigue/ fatigue#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N	
	NERV	Headache/ headache#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N	
16-55/ C4591001 1068 10681037	RESP	Dyspnoea/ shortness of breath	1	29AUG2020	6/10	1	No	O	NA	R (07SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1068 10681042	GENRL	Wheezing/ wheezing	1	29AUG2020	6/10	1	No	O	NA	R (07SEP2020)	N/N	
		Fatigue/ fatigue#	3	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N	
	MUSC	Myalgia/ left arm muscle aches#	3	24FEB2021	1/3	2	Yes		NA	R (26FEB2021)	N/N	
	GASTR	Nausea/ Nausea	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N	
	GENRL	Chills/ Chills	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N	
		Pyrexia/ Fever	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N	
	MUSC	Myalgia/ Muscle aches	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N	
	NERV	Headache/ Headache	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N	
16-55/ C4591001 1068 10681046	GENRL	Chills/ Chills	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N	
		Injection site pain/ Injection Site Pain	1	16SEP2020	22/1	1	Yes		NA	R (16SEP2020)	N/N	
		Pyrexia/ Fever	1	16SEP2020	22/3	1	Yes		NA	R (18SEP2020)	N/N	
	MUSC	Myalgia/ Muscle Aches	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
	EYE	Eye pruritus/ Right Eye Itching	2	17OCT2020	32/2	1	No	O	NA	R (18OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1068 10681052	MUSC	Tendonitis/ Tendonitis of the right forearm	1	15SEP2020	20/C	1	No	O	NA/TC	RG	N/N	
	NERV	Headache/ headache#	3	30DEC2020	3/5	2	Yes		NA	R (03JAN2021)	N/N	
16-55/ C4591001 1068 10681053	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N	
	MUSC	Joint range of motion decreased/ Decreased left shoulder mobility	1	27AUG2020	1/3	2	Yes		NA	R (29AUG2020)	N/N	
	GENRL	Injection site pain/ injection Site Pain	1	05SEP2020	10/2	1	Yes		NA	R (06SEP2020)	N/N	
16-55/ C4591001 1068 10681058	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	1/1	1	Yes		NA/TC	R (17SEP2020)	N/N	
	GENRL	Pain/ Body aches	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N	
16-55/ C4591001 1068 10681060	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	1/3	2	Yes		NA/TC/TCN	R (30AUG2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N	
	GENRL	Chills/ Chills	2	18SEP2020	2/2	2	Yes		NA/TC	R (19SEP2020)	N/N	
		Pain/ Body aches	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1068 10681064	GASTR	Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
		Nausea/ Nausea	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	18FEB2021	2/2	2	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1068 10681066	BLOOD	Lymphadenopathy/ Left swollen cervical lymph node	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
	GASTR	Gingival swelling/ Gum Swelling	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Chills/ chills#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1068 10681071	GENRL	Pain/ body aches#	4	13JAN2021	2/2	1	Yes		NA/TC	R (14JAN2021)	N/N
		Fatigue/ fatigue#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	18DEC2020	1/4	1	Yes		NA	R (21DEC2020)	N/N
		Chills/ chills#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
		Pain/ body aches#	4	08JAN2021	1/3	1	Yes		NA/TC	R (10JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1068 10681074	NERV	Headache/ headache#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Chills/ chills#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
		Pain/ body aches#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1068 10681077	NERV	Headache/ headache#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1068 10681080	MUSC	Myalgia/ Muscle Aches	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	NERV	Headache/ headache	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	GASTR	Nausea/ nausea#	4	12MAR2021	1/2	1	Yes		NA/TC	R (13MAR2021)	N/N
16-55/ C4591001 1068 10681083	GENRL	Chills/ chills#	4	12MAR2021	1/2	1	Yes		NA	R (13MAR2021)	N/N
	GENRL	Chills/ chills#	3	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1068 10681086	GENRL	Pain/ body aches	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N	
16-55/ C4591001 1068 10681098	GENRL	Injection site pain/ Pain at injection site	1	03SEP2020	1/5	2	Yes		NA	R (07SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	04SEP2020	2/1	1	Yes		NA	R (04SEP2020)	N/N	
		Pain/ Body Aches	1	04SEP2020	2/1	2	Yes		NA/TC	R (04SEP2020)	N/N	
16-55/ C4591001 1068 10681100	GENRL	Fatigue/ Fatigue	1	06SEP2020	4/9	1	Yes		NA/TC	R (14SEP2020)	N/N	
	MUSC	Myalgia/ Muscle Aches	1	06SEP2020	4/3	1	Yes		NA	R (08SEP2020)	N/N	
	NERV	Headache/ headache	1	06SEP2020	4/3	1	Yes		NA	R (08SEP2020)	N/N	
16-55/ C4591001 1068 10681106	GENRL	Chills/ Chills	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N	
		Injection site pain/ injection site pain	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N	
		Pyrexia/ Fever	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N	
	GASTR	Nausea/ Nausea	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1068 10681109	NERV	Headache/ Headache	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	1/3	2	Yes		NA/TC	R (06SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	25SEP2020	1/5	1	Yes		NA	R (29SEP2020)	N/N	
	GENRL	Chills/ Chills	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N	
	GENRL	Pyrexia/ Fever	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N	
16-55/ C4591001 1068 10681110	SKIN	Urticaria/ Left forearm hives	1	04SEP2020	1/4	1	Yes		NA	R (07SEP2020)	N/N	
16-55/ C4591001 1068 10681113	SKIN	Rash/ Rash on arm	1	11SEP2020	4/3	1	Yes		NA	R (13SEP2020)	N/N	
16-55/ C4591001 1068 10681114	GASTR	Nausea/ nausea	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N	
	NERV	Presyncope/ near syncope	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N	
	INFEC	Sinusitis/ Maxillary Sinusitis	1	26SEP2020	19/10	1	No	O	NA	R (05OCT2020)	N/N	
	GENRL	Chills/ rigors#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1068 10681117	MUSC	Myalgia/ myalgia#	4	09JAN2021	2/2	1	Yes		NA/TC	R (10JAN2021)	N/N	
	NERV	Headache/ headache#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N	
16-55/ C4591001 1068 10681119	GENRL	Chills/ chills	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N	
		Fatigue/ fatigue	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N	
		Pyrexia/ fever	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N	
	NERV	Headache/ headache	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N	
16-55/ C4591001 1068 10681121	GENRL	Injection site pain/ injection site pain in left arm	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N	
	MUSC	Myalgia/ muscle aches in back	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N	
	NERV	Headache/ headache	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N	
	MUSC	Musculoskeletal chest pain/ chest tightness consistent with skeletal pain	2	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N	
16-55/ C4591001	RESP	Oropharyngeal pain/ SORE THROAT	2	23SEP2020	21/1	1	No	O	NA	R (23SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1071 10711004	NERV	Headache/ HEADACHE	2	07SEP2020	6/4	2	Yes		NA	R (10SEP2020)	N/N	
16-55/ C4591001 1071 10711019	GENRL	Pain/ BODY ACHES#	3	21JAN2021	2/3	1	Yes		NA	R (23JAN2021)	N/N	
16-55/ C4591001 1071 10711022	NERV	Headache/ HEADACHE#	3	21JAN2021	2/3	1	Yes		NA	R (23JAN2021)	N/N	
16-55/ C4591001 1071 10711027	PSYCH	Irritability/ IRRITABILITY	1	12AUG2020	1/8	1	No	O	NA	R (19AUG2020)	N/N	
16-55/ C4591001 1071 10711028	GENRL	Fatigue/ FATIGUE	1	13AUG2020	2/7	1	No	O	NA	R (19AUG2020)	N/N	
16-55/ C4591001 1071 10711028	MUSC	Pain in extremity/ SORE ARM#	4	11FEB2021	2/6	1	Yes		NA	R (16FEB2021)	N/N	
16-55/ C4591001 1071 10711039	GENRL	Fatigue/ FATIGUE	2	09SEP2020	6/13	2	Yes		NA	R (21SEP2020)	N/N	
16-55/ C4591001	NERV	Headache/ HEADACHE	2	09SEP2020	6/13	1	Yes		NA	R (21SEP2020)	N/N	
16-55/ C4591001	GENRL	Chills/ CHILLS#	4	15FEB2021	2/2	1	Yes		NA	R (16FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1071 10711042	INV	Body temperature increased/ ELEVATED TEMPERATURE#	4	15FEB2021	2/2	1	Yes		NA	R (16FEB2021)	N/N	
	NERV	Headache/ HEADACHE#	4	15FEB2021	2/2	1	Yes		NA	R (16FEB2021)	N/N	
16-55/ C4591001 1071 10711055	MUSC	Myalgia/ MUSCLE ACHES#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N	
		Pain in extremity/ SORE ARM#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N	
16-55/ C4591001 1071 10711056	MUSC	Arthralgia/ RIGHT SHOULDER PAIN	2	17SEP2020	10/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1071 10711057	MUSC	Neck pain/ SORENESS, RIGHT SIDE, BASE OF NECK#	3	21JAN2021	1/4	1	Yes		NA	R (24JAN2021)	N/N	
		Pain in extremity/ RIGHT ARM SORENESS#	3	21JAN2021	1/4	1	Yes		NA	R (24JAN2021)	N/N	
	GENRL	Fatigue/ FATIGUE#	4	14FEB2021	1/3	1	Yes		NA	R (16FEB2021)	N/N	
		Injection site pain/ PAIN AT INJECTION SITE#	4	14FEB2021	1/3	1	Yes		NA	R (16FEB2021)	N/N	
		Pain/ BODY ACHES#	4	14FEB2021	1/3	1	Yes		NA	R (16FEB2021)	N/N	
		Pain/ GENERALIZED BODY ACHES#	4	14FEB2021	1/3	1	Yes		NA	R (16FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1071 10711061	GENRL	Injection site pain/ INJECTION SITE SORENESS	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	
		Pain/ GENERALIZED BODY PAIN	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	
	NERV	Headache/ HEADACHE	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	
16-55/ C4591001 1071 10711065	NERV	Headache/ HEADACHE	2	15SEP2020	7/2	1	Yes		NA	R (16SEP2020)	N/N	
16-55/ C4591001 1071 10711080	MUSC	Neck pain/ NECK PAIN	1	04SEP2020	14/2	1	No	O	NA	R (05SEP2020)	N/N	
16-55/ C4591001 1071 10711083	GASTR	Diarrhoea/ DIARRHEA	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N	
		Vomiting/ VOMITTING	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N	
	GENRL	Chills/ CHILLS	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N	
	MUSC	Back pain/ WORSENING OF BACK PAIN	1	28AUG2020	5/3	1	Yes		NA	R (30AUG2020)	N/N	
16-55/ C4591001 1071 10711097	GENRL	Chills/ CHILLS#	4	14FEB2021	4/2	1	Yes		NA	R (15FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1071 10711119	MUSC	Fatigue/ FATIGUE#	4	14FEB2021	4/2	1	Yes		NA	R (15FEB2021)	N/N
		Myalgia/ GENERAL MUSCLE PAIN	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1071 10711124	MUSC	Myalgia/ MUSCLE ACHES#	4	22FEB2021	3/7	1	No	O	NA	R (28FEB2021)	N/N
16-55/ C4591001 1071 10711125	GENRL	Chills/ CHILLS	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1071 10711133	NERV	Pain/ GENERAL BODY ACHES	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Headache/ HEADACHE	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1071 10711138	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1071 10711138	GENRL	Pyrexia/ FEVER AFTER INJECTION	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
		Pyrexia/ FEVER AFTER INJECTION	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1071 10711151	SKIN	Night sweats/ NIGHT SWEATS	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N	
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N	
16-55/ C4591001 1071 10711153	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	2	01OCT2020	3/4	1	Yes		NA	R (04OCT2020)	N/N	
16-55/ C4591001 1071 10711156		Injection site pain/ PAIN AT INJECTION SITE	2	01OCT2020	3/4	1	Yes		NA	R (04OCT2020)	N/N	
		Injection site swelling/ SWELLING AT INJECTION SITE	2	01OCT2020	3/4	1	Yes		NA	R (04OCT2020)	N/N	
	MUSC	Pain in extremity/ SORE ARM#	3	20FEB2021	1/15	1	Yes		NA	R (06MAR2021)	N/N	
16-55/ C4591001 1071 10711159	NERV	Paraesthesia/ TINGLING IN IMMUNIZATION ARM#	3	20FEB2021	1/15	1	Yes		NA	R (06MAR2021)	N/N	
	GENRL	Fatigue/ FATIGUE	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N	
16-55/ C4591001 1071 10711160	MUSC	Myalgia/ MUSCLE ACHES	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N	
	NEOPL	Lipoma/ BENIGN LIPOMA LEFT ARM	1	28SEP2020	18/5	1	No	O	NA	R (02OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1071 10711167	INJ&P	Contusion/ BRUISING LEFT ARM	1	18SEP2020	4/13	2	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1071 10711171	BLOOD	Lymphadenopathy/ SWOLLEN LYMPH NODE UNDER LEFT ARMPIT	2	07OCT2020	3/6	2	Yes		NA	R (12OCT2020)	N/N
16-55/ C4591001 1071 10711176	GENRL	Injection site pain/ MUSCLE PAIN AT INJECTION SITE	1	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1071 10711183	NERV	Headache/ HEADACHE	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1071 10711193	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/Y
16-55/ C4591001 1071 10711199	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1071 10711200	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1071 10711206	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	28SEP2020	3/1	1	Yes		NA	R (28SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1071 10711215	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1071 10711227	MUSC	Myalgia/ MUSCLE PAIN	1	02NOV2020	19/15	2	No	O	NA	R (16NOV2020)	N/N
16-55/ C4591001 1071 10711230	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1071 10711250	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	30OCT2020	1/4	1	Yes		NA	R (02NOV2020)	N/N
16-55/ C4591001 1072 10721001	GASTR	Nausea/ Nausea	1	22AUG2020	6/2	1	No	O	NA	R (23AUG2020)	N/N
	GENRL	Malaise/ General Malaise	1	22AUG2020	6/2	1	No	O	NA/TC	R (23AUG2020)	N/N
16-55/ C4591001 1072 10721022	MUSC	Metatarsalgia/ metatarsalgia	2	SEP2020	1/C	1	No	O	NA	N	N/N
16-55/ C4591001	METAB	Hypercholesterolaemia/ HYPERCHOLESTERemia	2	DEC2020	79/C	1	No	CD	NA/TC	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1072 10721031	VASC	Hypertension/ HYPERTENSION	2	DEC2020	79/C	1	No	CD	NA/TC	N	N/N	
16-55/ C4591001 1072 10721035	GENRL	Injection site pain/ Injection Site Pain Left Arm	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/N	
16-55/ C4591001 1072 10721084	INFEC	Gingival abscess/ gum abscess	2	21NOV2020	60/4	1	No	O	NA/TC	R (24NOV2020)	N/N	
	SURG	Endodontic procedure/ Root Canal Procedure	2	21NOV2020	60/1	2	No	O	NA/TC	R (21NOV2020)	N/N	
16-55/ C4591001 1072 10721099	SKIN	Dermatitis atopic/ (Atopic Dermatitis) rash on arms, abd, head	2	DEC2020	64/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1077 10771003	GASTR	Coeliac disease/ CELIACS DISEASE	2	15OCT2020	46/C	1	No	O	NA/TC/TCN	N	N/N	
16-55/ C4591001 1077 10771004	MUSC	Pain in extremity/ BILATERAL HAND PAIN	2	07SEP2020	8/6	1	No	O	NA/TC	R (12SEP2020)	N/N	
	INFEC	Diverticulitis/ FLARE OF DIVERTICULITIS	2	02OCT2020	33/6	1	No	O	NA/TC	R (07OCT2020)	N/N	
	MUSC	Arthralgia/ WORSENING RIGHT KNEE PAIN	2	01DEC2020	93/C	2	No	O	NA	N	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1077 10771007	GENRL	Pyrexia/ FEVER OF 101.0	1	17AUG2020	8/2	1	Yes		NA/TC	R (18AUG2020)	N/N	
	RESP	Sinus congestion/ SINUS CONGESTION	1	17AUG2020	8/3	2	Yes		NA	R (19AUG2020)	N/N	
	NERV	Dizziness/ DIZZINESS	2	02OCT2020	29/1	2	No	O	NA	R (02OCT2020)	N/N	
16-55/ C4591001 1077 10771009	NEOPL	Lipoma/ LIPOMA, LOWER BACK	2	05JAN2021	128/11	1	No	O	NA/TCN	R (15JAN2021)	N/N	
16-55/ C4591001 1077 10771013	PSYCH	Depression/ WORSENING DEPRESSION	1	21AUG2020	12/C	2	No	O	NA/TC	N	N/N	
	INFEC	Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	2	26SEP2020	27/47	1	No	O	NA/TC	R (11NOV2020)	N/N	
16-55/ C4591001 1077 10771014	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE#	4	17FEB2021	3/4	1	Yes		NA	R (20FEB2021)	N/N	
16-55/ C4591001 1077 10771038	VASC	Haematoma/ HEMATOMA LEFT ARM	2	01OCT2020	30/18	2	No	O	NA	R (18OCT2020)	N/N	
16-55/ C4591001 1077 10771041	GENRL	Injection site pain/ PAIN AT INJECTION SITE- LEFT ARM	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ HEADACHE	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE- LEFT ARM	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1077 10771042	GENRL	Fatigue/ FATIGUE	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
16-55/ C4591001 1077 10771044	INFEC	Herpes zoster/ ZOSTER WITHOUT COMPLICATIONS	2	26SEP2020	19/12	2	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1077 10771045	GENRL	Fatigue/ FATIGUE	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
	METAB	Type 2 diabetes mellitus/ TYPE II DIABETES	2	09OCT2020	30/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1077 10771054	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE- LEFT ARM	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE- LEFT ARM	1	17AUG2020	1/4	1	Yes		NA	R (20AUG2020)	N/N
		Injection site swelling/ SWELLING AT INJECTION SITE- LEFT ARM	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	INFEC	Nasopharyngitis/ COMMON COLD	1	29AUG2020	13/7	1	No	O	NA	R (04SEP2020)	N/N	
	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	1	06SEP2020	21/11	2	No	O	NA/TC	R (16SEP2020)	N/N	
	REPRO	Polycystic ovaries/ POLYCYSTIC OVARIAN SYNDROME	2	01OCT2020	23/C	1	No	O	NA	N	N/N	
	METAB	Glucose tolerance impaired/ PRE-DIABETIC MELLITUS#	2	20FEB2021	165/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1077 10771058	GASTR	Nausea/ NAUSEA	1	21AUG2020	5/15	2	No	CD	NA	R (04SEP2020)	N/N	
		Vomiting/ INTERMITTENT VOMITING	1	21AUG2020	5/15	2	No	CD	NA	R (04SEP2020)	N/N	
16-55/ C4591001 1077 10771089	NERV	Dizziness/ DIZZINESS	2	12OCT2020	29/1	1	No	O	NA	R (12OCT2020)	N/N	
16-55/ C4591001 1077 10771120	PSYCH	Attention deficit hyperactivity disorder/ ATTENTION DEFICIT HYPERACTIVITY DISORDER	2	11FEB2021	149/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1077 10771126	PSYCH	Anxiety/ WORSENING ANXIETY	1	09SEP2020	15/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1077 10771128	METAB	Type 2 diabetes mellitus/ WORSENING OF TYPE II DIABETES	2	12JAN2021	118/C	1	No	O	NA/TC	N	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1077 10771132	GENRL	Injection site pain/ PAIN AT INJECTION SITE- LEFT ARM	1	31AUG2020	5/2	1	Yes		NA	R (01SEP2020)	N/N
16-55/ C4591001 1077 10771134	INFEC	Herpes zoster/ SHINGLES	2	23NOV2020	68/7	1	No	O	NA/TC	R (29NOV2020)	N/N
16-55/ C4591001 1077 10771137	GASTR	Diarrhoea/ DIARRHEA	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	28AUG2020	2/3	2	Yes		NA	R (30AUG2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE- LEFT ARM	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
		Injection site swelling/ SWELLING AT INJECTION SITE- LEFT ARM	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	30AUG2020	4/2	1	Yes		NA	R (31AUG2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN	1	30AUG2020	4/2	1	Yes		NA	R (31AUG2020)	N/N
	INJ&P	Tibia fracture/ LEFT TIBIAL PLATEAU FRACTURE	2	28JAN2021	134/C	2	No	O	NA/TC/TCN	RG	Y/N
16-55/ C4591001 1077 10771140	NEOPL	Skin papilloma/ SCALP VIRAL WART#	4	20FEB2021	17/7	1	No	O	NA/TCN	R (26FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1077 10771169	METAB	Hyperlipidaemia/ HYPERLIPIDEMIA	2	07OCT2020	17/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1077 10771171	PSYCH	Anxiety/ WORSENING ANXIETY	2	02OCT2020	10/C	1	No	O	NA/TC	N	N/N	
	REPRO	Postmenopausal haemorrhage/ POSTMENOPAUSAL BLEEDING	2	20NOV2020	59/11	2	No	O	NA/TCN	R (30NOV2020)	N/N	
16-55/ C4591001 1077 10771178	SKIN	Dermatitis contact/ POISON IVY RASH	2	10OCT2020	17/28	1	No	O	NA/TC	R (06NOV2020)	N/N	
16-55/ C4591001 1077 10771184	METAB	Hyperlipidaemia/ HYPERLIPIDEMIA	2	22OCT2020	28/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1077 10771188	NERV	Seizure like phenomena/ Subject reports Seizure like activity#	2	27FEB2021	157/1	2	No	O	NA	R (27FEB2021)	N/N	
16-55/ C4591001 1077 10771189	SKIN	Urticaria/ URTICARIA	1	08SEP2020	6/2	2	No	O	NA/TC	R (09SEP2020)	N/N	
	INFEC	Lyme disease/ LYME'S DISEASE	2	19OCT2020	28/7	1	No	O	NA/TC	R (25OCT2020)	N/N	
16-55/ C4591001	MUSC	Intervertebral disc protrusion/ HERNIATED DISK L5	2	07JAN2021	105/C	2	No	O	NA/TC	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1077 10771193 16-55/ C4591001	MUSC	Periarthritis/ LEFT SHOULDER ADHESIVE CAPSULITIS#	2	18JAN2021	118/C	2	No	O	NA/TC	N	N/N	
1077 10771201 16-55/ C4591001	GENRL	Fatigue/ FATIGUE	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
1077 10771209		Injection site pain/ PAIN AT INJECTION SITE- LEFT ARM	1	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/N	
16-55/ C4591001 1077 10771238	INFEC	Ear infection/ LEFT EAR INFECTION	1	02OCT2020	15/10	1	No	O	NA/TC	R (11OCT2020)	N/N	
16-55/ C4591001 1077 10771247	INFEC	Hepatitis A/ HEPATITIS A	1	30OCT2020	12/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1077 10771248	GENRL	Injection site pain/ PAIN AT INJECTION SITE- LEFT ARM	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N	
16-55/ C4591001 1077 10771261	INFEC	Impetigo/ IMPETIGO	2	01DEC2020	22/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001	NEOPL	Adenocarcinoma gastric/ INFILTRATING, POORLY	1	20AUG2020	23/C	3	No	O	P/W	N	Y/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1079 10791004		DIFFERENTIATED ADENOCARCINOMA - STOMACH									
16-55/ C4591001 1079 10791010	RESP	Productive cough/ Wet Cough	1	30JUL2020	1/1	1	No	O	NA	R (30JUL2020)	N/N
16-55/ C4591001 1079 10791143	SKIN	Rhinorrhoea/ Runny Nose Dermatitis contact/ Poison Ivy RASH (Arms and Legs)	1	30JUL2020	1/1	1	No	O	NA	R (30JUL2020)	N/N
16-55/ C4591001 1079 10791143	SKIN	Dermatitis contact/ Poison Ivy RASH (Arms and Legs)	1	08SEP2020	22/11	2	No	O	NA/TC/TCN	R (18SEP2020)	N/N
16-55/ C4591001 1079 10791199	NERV	Seizure/ Seizure#	2	03MAR2021	169/C	4	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1079 10791245	GENRL	Non-cardiac chest pain/ NON CARDIAC CHEST PAIN	2	05OCT2020	13/3	1	No	O	NA	R (07OCT2020)	N/N
16-55/ C4591001 1079 10791290	PSYCH	Attention deficit hyperactivity disorder/ ADHD (Difficulty Focusing)	2	18NOV2020	45/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1079 10791296	PSYCH	Attention deficit hyperactivity disorder/ ADHD diagnosis#	3	14JAN2021	24/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001	GASTR	Gastric ulcer haemorrhage/ Bleeding Ulcers (Stomach)	1	11AUG2020	2/C	2	No	O	NA/TC	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1080 10801002	GENRL	Injection site pain/ Injection site pain#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N	
16-55/ C4591001 1080 10801004	NERV	Headache/ Headache#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N	
16-55/ C4591001 1080 10801017	MUSC	Pain in extremity/ Sore arm#	3	24FEB2021	2/3	1	Yes		NA	R (26FEB2021)	N/N	
16-55/ C4591001 1080 10801032	GASTR	Abdominal discomfort/ GI Distress#	4	04MAR2021	1/1	1	Yes		NA	R (04MAR2021)	N/N	
		Diarrhoea/ Diarrhea#	4	04MAR2021	1/1	1	Yes		NA	R (04MAR2021)	N/N	
	NERV	Headache/ Headache#	4	05MAR2021	2/1	2	Yes		NA	R (05MAR2021)	N/N	
16-55/ C4591001 1080 10801033	GENRL	Chills/ Chills#	4	05MAR2021	2/1	1	Yes		NA	R (05MAR2021)	N/N	
		Fatigue/ Fatigue#	4	05MAR2021	2/1	1	Yes		NA	R (05MAR2021)	N/N	
16-55/ C4591001 1080 10801045	GASTR	Diarrhoea/ diarrhea	2	08SEP2020	1/1	1	Yes		NA/TC	R (08SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1080 10801051	GENRL	Nausea/ Nausea	2	08SEP2020	1/2	1	Yes		NA/TC	R (09SEP2020)	N/N	
		SKIN	Injection site pain/ Injection site pain - Right Arm	2	08SEP2020	1/3	1	Yes		NA/TC	R (10SEP2020)	N/N
			Erythema/ Redness in Right arm	2	09SEP2020	2/5	1	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Chest discomfort/ Chest Pressure	1	22AUG2020	6/2	2	No	O	NA/TC	R (23AUG2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N	
	GENRL	Injection site erythema/ Redness at injection site	2	09SEP2020	1/6	1	Yes		NA	R (14SEP2020)	N/N	
	16-55/ C4591001 1080 10801059	PSYCH	Injection site pain/ Soreness at injection site	2	09SEP2020	1/7	1	Yes		NA	R (15SEP2020)	N/N
			Anxiety/ Anxiety	2	SEP2020	1/C	2	No	O	NA/TC	N	N/N
			INFECTION	Appendicitis/ Appendicitis	2	09FEB2021	153/1	3	No	O	NA/TCN	R (09FEB2021)
	16-55/ C4591001 1080 10801068	GASTR	Nausea/ Nausea	2	10SEP2020	1/6	1	Yes		NA	R (15SEP2020)	N/N
GENRL	Chills/ Chills	2	10SEP2020	1/6	2	Yes		NA	R (15SEP2020)	N/N		

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	2	10SEP2020	1/6	2	Yes		NA	R (15SEP2020)	N/N
	REPRO	Menstruation irregular/ Irregular Menses	2	10SEP2020	1/C	1	No	O	NA	N	N/N
	GASTR	Noninfective gingivitis/ Inflamed Gums	2	14SEP2020	5/2	1	No	O	NA	R (15SEP2020)	N/N
16-55/ C4591001 1080 10801081	GENRL	Injection site pain/ Pain at injection site#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1080 10801082	GENRL	Injection site pain/ Soreness at injection site	2	16SEP2020	3/7	1	Yes		NA	R (22SEP2020)	N/N
		Pyrexia/ Fever	2	16SEP2020	3/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1080 10801096	GENRL	Chills/ Chills	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1080 10801100	GENRL	Injection site pain/ Injection site arm pain#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1080 10801109	GENRL	Pyrexia/ Fever	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1080 10801114	MUSC	Pain in extremity/ injection arm pain#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N	
	NERV	Headache/ headache#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N	
16-55/ C4591001 1080 10801117	GENRL	Injection site pain/ Soreness at injection site	1	28AUG2020	1/4	2	Yes		NA	R (31AUG2020)	N/N	
16-55/ C4591001 1080 10801131	GENRL	Pyrexia/ fever#	4	19FEB2021	2/2	2	Yes		NA/TC	R (20FEB2021)	N/N	
16-55/ C4591001 1080 10801153	MUSC	Pain in extremity/ Sore arm#	3	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N	
16-55/ C4591001 1080 10801159	GASTR	Diarrhoea/ Diarrhea	2	01OCT2020	7/1	1	No	O	NA	R (01OCT2020)	N/N	
	GENRL	Pain/ Body Aches#	3	17FEB2021	2/2	2	Yes		NA	R (18FEB2021)	N/N	
	GENRL	Pyrexia/ Low-grade fever 99.3#	4	12MAR2021	2/1	2	Yes		NA	R (12MAR2021)	N/N	
16-55/ C4591001 1080 10801180	GENRL	Injection site pain/ Injection site pain#	3	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1080 10801183	GENRL	Injection site mass/ Lump at injection site	2	02OCT2020	1/4	2	Yes		NA	R (05OCT2020)	N/N
	GENRL	Chills/ Chills	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
		Fatigue/ Fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
	NERV	Headache/ Headache	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1080 10801212	GENRL	Injection site pain/ Pain at injection site#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	NERV	Headache/ Headache#	3	17DEC2020	1/4	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
		Pain/ Body Aches#	4	08JAN2021	1/2	2	Yes		NA	R (09JAN2021)	N/N
		Pyrexia/ Fever of 100.8 F#	4	08JAN2021	1/2	2	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1080 10801221	GENRL	Fatigue/ fatigue#	3	19JAN2021	1/3	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Pain/ body aches#	3	20JAN2021	2/2	2	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001	GASTR	Nausea/ Nausea#	3	07FEB2021	5/1	2	Yes		NA	R (07FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1081 10811009		Vomiting/ Vomiting#	3	07FEB2021	5/2	2	Yes		NA	R (08FEB2021)	N/N	
16-55/ C4591001 1081 10811012	GENRL	Injection site pain/ pain at site of injection (left deltoid)#	3	01MAR2021	1/2	1	Yes		NA	R (02MAR2021)	N/N	
	GASTR	Diarrhoea/ diarrhea (one episode)#	3	02MAR2021	2/1	1	Yes		NA	R (02MAR2021)	N/N	
	GENRL	Chills/ chills#	3	02MAR2021	2/1	1	Yes		NA	R (02MAR2021)	N/N	
		Pyrexia/ fever (101.9)#	3	02MAR2021	2/2	1	Yes		NA/TC	R (03MAR2021)	N/N	
16-55/ C4591001 1081 10811036	INFEC	Appendicitis/ Appendicitis	1	21AUG2020	9/3	3	No	O	NA/TC/TCN	R (23AUG2020)	Y/N	
	BLOOD	Anaemia/ Anemia	2	02NOV2020	61/C	2	No	O	NA	N	N/N	
16-55/ C4591001 1081 10811046	METAB	Diabetic ketoacidosis/ Diabetic Ketoacidosis	2	17SEP2020	9/2	3	No	O	NA	R (18SEP2020)	Y/N	
16-55/ C4591001 1081 10811075	RESP	Paranasal sinus discomfort/ sinus nasal pressure	2	03OCT2020	24/2	1	No	O	NA/TC	R (04OCT2020)	N/N	
16-55/ C4591001	GENRL	Fatigue/ fatigue	2	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1081 10811085	NERV	Headache/ headache	2	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1081 10811086	GENRL	Malaise/ Malaise#	3	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
		Pyrexia/ Fever#	3	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	12MAR2021	2/1	1	Yes		NA	R (12MAR2021)	N/N
16-55/ C4591001 1081 10811096	RENAL	Nephrolithiasis/ Kidney Stone	1	06SEP2020	13/1	2	No	O	NA	R (06SEP2020)	N/N
16-55/ C4591001 1081 10811119	NERV	Syncope/ Episode of Syncopy	2	29SEP2020	15/1	1	No	O	NA	R (29SEP2020)	N/N
16-55/ C4591001 1081 10811127	GASTR	Diarrhoea/ Diarrhea#	4	13MAR2021	2/C	1	Yes		NA	N	N/N
	GENRL	Chills/ Chills#	4	13MAR2021	2/1	1	Yes		NA	R (13MAR2021)	N/N
		Pyrexia/ Fever#	4	13MAR2021	2/1	1	Yes		NA	R (13MAR2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	13MAR2021	2/C	1	Yes		NA	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1081 10811133	INJ&P	Foreign body in eye/ Foreign body eye	2	04OCT2020	13/1	1	No	O	NA/TC	R (04OCT2020)	N/N	
16-55/ C4591001 1081 10811134	NERV	Headache/ Headache	2	12OCT2020	21/2	1	No	O	NA	R (13OCT2020)	N/N	
	RESP	Oropharyngeal pain/ Sore throat	2	12OCT2020	21/2	1	No	O	NA	R (13OCT2020)	N/N	
16-55/ C4591001 1081 10811135	VASC	Essential hypertension/ New onset Essential Hypertension*		31AUG2020	1/C	2	No	O	NA/TC	RG	N/N	
	CARD	Myocardial infarction/ Myocardial Infarction	2	21OCT2020	30/8	4	No	O	NA/TC/TCN	RS (28OCT2020)	Y/N	
	METAB	Type 2 diabetes mellitus/ Type II Diabetes Mellitus	2	27OCT2020	36/C	3	No	O	NA/TC	RG	Y/N	
	METAB	Hyperlipidaemia/ New onset Unspecified Hyperlipidemia	2	29OCT2020	38/C	2	No	O	NA/TC	RG	N/N	
	CARD	Coronary artery disease/ Coronary Artery disease	2	04NOV2020	44/C	2	No	O	NA/TC/TCN	N	N/N	
16-55/ C4591001 1081 10811141	NERV	Migraine/ Migraine	2	07DEC2020	77/1	2	No	O	NA	R (07DEC2020)	N/N	
16-55/ C4591001 1081 10811194	CARD	Myocardial infarction/ Myocardial Infarction	2	04NOV2020	37/1	4	No	O	NA/W	F (04NOV2020)	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1081 10811196	INFEC	Hordeolum/ left eye lower lid sty	2	03OCT2020	3/11	1	No	O	NA/TC	R (13OCT2020)	N/N	
16-55/ C4591001 1081 10811198	GENRL	Chills/ Chills	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N	
		Pain/ Body Aches	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N	
		Pyrexia/ Fever	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N	
16-55/ C4591001 1081 10811206	GENRL	Pyrexia/ Fever	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N	
	NERV	Headache/ Headache	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N	
16-55/ C4591001 1082 10821011	INJ&P	Ligament rupture/ left knee ACL rupture#	2	17FEB2021	176/8	2	No	O	NA	R (24FEB2021)	N/N	
16-55/ C4591001 1082 10821028	HEPAT	Cholecystitis/ cholecystitis	2	05JAN2021	134/1	2	No	O	NA/TC	R (05JAN2021)	N/N	
16-55/ C4591001 1082 10821083	CARD	Myocardial infarction/ myocardial infarction	2	28OCT2020	62/8	4	No	O	NA	R (04NOV2020)	Y/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1082 10821149	MUSC	Neck pain/ neck pain	1	21SEP2020	19/C	1	No	O	NA/TC	N	N/N	
	NEOPL	Malignant melanoma/ Malignant Melanoma (etiology unknown)	2	24NOV2020	63/C	3	No	O	NA/W	N	Y/N	
16-55/ C4591001 1082 10821163	CARD	Ventricular tachycardia/ paroxysmal ventricular tachycardia (etiology unknown)	2	06NOV2020	26/2	2	No	O	NA	R (07NOV2020)	N/N	
16-55/ C4591001 1082 10821195	INFEC	Tooth abscess/ dentoalveolar abscess tooth #15	1	20OCT2020	12/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1082 10821198	INFEC	Abscess/ abscess of lower lip	2	24NOV2020	23/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1083 10831001	INJ&P	Fall/ Fall	2	26AUG2020	6/1	2	No	O	NA	R (26AUG2020)	N/N	
		Fibula fracture/ Fibula fracture	2	26AUG2020	6/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1083 10831004	SKIN	Hangnail/ Hang Nail	1	31JUL2020	3/8	1	No	O	NA/TC	R (07AUG2020)	N/N	
16-55/ C4591001	INV	Heart rate increased/ Rapid Heart Beat	1	31JUL2020	2/1	1	No	O	NA	R (31JUL2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1083 10831013	MUSC	Scoliosis/ Increased Back Pain secondary to Scoliosis	2	06OCT2020	48/11	2	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1083 10831017	GENRL	Injection site pain/ Injection Site Pain-Left Arm#	2	26FEB2021	192/3	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001 1083 10831029	NERV	Headache/ Headache#	3	27FEB2021	2/1	2	Yes		NA/TC	R (27FEB2021)	N/N
	CARD	Atrial fibrillation/ Paroxysmal Atrial fibrillation with rapid ventricular response	1	23AUG2020	20/17	3	No	O	P/TC/TCN	R (08SEP2020)	Y/N
	CARD	Left ventricular hypertrophy/ Left Ventricular Hypertrophy	1	24AUG2020	21/C	1	No	O	NA/TC	N	N/N
	VASC	Hypertension/ Hypertension	1	24AUG2020	21/C	1	No	O	NA/TC	N	N/N
	INJ&P	Skin laceration/ Laceration-Left Index Finger	1	01SEP2020	29/15	2	No	O	NA/TCN	R (15SEP2020)	N/N
	CARD	Atrial flutter/ Atrial Flutter	1	02SEP2020	30/7	3	No	O	NA/TC/TCN	R (08SEP2020)	N/N
	CARD	Myocardial infarction/ Prior Septual Myocardinal Infarction	1	08SEP2020	36/1	1	No	O	NA	R (08SEP2020)	N/N
	CARD	Left atrial enlargement/ Left Atrial Enlargement	1	09SEP2020	37/C	1	No	O	NA	N	N/N
		Mitral valve incompetence/ Mitral Regurgitation	1	09SEP2020	37/C	1	No	O	NA	RG	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1083 10831040	EAR	Mitral valve prolapse/ Bileaflet mitral valve prolapse	1	09SEP2020	37/C	1	No	O	NA	N	N/N
		Ear pain/ Ear Pain	1	04DEC2020	123/C	1	No	O	NA/TC	N	N/N
	PSYCH	Anxiety/ Situational Anxiety	2	27AUG2020	3/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1083 10831046	NEOPL	Uterine leiomyoma/ Worsening of Uterine Fibroids	2	16SEP2020	23/9	1	No	O	NA/TCN	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site-Right	2	26AUG2020	2/2	1	Yes		NA/TC	R (27AUG2020)	N/N
	NEOPL	Benign uterine neoplasm/ Benign Uterine Mass	2	07DEC2020	105/1	2	No	O	NA/TCN	R (07DEC2020)	N/N
16-55/ C4591001 1083 10831057	INFEC	Diverticulitis/ Diverticulitis Flare	1	09AUG2020	5/11	2	No	O	NA	R (19AUG2020)	N/N
16-55/ C4591001 1083 10831060	GASTR	Abdominal pain/ Worsening of Abdominal Pain	1	14AUG2020	9/11	4	No	O	NA/TC	R (24AUG2020)	N/N
	INJ&P	Diverticular perforation/ Ruptured diverticulum	1	14AUG2020	9/11	4	No	O	P/TC/TCN	R (24AUG2020)	Y/N
		Postoperative ileus/ Post Operative Ileus	1	18AUG2020	13/6	2	No	O	NA/TC	R (23AUG2020)	N/N
GASTR	Small intestinal obstruction/ Small Bowel Obstruction	1	20AUG2020	15/1	3	No	O	NA/TC/TCN	R (20AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1083 10831068	INFEC	Cellulitis/ Phlegmon Formation	1	20AUG2020	15/1	3	No	O	NA/TC/TCN	R (20AUG2020)	N/N	
		Diverticulitis/ Diverticulitis	1	20AUG2020	15/6	4	No	O	NA/TC/TCN	R (25AUG2020)	N/N	
	INFEC	Diverticulitis/ Diverticulitis	1	26AUG2020	21/C	3	No	O	NA/TC	RG	N/N	
	GENRL	Fatigue/ Fatigue#	3	07MAR2021	2/2	1	Yes		NA	R (08MAR2021)	N/N	
		Injection site pain/ Injection Site Pain-Left#	3	07MAR2021	2/2	1	Yes		NA	R (08MAR2021)	N/N	
	MUSC	Myalgia/ Muscle Aches#	3	07MAR2021	2/2	1	Yes		NA	R (08MAR2021)	N/N	
	NERV	Headache/ Slight Headache#	3	07MAR2021	2/2	1	Yes		NA	R (08MAR2021)	N/N	
	INFEC	Cellulitis/ Left Ear Cellulitis	2	20NOV2020	82/C	1	No	O	NA/TC	N	N/N	
	IMMUN	Drug hypersensitivity/ Allergic Reaction to Ear Drops-left ear	2	22NOV2020	84/C	1	No	CD	NA	N	N/N	
	16-55/ C4591001 1083 10831070	MUSC	Tendonitis/ Tendentitis-Right Knee#	2	05MAR2021	187/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1083 10831074	GASTR	Diarrhoea/ Diarrhea	1	16AUG2020	7/46	2	No	O	NA/TC	R (30SEP2020)	N/N	
	GASTR	Toothache/ Toothache	1	18AUG2020	9/32	2	No	O	NA/TC	R (18SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	IMMUN	Drug hypersensitivity/ Oral Penicillin Reaction	1	25AUG2020	16/3	1	No	O	NA	R (27AUG2020)	N/N	
	GASTR	Pancreatic failure/ Exocrine pancreatic insufficiency	2	12SEP2020	13/C	1	No	O	NA	N	N/N	
	GASTR	Submaxillary gland enlargement/ Swollen Submandibular Gland Neck Right Side#	3	08JAN2021	1/2	1	No	O	NA	R (09JAN2021)	N/N	
	GASTR	Submaxillary gland enlargement/ Submandibular Gland facial swelling- Right side#	4	28JAN2021	1/2	1	No	O	NA	R (29JAN2021)	N/N	
	NERV	Headache/ Headache#	3	28JAN2021	21/3	2	Yes		NA/TC	R (30JAN2021)	N/N	
16-55/ C4591001 1083 10831084	INJ&P	Meniscus injury/ Torn Meniscus-Right	1	17AUG2020	7/C	1	No	O	NA/TC/TCN	RG	N/N	
16-55/ C4591001 1083 10831086	MUSC	Arthralgia/ Wrist Pain	1	29AUG2020	19/C	1	No	O	NA/TC	RG	N/N	
	IMMUN	Seasonal allergy/ Worsening of Seasonal Allergies	2	26DEC2020	118/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1083 10831098	MUSC	Neck pain/ Neck Pain	1	17AUG2020	5/4	2	No	O	NA/TC	R (20AUG2020)	N/N	
	NERV	Headache/ Headache	1	18AUG2020	6/3	2	No	O	NA/TC	R (20AUG2020)	N/N	
16-55/ C4591001	INV	Body temperature increased/ Elevated Temperature	1	14AUG2020	2/1	1	Yes		NA	R (14AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1083 10831101	GASTR	Abdominal pain upper/ Intermittent Pain-Left Upper Quadrant	1	19AUG2020	7/C	2	No	O	NA/TC	RG	N/N	
	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	1	19AUG2020	7/42	2	No	O	NA/TC	R (29SEP2020)	N/N	
	GASTR	Constipation/ Constipation	2	29SEP2020	29/C	1	No	O	NA	RG	N/N	
		Gastrointestinal disorder/ Gastrointestinal Issue	2	29SEP2020	29/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1083 10831105	GASTR	Cheilitis/ Cheilitis	2	02OCT2020	25/15	1	No	O	NA	R (16OCT2020)	N/N	
16-55/ C4591001 1083 10831113	NERV	Syncope/ Syncope*		18AUG2020	1/1	1	No	O	NA	R (18AUG2020)	N/N	
16-55/ C4591001 1083 10831118	MUSC	Myalgia intercostal/ Intercostal Muscle Pain-Left	2	07DEC2020	91/4	2	No	O	NA/TC	R (10DEC2020)	N/N	
16-55/ C4591001 1083 10831119	GASTR	Toothache/ Toothache -Lower Left Side Wisdom tooth	1	04SEP2020	18/19	2	No	O	NA/TC	R (22SEP2020)	N/N	
	SURG	Wisdom teeth removal/ Tooth Extraction-Lower Left Side Wisdom tooth	2	22SEP2020	13/1	2	No	O	NA/TC	R (22SEP2020)	N/N	
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1083 10831122		Injection site pain/ Injection Site Soreness-Left#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1083 10831123	GENRL	Injection site pain/ Pain at injection site*		19AUG2020	1/4	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	09SEP2020	22/2	1	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ Pain at Injection Site	1	09SEP2020	22/4	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ Headache	1	09SEP2020	22/2	1	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1083 10831124	VASC	Varicose vein/ pain secondary to varicose vein in left thigh	2	06OCT2020	28/15	1	No	O	NA/TC	R (20OCT2020)	N/N
	INJ&P	Stress fracture/ StressFracture-Right Foot	2	14JAN2021	128/C	1	No	O	NA	RG	N/N
	NERV	Headache/ Headache#	2	06MAR2021	179/3	1	Yes		NA/TC	R (08MAR2021)	N/N
	BLOOD	Lymphadenopathy/ Enlarged Lymph Node-Left Side#	3	07MAR2021	2/C	1	Yes		NA/TC	RG	N/N
	GENRL	Fatigue/ Fatigue#	3	07MAR2021	2/2	1	Yes		NA/TC	R (08MAR2021)	N/N
		Injection site erythema/ Injection Site Redness-5.5 centimeters#	3	07MAR2021	2/C	2	Yes		NA	RG	N/N
		Injection site pain/ Injection Site Pain-Left#	3	07MAR2021	2/2	1	Yes		NA	R (08MAR2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1083 10831127	MUSC	Myalgia/ Muscle Aches#	3	07MAR2021	2/2	1	Yes		NA/TC	R (08MAR2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness-Left Arm#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1083 10831140	NERV	Headache/ Headache	1	10SEP2020	21/3	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1083 10831142	GENRL	Chills/ Chills	2	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N
		Fatigue/ Fatigue	2	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N
		Pain/ Body Aches	2	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N
		Pyrexia/ Fever	2	11SEP2020	2/2	2	Yes		NA/TC	R (12SEP2020)	N/N
		Sinusitis/ Sinus Infection	2	16NOV2020	68/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1083 10831142	PSYCH	Panic attack/ Worsening of Panic Attacks	1	31AUG2020	8/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1083 10831143	SURG	Dental implantation/ Upper Dental Implant Surgery-Cosmetic	2	01OCT2020	18/1	1	No	O	NA/TC	R (01OCT2020)	N/N
	MUSC	Pain in extremity/ Toe Pain- Right 5th toe	2	11NOV2020	59/C	1	No	O	NA	RG	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1083 10831148	EAR	Vertigo/ Vertigo	2	13JAN2021	122/8	1	No	O	NA/TC	R (20JAN2021)	N/N	
	NERV	Headache/ Headache#	3	06MAR2021	1/C	1	Yes		NA	RG	N/Y	
16-55/ C4591001 1083 10831152	SKIN	Dermatitis acneiform/ Acneiform Rash-Torso,Thighs,Upper Arms	1	03SEP2020	10/38	1	No	O	NA/TC	R (10OCT2020)	N/N	
	SKIN	Eczema/ eczema	1	01OCT2020	38/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1083 10831162	GASTR	Abdominal pain upper/ Worsening of Right Upper Quadrant Pain	1	14SEP2020	20/C	1	No	O	NA	RG	N/N	
	GASTR	Vomiting/ Vomiting	2	18SEP2020	3/3	2	No	O	NA	R (20SEP2020)	N/N	
	PREG	Abortion spontaneous/ Miscarriage	2	04DEC2020	80/2	2	No	O	NA	R (05DEC2020)	Y/N	
16-55/ C4591001 1083 10831163	GENRL	Pain/ Body Aches#	3	25JAN2021	21/2	1	Yes		NA	R (26JAN2021)	N/N	
		Pyrexia/ Fever 100.4#	3	25JAN2021	21/2	1	Yes		NA	R (26JAN2021)	N/N	
16-55/ C4591001 1083 10831179	GASTR	Diarrhoea/ Diarrhea-Intermittent	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1083 10831181	MUSC	Back pain/ Worsening of Lumbar Back Pain	1	18SEP2020	19/C	1	No	O	NA/TC	RG	N/N	
	GASTR	Intra-abdominal fluid collection/ Water Retention in the abdomen	2	01DEC2020	72/C	1	No	O	NA/TC	RG	N/N	
	MUSC	Muscle spasms/ Chest Muscle Spasm causing Chest Pain	2	01DEC2020	72/5	1	No	O	NA	R (05DEC2020)	N/N	
	INFEC	Urinary tract infection/ Urinary tract infection	1	01SEP2020	2/7	1	No	O	NA/TC	R (07SEP2020)	N/N	
16-55/ C4591001 1083 10831194	INFEC	Oral herpes/ Lip Fever Blister	2	03DEC2020	74/22	2	No	O	NA/TC	R (24DEC2020)	N/N	
	CARD	Atrial fibrillation/ New Onset Atrial Fibrillation with rapid ventricular response	2	26OCT2020	34/C	2	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1083 10831197		Mitral valve incompetence/ Trivial Mitral Regurgitation	2	26OCT2020	34/C	1	No	O	NA/TC	N	N/N	
		Palpitations/ Heart Palpitations	2	26OCT2020	34/3	2	No	O	NA/TC	R (28OCT2020)	N/N	
	GENRL	Chest pain/ Chest Pain	2	26OCT2020	34/3	2	No	O	NA/TC	R (28OCT2020)	N/N	
	BLOOD	Lymphadenitis/ Inflamed lymph nodes left breast	1	22SEP2020	19/C	1	No	O	NA	N	N/N	
	INV	Mammogram abnormal/ Abnormal breast tissue on mammogram-left breast	1	22SEP2020	19/C	1	No	O	NA	N	N/N	
	GENRL	Fatigue/ Fatigue	1	22OCT2020	49/2	1	Yes		NA	R (23OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1083 10831205	ENDO	Pyrexia/ Low Grade Temperature	1	22OCT2020	49/2	1	Yes		NA	R (23OCT2020)	N/N	
		Autoimmune thyroiditis/ Hashimotos	2	19NOV2020	29/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1083 10831207	RENAL	Pollakiuria/ Urinary Frequency	1	29SEP2020	21/3	1	No	O	NA/TC	R (01OCT2020)	N/N	
	PSYCH	Insomnia/ Trouble Sleeping	2	01NOV2020	32/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1083 10831207	PSYCH	Depression/ Worsening of Situational Depression	2	04NOV2020	37/C	1	No	O	NA/TC	RG	N/N	
		GENRL	Injection site pain/ Left Arm Pain at Injection Site	2	03OCT2020	2/4	2	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1083 10831249	NERV	Pyrexia/ Fever 101.0 degree fahrenheit	2	03OCT2020	2/3	2	Yes		NA/TC	R (05OCT2020)	N/N	
		Headache/ Headache	2	03OCT2020	2/3	2	Yes		NA/TC	R (05OCT2020)	N/N	
16-55/ C4591001 1083 10831254	GENRL	Chills/ Chills	1	14OCT2020	23/2	2	Yes		NA/TC	R (15OCT2020)	N/N	
16-55/ C4591001 1083 10831262	INJ&P	Contusion/ Bruised Right Knee	2	29OCT2020	15/24	1	No	O	NA	R (21NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1083 10831268	MUSC	Fall/ Fall	2	29OCT2020	15/1	1	No	O	NA	R (29OCT2020)	N/N	
		Joint injury/ Ankle Strain-Left	2	29OCT2020	15/5	1	No	O	NA	R (02NOV2020)	N/N	
		Arthralgia/ Knee Pain-Right	2	02NOV2020	19/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1083 10831272	MUSC	Arthralgia/ Wrist Pain-Right	2	02JAN2021	80/C	1	No	O	NA/TC	RG	N/N	
	RESP	Nasal discomfort/ Bilateral Nostril Irritation	1	22OCT2020	2/23	1	No	O	NA	R (13NOV2020)	N/N	
16-55/ C4591001 1083 10831276	GASTR	Vomiting/ Vomiting	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N	
	GENRL	Pyrexia/ Fever-102.0	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N	
16-55/ C4591001 1083 10831278	GENRL	Pyrexia/ Low Grade Temperature 99.0 Fahrenheit	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N	
		Injection site pain/ Site Injection Pain-Left Arm#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N	
16-55/ C4591001	GENRL	Pyrexia/ Fever-100.3 Fahrenheit	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1083 10831281	MUSC	Arthralgia/ Joint Pain-Bilateral Shoulders, Bilateral Hips, Right Ankle and Right Elbow	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N	
16-55/ C4591001 1083 10831282	INJ&P	Skin laceration/ Third Finger Laceration- Left Hand	1	30OCT2020	9/1	1	No	O	NA/TC	R (30OCT2020)	N/N	
	GENRL	Injection site pain/ Site Injection Pain-Left Eye#	2	23DEC2020	42/2	1	Yes		NA	R (24DEC2020)	N/N	
16-55/ C4591001 1083 10831284	GENRL	Fatigue/ Fatigue#	2	02MAR2021	111/9	1	Yes		NA	R (10MAR2021)	N/N	
		Injection site bruising/ Injection Site Bruising-Left#	2	02MAR2021	111/9	1	Yes		NA	R (10MAR2021)	N/N	
		Injection site pain/ Injection Site Pain-Left#	2	02MAR2021	111/2	1	Yes		NA	R (03MAR2021)	N/N	
	SKIN	Hyperhidrosis/ Hyperhidrosis#	2	02MAR2021	111/9	1	Yes		NA	R (10MAR2021)	N/N	
16-55/ C4591001 1084 10841004	SKIN	Rash/ rash all over body	1	14AUG2020	8/13	2	No	O	NA/TC	R (26AUG2020)	N/N	
	GASTR	Dental caries/ tooth cavity	2	OCT2020	35/	2	No	O	NA/TC	R (20JAN2021)	N/N	
16-55/ C4591001 1084 10841056	GENRL	Fatigue/ Fatigue	2	26AUG2020	1/8	1	Yes		NA	R (02SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1084 10841062	INJ&P	Fall/ Fall	1	28AUG2020	22/1	1	No	O	NA	R (28AUG2020)	N/N	
	MUSC	Arthralgia/ BILATERAL ANKLE PAIN	1	28AUG2020	22/30	2	No	O	NA	R (26SEP2020)	N/N	
16-55/ C4591001 1084 10841090	INFEC	Tooth infection/ Left Upper Tooth Infection	2	28SEP2020	32/15	1	No	O	NA/TC	R (12OCT2020)	N/N	
16-55/ C4591001 1084 10841095	INFEC	Ear infection/ left ear infection#	2	09FEB2021	163/C	2	No	O	NA/TC	N	N/N	
	SKIN	Rash/ generalized rash on torso#	2	20FEB2021	174/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1084 10841099	PSYCH	Anxiety/ anxiety	2	OCT2020	32/C	2	No	O	NA/TC	RG	N/N	
	GASTR	Nausea/ nausea#	3	08FEB2021	20/3	1	No	O	NA	R (10FEB2021)	N/N	
16-55/ C4591001 1084 10841100	PSYCH	Depression/ increased depression#	2	18DEC2020	108/C	1	No	O	NA/TC/TCN	N	N/N	
16-55/ C4591001 1084 10841102	MUSC	Osteoarthritis/ OSTEO ARTHRITIS	2	15SEP2020	16/C	1	No	O	NA	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	NERV	Radiculopathy/ radiculopathy (femoral nerve)	2	15SEP2020	16/C	2	No	O	NA	N	N/N	
16-55/ C4591001 1084 10841107	INFEC	Sinusitis/ Sinusitis	2	28SEP2020	29/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1084 10841117	INFEC	Cellulitis/ Cellulitis FRONT OF ABDOMEN	1	24AUG2020	15/3	2	No	O	NA	R (26AUG2020)	N/N	
	GASTR	Diarrhoea/ Diarrhea	2	13SEP2020	14/7	1	Yes		NA	R (19SEP2020)	N/N	
	INV	Alanine aminotransferase increased/ Elevated ALT#	3	18JAN2021	6/C	1	No	O	NA	N	N/N	
		Aspartate aminotransferase increased/ Elevated AST#	3	18JAN2021	6/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1084 10841118	INV	Weight decreased/ Weight-Loss	2	01SEP2020	5/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1084 10841121	NERV	Ageusia/ LOSS OF TASTE	2	05SEP2020	2/7	1	Yes		NA	R (11SEP2020)	N/N	
16-55/ C4591001 1084 10841136	MUSC	Pain in jaw/ Right Jaw Pain	1	12AUG2020	1/2	2	Yes		NA	R (13AUG2020)	N/N	
16-55/ C4591001	INFEC	Appendicitis/ Appendicitis	2	20DEC2020	110/3	3	No	O	NA/TC/TCN	R (22DEC2020)	Y/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1084 10841141	GENRL	Injection site pain/ Injection Site Pain	1	15AUG2020	2/2	1	Yes	NA	NA	R (16AUG2020)	N/N
1084 10841182	GENRL	Injection site pain/ Injection Site Pain	1	17AUG2020	1/1	1	Yes	NA	NA	R (17AUG2020)	N/N
1084 10841189	GASTR	Vomiting/ Vomiting	1	17AUG2020	1/1	1	Yes	NA	NA	R (17AUG2020)	N/N
1084 10841197	GENRL	Chills/ Chills	1	17AUG2020	1/1	1	Yes	NA	NA	R (17AUG2020)	N/N
		Fatigue/ Fatigue	1	17AUG2020	1/4	2	Yes	NA	NA	R (20AUG2020)	N/N
		Injection site pain/ Injection Site Pain	1	17AUG2020	1/2	2	Yes	NA	NA	R (18AUG2020)	N/N
	MUSC	Myalgia/ Muscle Pain	1	17AUG2020	1/2	2	Yes	NA	NA	R (18AUG2020)	N/N
	NERV	Headache/ Headache	1	17AUG2020	1/2	1	Yes	NA	NA	R (18AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	18AUG2020	2/1	1	Yes	NA	NA	R (18AUG2020)	N/N
	GENRL	Chills/ Chills	1	18AUG2020	2/1	2	Yes	NA	NA	R (18AUG2020)	N/N
	MUSC	Arthralgia/ Joint Pain	1	18AUG2020	2/1	2	Yes	NA/TC	NA/TC	R (18AUG2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1084 10841200 16-55/ C4591001 1084 10841208 16-55/ C4591001 1084 10841209 16-55/ C4591001 1084 10841215	GENRL	Injection site pain/ Injection Site Pain	1	19AUG2020	3/3	1	Yes		NA	R (21AUG2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	1	18AUG2020	2/1	2	Yes		NA	R (18AUG2020)	N/N	
	NERV	Headache/ Headache	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	1	19AUG2020	3/1	1	Yes		NA	R (19AUG2020)	N/N	
	NERV	Headache/ Headache	1	19AUG2020	3/1	3	Yes		NA	R (19AUG2020)	N/N	
	GENRL	Injection site erythema/ Redness at Injection Site	1	18AUG2020	2/4	1	Yes		NA	R (21AUG2020)	N/N	
			Injection site pain/ Injection Site Pain	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N
	INFEC	Pharyngitis streptococcal/ Strep Throat	2	16SEP2020	8/8	2	No	O	NA/TC	R (23SEP2020)	N/N	
	VASC	Hypertension/ Hypertension#	2	10JAN2021	124/C	2	No	O	NA/TC	N	N/N	
GENRL	Injection site pain/ Injection Site Pain	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N		

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1084 10841228	GASTR	Diarrhoea/ Diarrhea	1	20AUG2020	2/1	2	Yes		NA	R (20AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	20AUG2020	2/3	1	Yes		NA	R (22AUG2020)	N/N
		Injection site erythema/ Redness at Injection Site	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N
		Injection site pain/ Injection Site Pain	1	20AUG2020	2/1	2	Yes		NA	R (20AUG2020)	N/N
	NERV	Headache/ Headache	1	21AUG2020	3/2	1	Yes		NA	R (22AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	22AUG2020	4/1	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	23AUG2020	5/3	2	Yes		NA	R (25AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	24AUG2020	6/1	2	Yes		NA	R (24AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	25AUG2020	7/1	1	Yes		NA	R (25AUG2020)	N/N
		Vomiting/ Vomiting	1	25AUG2020	7/1	1	Yes		NA	R (25AUG2020)	N/N
	GENRL	Chills/ Chills	1	25AUG2020	7/1	1	Yes		NA	R (25AUG2020)	N/N
	NERV	Headache/ Headache	1	25AUG2020	7/1	2	Yes		NA	R (25AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	11SEP2020	24/4	1	No	O	NA/TC	R (14SEP2020)	N/N
	16-55/ C4591001	NERV	Headache/ Headache	1	21AUG2020	3/3	1	Yes		NA	R (23AUG2020)

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1084 10841241 16-55/ C4591001 1084 10841268	INFEC	Urinary tract infection/ Urinary Tract Infection	2	11DEC2020	92/3	2	No	O	NA/TC	R (13DEC2020)	N/N	
16-55/ C4591001 1084 10841269	INFEC	Urinary tract infection/ Urinary Tract Infection	2	29SEP2020	19/9	2	No	O	NA/TC	R (07OCT2020)	N/N	
16-55/ C4591001 1084 10841283	SKIN	Rash/ Left Inner Forearm Rash#	3	14JAN2021	2/4	1	Yes		NA/TC	R (17JAN2021)	N/N	
16-55/ C4591001 1084 10841287	MUSC	Pain in extremity/ right hand and foot pain	2	23OCT2020	29/4	2	No	O	NA/TC	R (26OCT2020)	N/N	
16-55/ C4591001 1084 10841287	METAB	Vitamin D deficiency/ vitamin d deficiency#	3	15FEB2021	18/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1084 10841294	INJ&P	Fall/ Fall	1	04SEP2020	10/1	2	No	O	NA/TC	RS (04SEP2020)	N/N	
16-55/ C4591001 1084 10841301	INJ&P	Ligament sprain/ Left Ankle Sprain Ligament sprain/ Right Ankle Sprain	1 2	04SEP2020 14OCT2020	10/C 29/C	1 2	No No	O O	NA/TC NA	N N	N/N N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1084 10841306	NERV	Headache/ Headache in Frontal Lobe	2	12OCT2020	27/1	1	No	O	NA	R (12OCT2020)	N/N	
16-55/ C4591001 1084 10841307	GENRL	Peripheral swelling/ Bilateral Leg Swelling	1	29AUG2020	4/8	1	No	O	NA	R (05SEP2020)	N/N	
16-55/ C4591001 1084 10841309	NERV	Headache/ Headache	1	29AUG2020	2/1	1	No	O	NA	R (29AUG2020)	N/N	
	INFEC	Urinary tract infection/ urinary tract infection#	2	27FEB2021	163/6	1	No	O	NA/TC	R (04MAR2021)	N/N	
16-55/ C4591001 1084 10841315	MUSC	Back pain/ Back pain	2	15OCT2020	28/2	1	No	O	NA	R (16OCT2020)	N/N	
16-55/ C4591001 1084 10841316	INFEC	Sinusitis/ Sinus Infection	1	01SEP2020	5/23	2	No	O	NA/TC	R (23SEP2020)	N/N	
16-55/ C4591001 1084 10841317	INFEC	Cellulitis/ Cellulitis in Left leg	1	08SEP2020	12/9	2	No	O	NA/TC/TCN	R (16SEP2020)	Y/N	
16-55/ C4591001 1084 10841321	SKIN	Rash/ rash on right side of abdomen#	2	19DEC2020	90/3	1	No	O	NA/TC	R (21DEC2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1084 10841327	RESP	Nasal congestion/ Worsening of Nasal Congestion	2	22SEP2020	2/21	1	No	O	NA	R (12OCT2020)	N/N
16-55/ C4591001 1084 10841376	NERV	Parosmia/ olfactory hallucinations (phantosmia)	1	12SEP2020	2/35	1	No	O	NA	R (16OCT2020)	N/N
16-55/ C4591001 1084 10841381	GENRL	Fatigue/ Fatigue	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	15SEP2020	5/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1084 10841384	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	12SEP2020	2/1	2	Yes		NA	R (12SEP2020)	N/N
		Injection site erythema/ Redness at Injection Site	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	12SEP2020	2/1	2	Yes		NA	R (12SEP2020)	N/N
		Injection site swelling/ Swelling at Injection Site	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	13SEP2020	3/3	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1084 10841391	GASTR	Gastroesophageal reflux disease/ Gerd	1	17SEP2020	4/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1084 10841393	RENAL	Haematuria/ haematuria	2	08OCT2020	2/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1084 10841404	INFEC	Ear infection/ left ear infection	1	01OCT2020	18/4	2	No	O	NA/TC	R (04OCT2020)	N/N	
16-55/ C4591001 1084 10841422	INJ&P	Ligament rupture/ Torn Ligament in Right Arm	1	07OCT2020	20/97	2	No	O	NA	R (11JAN2021)	N/N	
16-55/ C4591001 1084 10841428	INJ&P	Arthropod sting/ Wasp Sting on right forearm	1	25SEP2020	8/2	1	No	O	NA/TC	R (26SEP2020)	N/N	
16-55/ C4591001 1084 10841429	MUSC	Back pain/ WORSERING BACK PAIN	2	12NOV2020	30/C	1	No	O	NA/TC/TCN	N	N/N	
16-55/ C4591001 1084 10841449	GENRL	Injection site pain/ injection site tenderness left arm	2	15OCT2020	2/C	1	Yes		NA	N	N/N	
16-55/ C4591001 1084 10841454	GASTR	Nausea/ Post dose Nausea	2	16OCT2020	1/1	1	No	O	NA	R (16OCT2020)	N/Y	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1084 10841464	INJ&P	Fall/ Fall	2	16NOV2020	29/1	1	No	O	NA	R (16NOV2020)	N/N	
	MUSC	Arthralgia/ Left shoulder pain	2	16NOV2020	29/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1084 10841480	CARD	Acute coronary syndrome/ Acute Coronary Syndrome	1	26OCT2020	13/1	3	No	O	NA/TC/TCN	R (26OCT2020)	N/N	
		Acute myocardial infarction/ ST-segment elevated MYOCARDIAL INFARCTION	1	26OCT2020	13/1	2	No	O	NA/TC	R (26OCT2020)	Y/N	
	INV	Blood creatinine increased/ Elevated Creatinine	1	26OCT2020	13/2	1	No	O	NA	R (27OCT2020)	N/N	
	METAB	Hyperglycaemia/ Hyperglycemia	1	26OCT2020	13/2	1	No	O	NA	R (27OCT2020)	N/N	
	VASC	Hypertensive urgency/ Hypertensive Urgency	1	26OCT2020	13/4	2	No	O	NA/TC	R (29OCT2020)	N/N	
16-55/ C4591001 1084 10841484	RESP	Pleuritic pain/ bilateral Pleuritic lung pain	1	01NOV2020	19/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1084 10841499	INFEC	Ear infection/ Right Ear Infection#	3	25JAN2021	13/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1084 10841511	INJ&P	Concussion/ concussion	2	03DEC2020	23/4	1	No	O	NA	R (06DEC2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1084 10841526	INFEC	Road traffic accident/ motor vehicle accident	2	03DEC2020	23/1	1	No	O	NA	R (03DEC2020)	N/N	
16-55/ C4591001 1084 10841526	INFEC	Labyrinthitis/ left inner ear infection#	2	15JAN2021	66/24	1	No	O	NA/TC	R (07FEB2021)	N/N	
16-55/ C4591001 1084 10841538	PSYCH	Bipolar I disorder/ Bipolar I#	2	31JAN2021	63/C	3	No	O	NA/TC/TCN	RG	Y/N	
16-55/ C4591001 1085 10851018	REPRO	Endometrial thickening/ Endometrial thickening#	2	09FEB2021	172/3	3	No	O	NA/TCN	R (11FEB2021)	Y/N	
16-55/ C4591001 1085 10851023	RESP	Endometriosis/ Endometriosis# Respiratory tract congestion/ CHEST CONGESTION#	2	09FEB2021	172/3	3	No	O	NA/TCN	R (11FEB2021)	Y/N	
16-55/ C4591001 1085 10851129	INJ&P	Respiratory tract congestion/ CHEST CONGESTION#	2	22JAN2021	152/15	2	No	O	NA/TC	R (05FEB2021)	N/N	
16-55/ C4591001 1085 10851129	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	23DEC2020	105/C		No	O	NA/W	N	N/N	
16-55/ C4591001 1085 10851142	GENRL	Fatigue/ FATIGUE	2	21SEP2020	6/2	1	Yes		NA	R (22SEP2020)	N/N	
16-55/ C4591001 1085 10851142	GENRL	Pyrexia/ low grade fever	2	21SEP2020	6/2	1	Yes		NA/TC	R (22SEP2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ MUSCLE ACHES	2	21SEP2020	6/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1085 10851178	INFEC	Sinusitis/ sinus infection#	3	07FEB2021	13/16	2	No	O	NA/TC	R (22FEB2021)	N/N
16-55/ C4591001 1085 10851191	INFEC	Gastrointestinal infection/ Gastrointestinal Infection	2	24NOV2020	70/25	1	Yes		NA/TC	R (18DEC2020)	N/N
16-55/ C4591001 1085 10851225	GENRL	Injection site pain/ Injection Site Pain	2	26SEP2020	3/2	2	Yes		NA	R (27SEP2020)	N/N
	INJ&P	Radius fracture/ fracture left radius#	2	17FEB2021	147/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C4591001 1085 10851246	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	19OCT2020	25/C		No	O	NA	UNK	N/N
16-55/ C4591001 1085 10851248	GENRL	Chills/ Chills	2	22SEP2020	2/6	1	Yes		NA	R (27SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	26SEP2020	6/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1085 10851250	INFEC	Conjunctivitis/ conjunctivitis	1	16SEP2020	14/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1085 10851253	GASTR	Diarrhoea/ Diarrhea	2	28OCT2020	35/1	1	No	CND	NA	R (28OCT2020)	N/N	
	GASTR	Diarrhoea/ Diarrhea	2	05NOV2020	43/1	1	No	CND	NA	R (05NOV2020)	N/N	
16-55/ C4591001 1085 10851280	GENRL	Chills/ CHILLS	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N	
		Pain/ BODY ACHES	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001 1085 10851304	GENRL	Pyrexia/ Fever	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N	
16-55/ C4591001 1085 10851337	GENRL	Chills/ Chills	2	08OCT2020	1/C	1	Yes		NA	RG	N/N	
16-55/ C4591001 1085 10851361	GENRL	Injection site pain/ Injection site tenderness	1	10OCT2020	6/4	1	Yes		NA	R (13OCT2020)	N/N	
16-55/ C4591001 1085 10851364	GENRL	Pyrexia/ Fever	2	30OCT2020	2/2	1	Yes		NA	R (31OCT2020)	N/N	
	MUSC	Myalgia/ Muscle pain	2	30OCT2020	2/2	1	Yes		NA	R (31OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1087 10871020	GENRL	Fatigue/ Fatigue#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
		Myalgia/ Generalized muscle pain#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	NERV	Headache/ Headache#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	23FEB2021	2/3	1	Yes		NA	R (25FEB2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	4	23FEB2021	2/3	1	Yes		NA	R (25FEB2021)	N/N
		Myalgia/ Generalized Muscle Pain#	4	23FEB2021	2/3	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1087 10871045	IMMUN	Food allergy/ Egg White/Yolk Allergy - Allergy Test Finding	1	28AUG2020	19/C	1	No	O	NA	N	N/N
		Food allergy/ Kidney Bean Allergy - Allergy Test Findings	1	28AUG2020	19/C	1	No	O	NA	N	N/N
		Milk allergy/ Dairy Allergy - Allergy Test Findings	1	28AUG2020	19/C	1	No	O	NA	N	N/N
	GENRL	Pyrexia/ Fever#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Chills/ Chills#	4	12MAR2021	2/2	1	Yes		NA/TC	R (13MAR2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1087 10871046	GASTR	Pyrexia/ Fever#  Toothache/ TOOTH ACHE	4  2	12MAR2021  02SEP2020	2/2  3/27	1  2	Yes  No	  O	NA/TC  NA/TC/TCN	R (13MAR2021)  R (28SEP2020)	N/N  N/N
16-55/ C4591001 1087 10871053	GENRL	Pain/ Body Ache#	4	12JAN2021	2/1	1	Yes		NA/TC	R (12JAN2021)	N/N
16-55/ C4591001 1087 10871064	INFEC	Pyrexia/ Fever#  Tooth infection/ Wisdom Teeth Infection - Right lower quadrant	4  2	12JAN2021  15JAN2021	2/1  136/15	1  2	Yes  No	  O	NA/TC  NA/TC	R (12JAN2021)  R (29JAN2021)	N/N  N/N
16-55/ C4591001 1087 10871078	RESP	Rhinitis allergic/ Worsening of Allergic Rhinitis	2	02FEB2021	156/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1087 10871089	EYE  CARD	Blepharitis/ Blepharitis - Right Eye#  Tachycardia/ TACHYCARDIA	2  1	19FEB2021  24SEP2020	173/C  39/7	1  2	No  No	O  O	NA/TC  NA/TC	N  R (30SEP2020)	N/N  N/N
16-55/ C4591001 1087 10871094	INFEC	Cellulitis/ CELLULITIS LEFT KNEE	1	03SEP2020	17/11	2	No	O	NA/TC	R (13SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1087 10871103	GENRL	Pain/ Body Ache#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
	NERV	Lethargy/ Lethargy#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1087 10871109	RESP	Nasal congestion/ NASAL CONGESTION	1	22AUG2020	5/2	1	No	O	NA	R (23AUG2020)	N/N
16-55/ C4591001 1087 10871113	GENRL	Injection site pain/ Pain at injection site - Left deltoid#	3	15JAN2021	2/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1087 10871114	IMMUN	Seasonal allergy/ WORSENING OF SEASONAL ALLERGIES	2	27SEP2020	19/8	1	No	O	NA/TC	R (04OCT2020)	N/N
	GASTR	Nausea/ NAUSEA	2	08OCT2020	30/2	1	No	O	NA	R (09OCT2020)	N/N
16-55/ C4591001 1087 10871127		Vomiting/ VOMITING	2	08OCT2020	30/2	1	No	O	NA	R (09OCT2020)	N/N
	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	20NOV2020	74/C	1	No	O	NA/TC	N	N/N
	GENRL	Chills/ Chills#	4	12JAN2021	2/1	1	Yes		NA/TC	R (12JAN2021)	N/N
		Pyrexia/ Fever#	4	12JAN2021	2/1	1	Yes		NA/TC	R (12JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1087 10871146	PSYCH	Anxiety/ ANXIETY	1	09SEP2020	21/C	1	No	O	NA/TC/TCN	N	N/N	
16-55/ C4591001 1087 10871148	GENRL	Pain/ Aches (generalized body)	2	14SEP2020	5/2	1	Yes		NA	R (15SEP2020)	N/N	
16-55/ C4591001 1087 10871149	INJ&P	Muscle rupture/ LEFT BICEP TEAR	2	29SEP2020	19/1	2	No	O	NA/TCN	R (29SEP2020)	N/N	
16-55/ C4591001 1087 10871152	BLOOD	Lymphadenopathy/ SWOLLEN LYMPH NODES IN LEFT AXILLA	2	12SEP2020	2/23	2	Yes		NA	R (04OCT2020)	N/N	
	SKIN	Acne cystic/ Cystic Acne	2	14OCT2020	34/C	3	No	O	NA/TC	N	N/N	
16-55/ C4591001 1087 10871153	GENRL	Fatigue/ Fatigue#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N	
		Injection site pain/ Injection Site Pain - Left Deltoid#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N	
		Pyrexia/ Fever#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N	
16-55/ C4591001 1087 10871171	GENRL	Chills/ Chills#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1087 10871172	NERV	Dizziness/ Dizziness#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	15SEP2020	2/5	1	Yes		NA	R (19SEP2020)	N/N	
16-55/ C4591001 1087 10871181	MUSC	Pyrexia/ FEVER	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N	
		Myalgia/ generalized muscle Soreness	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001 1087 10871186	INJ&P	Muscle strain/ RIGHT FOOT PAIN DUE TO STRAINING FOOT	1	05SEP2020	12/7	2	No	O	NA/TC	R (11SEP2020)	N/N	
16-55/ C4591001 1087 10871191	GENRL	Pyrexia/ Fever#	4	01MAR2021	1/1	2	Yes		NA	R (01MAR2021)	N/N	
16-55/ C4591001 1087 10871214	BLOOD	Lymphadenopathy/ Swollen Lymph Nodes - Left Axillary Region#	4	02MAR2021	2/C	2	Yes		NA	N	N/N	
	INJ&P	Upper limb fracture/ Arm Fracture - Left	2	15JAN2021	121/38	3	No	O	NA/TCN	R (21FEB2021)	N/N	
16-55/ C4591001 1087 10871239	GENRL	Pyrexia/ FEVER	2	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1087 10871241	IMMUN	Rubber sensitivity/ Latex Allergy#	2	11FEB2021	149/C	1	No	O	NA	N	N/N	
	SKIN	Rash/ Arm Rash - Left#	2	11FEB2021	149/6	1	No	O	NA	R (16FEB2021)	N/N	
	GENRL	Chills/ Chills#	4	10MAR2021	2/1	1	Yes		NA	R (10MAR2021)	N/N	
16-55/ C4591001 1087 10871252	EAR	Vertigo/ VERTIGO	2	22SEP2020	5/71	2	No	O	NA/TC	R (01DEC2020)	N/N	
	GASTR	Vomiting/ Vomiting#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N	
16-55/ C4591001 1087 10871299	GENRL	Chills/ chills	2	24SEP2020	2/8	1	Yes		NA	R (01OCT2020)	N/N	
		Fatigue/ fatigue	2	24SEP2020	2/8	1	Yes		NA	R (01OCT2020)	N/N	
		Pyrexia/ fever	2	24SEP2020	2/8	1	Yes		NA	R (01OCT2020)	N/N	
16-55/ C4591001 1087 10871308	GENRL	Fatigue/ Fatigue#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N	
16-55/ C4591001 1087 10871310	GENRL	Chills/ Chills#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1087 10871343	MUSC	Pyrexia/ Fever#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
		Myalgia/ Generalized Muscle Pain#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
		Chills/ Chills	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1087 10871348	RESP	Pyrexia/ Fever	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		Asthma/ ASTHMA EXACERBATION	1	30SEP2020	23/2	2	No	O	NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1087 10871349	MUSC	Chills/ Chills#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
		Fatigue/ Fatigue#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
16-55/ C4591001 1087 10871354	MUSC	Myalgia/ muscle aches#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
		Vaccination site pain/ Soreness in Vaccine Arm	1	08SEP2020	1/C	1	Yes		NA	N	N/N
		Fatigue/ Fatigue	1	11SEP2020	4/C	1	Yes		NA	N	N/N
	MUSC	Myalgia/ Myalgia	1	11SEP2020	4/C	1	Yes		P/W	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1087 10871355	BLOOD	Lymphadenopathy/ Swollen Right Cervical Lymph Node	2	05OCT2020	1/5	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1087 10871360	GENRL	Injection site pain/ Injection Site Pain - Left Deltoid#	4	09JAN2021	2/4	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1087 10871361	GASTR	Nausea/ Nausea	2	30SEP2020	2/3	1	Yes		NA/TC	R (02OCT2020)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	2/3	1	Yes		NA/TC	R (02OCT2020)	N/N
		Pain/ Body Ache	2	30SEP2020	2/3	1	Yes		NA/TC	R (02OCT2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	2/3	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1087 10871372	GENRL	Fatigue/ Fatigue	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Soreness	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1087 10871420	IMMUN	Seasonal allergy/ Seasonal Allergies#	2	09FEB2021	131/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001	GENRL	Injection site pain/ Deltoid Injection Site Pain - Left#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1087 10871457	NERV	Headache/ Headache#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N	
16-55/ C4591001 1087 10871471	GENRL	Chills/ Chills	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N	
		Pyrexia/ Fever	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N	
16-55/ C4591001 1087 10871486	MUSC	Myalgia/ Muscle Pain - Shoulder, Left#	4	06JAN2021	2/4	2	Yes		NA	R (09JAN2021)	N/N	
16-55/ C4591001 1087 10871487	GENRL	Chills/ Chills	2	10OCT2020	2/3	2	Yes		NA	R (12OCT2020)	N/N	
		Fatigue/ Fatigue	2	10OCT2020	2/3	2	Yes		NA	R (12OCT2020)	N/N	
		Pyrexia/ Fever	2	10OCT2020	2/3	2	Yes		NA	R (12OCT2020)	N/N	
16-55/ C4591001 1087 10871491	PSYCH	Insomnia/ Worsening of Insomnia	2	26OCT2020	20/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1087 10871493	MUSC	Myalgia/ Generalized Muscle Pain*		18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1087 10871510	GENRL	Chills/ Chills	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N	
		Fatigue/ Fatigue	1	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N	
		Injection site pain/ Left Deltoid Injection Site Pain	1	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N	
	GENRL	Chills/ Chills	2	07OCT2020	1/4	1	Yes		NA	R (10OCT2020)	N/N	
		Pain/ Body Aches	2	07OCT2020	1/8	1	Yes		NA	R (14OCT2020)	N/N	
		Pyrexia/ Fever	2	07OCT2020	1/4	1	Yes		NA	R (10OCT2020)	N/N	
	GENRL	Chills/ Chills	2	12OCT2020	1/3	2	Yes		NA	R (14OCT2020)	N/N	
		Fatigue/ Fatigue	2	12OCT2020	1/3	2	Yes		NA	R (14OCT2020)	N/N	
		Pyrexia/ low grade fever	2	12OCT2020	1/3	2	Yes		NA	R (14OCT2020)	N/N	
	16-55/ C4591001 1087 10871530	VASC	Hypertension/ Hypertension	2	31OCT2020	10/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1087 10871545	GENRL	Fatigue/ Fatigue	1	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N	
	NERV	Headache/ Headache	1	17OCT2020	5/2	1	Yes		NA	R (18OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1087 10871546	GENRL	Pyrexia/ Fever	2	04NOV2020	2/1	1	Yes		NA	R (04NOV2020)	N/N	
16-55/ C4591001 1087 10871550	MUSC	Rotator cuff syndrome/ Worsening of torn rotator cuff - shoulder, right	1	22OCT2020	10/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1087 10871554	GASTR	Diarrhoea/ Diarrhea	1	16OCT2020	3/5	2	Yes		NA	R (20OCT2020)	N/N	
		Vomiting/ Vomiting	1	16OCT2020	3/5	2	Yes		NA	R (20OCT2020)	N/N	
	NERV	Headache/ Headache	1	16OCT2020	3/5	2	Yes		NA	R (20OCT2020)	N/N	
16-55/ C4591001 1087 10871555	GASTR	Diarrhoea/ Diarrhea	1	16OCT2020	3/5	2	Yes		NA	R (20OCT2020)	N/N	
		Vomiting/ Vomiting	1	16OCT2020	3/5	2	Yes		NA	R (20OCT2020)	N/N	
16-55/ C4591001 1087 10871557	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	24OCT2020	11/C		No	O	P	UNK	N/N	
16-55/ C4591001 1087 10871584	GASTR	Gastroesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISEASE	1	09NOV2020	15/C	2	No	O	NA/TC	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1087 10871586	CARD	Tachycardia/ Tachycardia	2	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N	
16-55/ C4591001 1087 10871593	PSYCH	Depression/ Depression	1	08NOV2020	12/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1088 10881059	SURG	Chondroplasty/ Cartilage repaired with surgery	2	18DEC2020	102/C	2	No	O	NA	RG	N/N	
16-55/ C4591001 1088 10881107	GASTR	Oedema mouth/ Angioedema of the oral cavity#	4	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/Y	
		Tongue oedema/ Angioedema of the tongue#	4	01FEB2021	1/1	1	Yes		NA/TC	R (01FEB2021)	N/Y	
16-55/ C4591001 1088 10881201	SKIN	Dermatitis contact/ ALLERGY TO POISON SUMAC	2	05DEC2020	62/C	2	No	O	NA	N	N/N	
16-55/ C4591001 1088 10881213	MUSC	Myalgia/ MUSCLE PAIN/ACHE	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N	
16-55/ C4591001 1088 10881220	NEOPL	Meningioma/ right frontal meningioma	1	23SEP2020	6/C	2	No	O	NA	N	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1088 10881259	INV	Mammogram abnormal/ Abnormal mammogram	2	NOV2020	1/C	2	No	CND	NA	N	N/N	
16-55/ C4591001 1089 10891015	INFEC	Tonsillitis/ Tonsillitis	2	14SEP2020	28/1	2	No	O	NA/TCN	R (14SEP2020)	N/N	
	PSYCH	Depression/ worsening depression	2	02NOV2020	77/30	2	No	O	NA/TC	R (01DEC2020)	N/N	
16-55/ C4591001 1089 10891025	GENRL	Chills/ chills	2	29SEP2020	41/C	1	No	O	NA	N	N/N	
		Pyrexia/ fever	2	29SEP2020	41/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1089 10891065	INFEC	Diabetic foot infection/ Infection right pinky toe (secondary to diabetes)	2	17JAN2021	144/33	3	No	O	NA/TC/TCN	R (18FEB2021)	Y/N	
	VASC	Hypertension/ Hypertension#	2	14FEB2021	172/C	2	No	CD	NA/TC	N	N/N	
16-55/ C4591001 1089 10891067	MUSC	Muscle spasms/ back spasms	1	15AUG2020	10/10	2	No	O	NA/TC	R (24AUG2020)	N/N	
16-55/ C4591001 1089 10891103	INFEC	Skin infection/ right knee superficial infection of the skin	1	28AUG2020	18/14	2	No	O	NA/TC	R (10SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1089 10891105	INJ&P	Overdose/ unknown drug Overdose	2	05FEB2021	159/5	3	No	O	NA	R (09FEB2021)	N/N	
16-55/ C4591001 1089 10891107	RESP	Upper-airway cough syndrome/ post nasal drip	2	08JAN2021	129/2	1	No	O	NA	R (09JAN2021)	N/N	
16-55/ C4591001 1089 10891173	MUSC	Osteoarthritis/ Worsening of OA left knee#	3	03MAR2021	20/1	2	No	O	NA/TC/TCN	R (03MAR2021)	N/N	
16-55/ C4591001 1089 10891181	INJ&P	Exposure during pregnancy/ Exposure During Partner Pregnancy	2	25DEC2020	102/C		No	O	NA	N	N/N	
16-55/ C4591001 1089 10891182	RESP	Chronic obstructive pulmonary disease/ worsening of COPD	1	26AUG2020	2/2	2	No	O	NA/TC	R (27AUG2020)	N/N	
	INJ&P	Fall/ Fall	1	09SEP2020	16/1	2	No	O	NA	R (09SEP2020)	N/N	
		Hip fracture/ Left Hip Closed Fracture	1	09SEP2020	16/17	3	No	O	NA/TC	R (25SEP2020)	Y/N	
	GASTR	Nausea/ nausea	1	27SEP2020	34/2	2	No	O	NA	R (28SEP2020)	N/N	
	PSYCH	Psychotic disorder/ Psychosis	1	27SEP2020	34/C	3	No	O	NA/TC/TCN	N	Y/N	
		Substance abuse/ worsening of polysubstance abuse	1	27SEP2020	34/2	2	No	O	NA	R (28SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1089 10891193	IMMUN	Hypersensitivity/ worsening of allergies	1	08SEP2020	14/3	1	No	O	NA	R (10SEP2020)	N/N	
16-55/ C4591001 1089 10891205	SURG	Hysterectomy/ complete hysterectomy#	3	23DEC2020	6/1	2	No	O	NA	R (23DEC2020)	N/N	
16-55/ C4591001 1089 10891207	GENRL	Oedema peripheral/ bilateral edema legs	2	05NOV2020	49/3	1	No	O	NA	R (07NOV2020)	N/N	
16-55/ C4591001 1089 10891253	INFEC	Cellulitis/ left side facial cellulitis	1	11SEP2020	8/13	2	No	O	NA/TC	R (23SEP2020)	N/N	
	GASTR	Swollen tongue/ swollen tounge	1	12SEP2020	9/4	1	No	O	NA	R (15SEP2020)	N/N	
16-55/ C4591001 1089 10891261	INFEC	Herpes zoster/ worsening shingles right bottom	1	19SEP2020	12/4	1	No	O	NA/TC	R (22SEP2020)	N/N	
16-55/ C4591001 1089 10891273	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	2	25DEC2020	85/C		No	O	NA	UNK	N/N	
16-55/ C4591001 1089 10891289	HEPAT	Acute hepatic failure/ Acute Liver Failure#	2	19DEC2020	79/C	4	No	O	NA/W	N	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1090 10901015	GASTR	Diarrhoea/ diarrhea, single episode	2	04OCT2020	42/1	1	No	O	NA	R (04OCT2020)	N/N	
16-55/ C4591001 1090 10901020	RESP	Oropharyngeal pain/ sore throat, intermittent	1	14AUG2020	12/5	1	No	O	NA	R (18AUG2020)	N/N	
	GASTR	Nausea/ Nausea#	3	20FEB2021	2/3	2	Yes		NA	R (22FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	3	20FEB2021	2/4	2	Yes		NA	R (23FEB2021)	N/N	
	MUSC	Pain in extremity/ Left arm pain#	3	20FEB2021	2/4	2	Yes		NA/TC	R (23FEB2021)	N/N	
	NERV	Headache/ Headache#	3	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N	
16-55/ C4591001 1090 10901024	GENRL	Chills/ chills#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
	NERV	Headache/ headache#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/N	
16-55/ C4591001 1090 10901029	GENRL	Fatigue/ Fatigue#	3	02MAR2021	2/4	1	Yes		NA	R (05MAR2021)	N/N	
16-55/ C4591001 1090 10901038	RESP	Oropharyngeal pain/ sore throat	1	20AUG2020	17/4	2	No	O	NA	R (23AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901044	GENRL	Fatigue/ Fatigue#	3	17FEB2021	2/2	2	Yes		NA	R (18FEB2021)	N/N
		Injection site pain/ Injection site pain-right arm#	3	17FEB2021	2/2	2	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1090 10901046	GENRL	Chills/ Chills#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
		Pyrexia/ Fever#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N
16-55/ C4591001 1090 10901058	GASTR	Dry mouth/ Xerostomia#	4	12MAR2021	2/C	1	Yes		NA	N	N/N
16-55/ C4591001 1090 10901065	NERV	Headache/ headaches, daily in afternoon	2	28AUG2020	1/47	2	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 1090 10901076	GENRL	Pyrexia/ Fever#	4	05MAR2021	2/3	2	Yes		NA	R (07MAR2021)	N/N
16-55/ C4591001 1090 10901094	NERV	Burning sensation/ burning sensations, legs	1	18AUG2020	12/18	2	Yes		NA	R (04SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1090 10901099	MUSC	Tendonitis/ tendonitis. right wrist	2	30SEP2020	34/63	2	No	O	NA/TC	R (01DEC2020)	N/N	
	GENRL	Injection site pain/ Injection site pain-severe#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N	
	MUSC	Arthralgia/ Generalized arthralgia#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N	
16-55/ C4591001 1090 10901140	BLOOD	Lymphadenopathy/ Cervical lymphadenopathy-bilateral#	4	30JAN2021	2/5	2	Yes		NA	R (03FEB2021)	N/N	
	INFEC	Appendicitis perforated/ acute appendicitis with perforation#	3	04FEB2021	9/8	4	No	O	NA/TC/TCN	R (11FEB2021)	Y/N	
		Focal peritonitis/ localized peritonitis#	3	04FEB2021	9/8	4	No	O	NA/TC/TCN	R (11FEB2021)	Y/N	
		Pelvic abscess/ pelvic abscess#	3	04FEB2021	9/8	4	No	O	NA/TC/TCN	R (11FEB2021)	Y/N	
	GENRL	Injection site pain/ Injection site pain-right arm#	4	18FEB2021	1/3	2	Yes		NA/TC/W	R (20FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	1/3	2	Yes		NA/TC	R (20FEB2021)	N/N	
	NERV	Headache/ Headache#	4	18FEB2021	1/3	2	Yes		NA/TC	R (20FEB2021)	N/N	
16-55/ C4591001 1090 10901147	INFEC	Ear infection/ ear infection, both ears	2	01OCT2020	32/11	2	No	O	NA/TC	R (11OCT2020)	N/N	
16-55/ C4591001	GENRL	Chills/ Chills#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1090 10901154		Fatigue/ Fatigue#	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N	
	NERV	Headache/ Headache#	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N	
16-55/ C4591001 1090 10901172	INV	Body temperature increased/ elevated temperature	2	04SEP2020	2/2	1	Yes		NA/TC	R (05SEP2020)	N/N	
	MUSC	Myalgia/ muscle pain	2	04SEP2020	2/2	1	Yes		NA/TC	R (05SEP2020)	N/N	
16-55/ C4591001 1090 10901174	MUSC	Muscle spasms/ muscle spasms, injection arm	2	04SEP2020	2/3	2	Yes		NA	R (06SEP2020)	N/N	
16-55/ C4591001 1090 10901187	NERV	Facial paralysis/ Bell's Palsy right face	2	10SEP2020	3/3	1	Yes		NA/TC	R (12SEP2020)	N/N	
16-55/ C4591001 1090 10901201	GENRL	Chills/ Chills#	3	03MAR2021	1/3	2	Yes		NA	R (05MAR2021)	N/N	
	MUSC	Myalgia/ Myalgia#	3	03MAR2021	1/3	2	Yes		NA/TC	R (05MAR2021)	N/N	
16-55/ C4591001 1090 10901220	GENRL	Fatigue/ Fatigue#	4	20JAN2021	2/1	1	Yes		NA/TC	R (20JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901226	MUSC	Myalgia/ Myalgia#	4	20JAN2021	2/1	1	Yes		NA/TC	R (20JAN2021)	N/N
	GENRL	Chills/ Chills	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Pain/ Body aches	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1090 10901251	NERV	Headache/ Headache	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
	RESP	Oropharyngeal pain/ sore throat	1	24AUG2020	6/5	2	No	O	NA	R (28AUG2020)	N/N
16-55/ C4591001 1090 10901253	GENRL	Chills/ Chills	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ Fever	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1090 10901277	VASC	Hypertension/ High Blood pressure	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	01SEP2020	1/4	2	Yes		NA	R (04SEP2020)	N/N
	EAR	Ear pain/ Otalgia	1	02SEP2020	2/6	1	Yes		NA	R (07SEP2020)	N/N
	NERV	Headache/ Headache	1	03SEP2020	3/3	3	Yes		NA	R (05SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901291	EAR	Ear pain/ otalgia, left ear	1	06SEP2020	5/3	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C4591001 1090 10901294	GENRL	Fatigue/ Fatigue	2	23SEP2020	1/2	3	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	23SEP2020	1/2	3	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1090 10901295	GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Pain/ Body aches	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	1/1	2	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1090 10901316	MUSC	Spinal stenosis/ Spinal Stenosis	2	29SEP2020	6/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1090 10901325	GENRL	Chills/ Chills	1	23SEP2020	21/2	1	Yes		NA	R (24SEP2020)	N/N
		Fatigue/ Fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1090 10901326	MUSC	Pyrexia/ fever	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
		Myalgia/ Muscle aches	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Injection site pain/ Left arm injection site pain	2	24SEP2020	1/2	2	Yes		NA/TC	R (25SEP2020)	N/N	
	GENRL	Chills/ Chills	2	25SEP2020	2/2	2	Yes		NA	R (26SEP2020)	N/N	
16-55/ C4591001 1090 10901329	GENRL	Pyrexia/ Fever	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N	
		Injection site pain/ Injection site pain-left arm#	3	02MAR2021	2/2	1	Yes		NA	R (03MAR2021)	N/N	
16-55/ C4591001 1090 10901336	INFEC	Diverticulitis/ worsening diverticulitis#	2	04JAN2021	98/15	2	No	O	NA/TC	R (18JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	29JAN2021	3/1	1	Yes		NA	R (29JAN2021)	N/N	
	NERV	Headache/ Headache#	4	29JAN2021	3/1	2	Yes		NA	R (29JAN2021)	N/N	
16-55/ C4591001 1090 10901355	PSYCH	Anxiety/ worsening anxiety	1	23SEP2020	15/33	1	No	O	NA/TC	R (25OCT2020)	N/N	
16-55/ C4591001	GENRL	Chills/ Chills	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1090 10901360		Pyrexia/ Fever	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001 1090 10901366	GENRL	Chills/ Chills	2	29SEP2020	1/2	3	Yes		NA	R (30SEP2020)	N/N	
	MUSC	Arthralgia/ Generalized joint pains	2	29SEP2020	1/4	2	Yes		NA/TC	R (02OCT2020)	N/N	
		Myalgia/ Generalized muscle aches	2	29SEP2020	1/4	2	Yes		NA/TC	R (02OCT2020)	N/N	
	NERV	Headache/ Headache	2	29SEP2020	1/4	2	Yes		NA/TC	R (02OCT2020)	N/N	
16-55/ C4591001 1090 10901369	MUSC	Arthralgia/ left shoulder pain	1	17SEP2020	8/8	2	Yes		NA/TC	R (24SEP2020)	N/N	
16-55/ C4591001 1090 10901373	GENRL	Chills/ Chills	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N	
		Injection site pain/ Injection site pain-Left arm	1	10SEP2020	1/4	1	Yes		NA/TC	R (13SEP2020)	N/N	
		Pain/ Generalized body aches	1	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N	
	NERV	Headache/ Headache	1	10SEP2020	1/2	2	Yes		NA/TC	R (11SEP2020)	N/N	
	GENRL	Pyrexia/ Low grade fever	1	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901375	GENRL	Pyrexia/ Fever#	4	24FEB2021	2/2	2	Yes		NA/TC	R (25FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	24FEB2021	2/2	1	Yes		NA	R (25FEB2021)	N/N
	NERV	Headache/ Headache#	4	24FEB2021	2/2	2	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1090 10901380	GENRL	Fatigue/ Fatigue	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
	INJ&P	Fall/ Fall	2	12OCT2020	12/1	1	No	O	NA/TCN	R (12OCT2020)	N/N
		Skin laceration/ Forehead laceration	2	12OCT2020	12/1	2	No	O	NA/TCN	R (12OCT2020)	N/N
16-55/ C4591001 1090 10901383	GENRL	Chills/ chills	2	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/Y
		Injection site pain/ Injection site pain	2	07OCT2020	1/4	2	Yes		NA/TC	R (10OCT2020)	N/Y
	NERV	Headache/ headache	2	08OCT2020	2/6	1	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 1090 10901384	REPRO	Adnexal torsion/ Right ovarian torsion	2	07DEC2020	63/6	4	No	O	NA/TCN	R (12DEC2020)	Y/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901391	GENRL	Fatigue/ Fatigue#	3	28JAN2021	2/2	2	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	28JAN2021	2/2	2	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/2	2	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/2	2	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1090 10901392	GASTR	Nausea/ Nausea	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Chills/ Chills	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Left arm injection site pain	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ Fever	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1090 10901394	GENRL	Pyrexia/ fever	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	BLOOD	Lymphadenopathy/ Swollen lymph nodes-left axilla	2	07OCT2020	2/28	3	Yes		NA	R (03NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	07OCT2020	2/4	2	Yes		NA	R (10OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1090 10901397	MUSC	Myalgia/ Muscle aches	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	1	15SEP2020	1/5	1	Yes		NA/TC	R (19SEP2020)	N/N	
16-55/ C4591001 1090 10901398	MUSC	Myalgia/ Muscle aches	1	17SEP2020	3/1	1	Yes		NA/TC	R (17SEP2020)	N/N	
	NERV	Headache/ Headache	1	17SEP2020	3/1	1	Yes		NA/TC	R (17SEP2020)	N/N	
16-55/ C4591001 1090 10901398	MUSC	Exostosis/ Bone spur-right knee	2	06NOV2020	31/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1090 10901407	GENRL	Injection site pain/ injection side pain, left arm	1	17SEP2020	2/8	2	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 1090 10901408	NERV	Injection site pain/ left arm injection pain	1	17SEP2020	2/8	1	Yes		NA	R (24SEP2020)	N/N	
		Headache/ Headache#	3	24FEB2021	1/2	2	Yes		NA/TC	R (25FEB2021)	N/N	
16-55/ C4591001 1090 10901410	GENRL	Fatigue/ Fatigue	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N	
	MUSC	Myalgia/ muscle aches	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1090 10901417	GENRL	Fatigue/ fatigue	2	09OCT2020	1/1	1	Yes		NA	R (09OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain-left arm	1	18SEP2020	2/8	2	Yes		NA/TC	R (25SEP2020)	N/N	
	NERV	Headache/ Headache	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N	
16-55/ C4591001 1090 10901418	GENRL	Injection site pain/ Injection site pain-Left arm	2	08OCT2020	2/7	2	Yes		NA	R (14OCT2020)	N/N	
	GENRL	Fatigue/ Tiredness#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/N	
		Pyrexia/ Fever#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/N	
	NERV	Headache/ Headache#	4	07JAN2021	1/3	1	Yes		NA/TC	R (09JAN2021)	N/N	
16-55/ C4591001 1090 10901422	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N	
16-55/ C4591001 1090 10901424	GENRL	Fatigue/ Fatigue#	3	04MAR2021	3/4	1	Yes		NA	R (07MAR2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain-left arm	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1090 10901429	GENRL	Pyrexia/ Fever	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
16-55/ C4591001 1090 10901432	MUSC	Myalgia/ Muscle aches	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	13OCT2020	2/4	2	Yes		NA	R (16OCT2020)	N/N	
		Pyrexia/ Fever	2	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N	
	MUSC	Myalgia/ Muscle aches	2	13OCT2020	2/3	2	Yes		NA	R (15OCT2020)	N/N	
16-55/ C4591001 1090 10901441	GENRL	Chills/ Chills	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N	
		Fatigue/ Fatigue	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N	
		Pyrexia/ Fever	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N	
	NERV	Headache/ Headache	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N	
16-55/ C4591001 1090 10901443	GENRL	Pain/ Body aches	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1090 10901452	INJ&P	Arthropod sting/ Hornet sting, R thigh, with localized inflammatory response	1	29SEP2020	7/10	1	No	O	NA/TC	R (08OCT2020)	N/N	
	GENRL	Chills/ Chills#	4	28JAN2021	1/3	2	Yes		NA	R (30JAN2021)	N/N	
		Injection site pain/ Injection site pain-left arm#	4	28JAN2021	1/3	2	Yes		NA/TC	R (30JAN2021)	N/N	
		Malaise/ Malaise#	4	28JAN2021	1/3	2	Yes		NA	R (30JAN2021)	N/N	
	MUSC	Arthralgia/ Arthralgia-generalized#	4	28JAN2021	1/3	2	Yes		NA/TC	R (30JAN2021)	N/N	
		Myalgia/ Myalgia#	4	28JAN2021	1/3	2	Yes		NA/TC	R (30JAN2021)	N/N	
	NERV	Headache/ Headache#	4	28JAN2021	1/3	2	Yes		NA/TC	R (30JAN2021)	N/N	
16-55/ C4591001 1090 10901457	GENRL	Fatigue/ Fatigue	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N	
		Injection site pain/ Injection site pain-left arm	2	15OCT2020	2/5	2	Yes		NA/TC	R (19OCT2020)	N/N	
		Pyrexia/ Fever	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001 1090 10901461	GENRL	Injection site pain/ Injection site pain-left arm	2	16OCT2020	1/4	1	Yes		NA	R (19OCT2020)	N/Y	
	GENRL	Pain/ Body aches	2	17OCT2020	2/4	2	Yes		NA	R (20OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901465	GENRL	Injection site pain/ Injection site pain-left arm	2	13OCT2020	1/3	2	Yes		NA	R (15OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	14OCT2020	2/4	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1090 10901474	GENRL	Injection site pain/ Injection site pain-left arm	2	17OCT2020	2/4	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 1090 10901477	GENRL	Chills/ chills	1	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
		Fatigue/ Fatigue	1	26SEP2020	2/1	2	Yes		NA	R (26SEP2020)	N/N
		Pain/ Body aches	1	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1090 10901480	GENRL	Pain/ Body aches	2	14OCT2020	1/4	1	Yes		NA/TC	R (17OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	14OCT2020	1/4	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 1090 10901481	INJ&P	Fall/ Fall#	3	11MAR2021	16/1	2	No	O	NA	R (11MAR2021)	N/N
		Radius fracture/ Right radial head fracture#	3	11MAR2021	16/C	2	No	O	NA/TC	RG	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901482	MUSC	Myalgia/ Cervical myalgia	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1090 10901484	GENRL	Chills/ Chills	2	26OCT2020	1/2	2	Yes		NA	R (27OCT2020)	N/N
		Injection site pain/ Injection site pain-left arm	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
		Pyrexia/ Fever	2	26OCT2020	1/2	2	Yes		NA/TC	R (27OCT2020)	N/N
	GENRL	Pain/ Bodyaches	2	27OCT2020	2/2	1	Yes		NA/TC	R (28OCT2020)	N/N
	NERV	Headache/ Headache	2	27OCT2020	2/2	1	Yes		NA/TC	R (28OCT2020)	N/N
16-55/ C4591001 1090 10901489	GENRL	Chills/ Chills	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N
		Fatigue/ Tiredness	2	31OCT2020	2/3	1	Yes		NA	R (02NOV2020)	N/N
	NERV	Headache/ Headache	2	31OCT2020	2/3	1	Yes		NA	R (02NOV2020)	N/N
16-55/ C4591001 1090 10901498	GASTR	Nausea/ Nausea#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Chills/ Chills#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1090 10901502	MUSC	Fatigue/ Fatigue#	4	14JAN2021	2/3	2	Yes		NA	R (16JAN2021)	N/N	
		Injection site swelling/ Swelling at injection site-left arm#	4	14JAN2021	2/3	2	Yes		NA	R (16JAN2021)	N/N	
		Pyrexia/ Fever#	4	14JAN2021	2/2	2	Yes		NA/TC	R (15JAN2021)	N/N	
		Myalgia/ Myalgia#	4	14JAN2021	2/2	2	Yes		NA/TC	R (15JAN2021)	N/N	
		Headache/ Headache#	4	14JAN2021	2/3	2	Yes		NA/TC	R (16JAN2021)	N/N	
	GENRL	Chills/ Chills	2	06NOV2020	2/2	2	Yes		NA	R (07NOV2020)	N/N	
	NERV	Pyrexia/ Fever	2	06NOV2020	2/2	1	Yes		NA/TC	R (07NOV2020)	N/N	
		Headache/ Headache	2	06NOV2020	2/3	1	Yes		NA/TC	R (08NOV2020)	N/N	
	16-55/ C4591001 1090 10901503	GENRL	Injection site pain/ Injection site pain-Left arm	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
	16-55/ C4591001 1090 10901507	SKIN	Urticaria/ Hives, upper chest	1	19OCT2020	4/4	2	Yes		P/TC	R (22OCT2020)	N/N
16-55/ C4591001 1090 10901508	GENRL	Injection site pain/ Injection site pain-left arm	1	16OCT2020	1/5	1	Yes		NA	R (20OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1090 10901509	GENRL	Pyrexia/ Fever	1	19OCT2020	1/2	1	Yes		NA/TC	R (20OCT2020)	N/N	
	GENRL	Chest discomfort/ chest tightness	1	24OCT2020	6/5	1	No	O	NA/TC	R (28OCT2020)	N/N	
16-55/ C4591001 1090 10901510	GENRL	Fatigue/ Fatigue	2	07NOV2020	2/2	2	Yes		NA	R (08NOV2020)	N/N	
		Pyrexia/ Fever	2	07NOV2020	2/1	2	Yes		NA/TC	R (07NOV2020)	N/N	
	NERV	Headache/ Headache	2	07NOV2020	2/1	1	Yes		NA	R (07NOV2020)	N/N	
16-55/ C4591001 1090 10901513	GENRL	Pyrexia/ fever#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N	
	SKIN	Urticaria/ Hives on face, neck and arms#	4	25JAN2021	15/1	2	No	O	NA/TC	R (25JAN2021)	N/N	
16-55/ C4591001 1090 10901516	GENRL	Fatigue/ Fatigue#	4	23FEB2021	1/5	2	Yes		NA	R (27FEB2021)	N/N	
		Injection site pain/ Injection site pain-left arm#	4	23FEB2021	1/5	2	Yes		NA/TC	R (27FEB2021)	N/N	
		Pyrexia/ Fever#	4	23FEB2021	1/5	2	Yes		NA/TC	R (27FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901517	GENRL	Fatigue/ Fatigue	2	11NOV2020	1/2	2	Yes		NA/TC	R (12NOV2020)	N/N
		Pain/ Bodyaches	2	11NOV2020	1/2	2	Yes		NA/TC	R (12NOV2020)	N/N
	NERV	Headache/ Headache	2	11NOV2020	1/2	2	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1090 10901518	GENRL	Fatigue/ Fatigue	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
		Injection site pain/ Injection site pain-left arm	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	MUSC	Arthralgia/ Joint pains- generalized	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	NERV	Headache/ Headache	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Pain/ Body Aches	2	11NOV2020	1/2	1	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1090 10901526	GENRL	Injection site pain/ Injection site pain-left arm	1	21OCT2020	1/6	1	Yes		NA	R (26OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain- left arm	2	14NOV2020	2/3	1	Yes		NA	R (16NOV2020)	N/N
16-55/ C4591001 1090 10901530	GENRL	Fatigue/ Fatigue	1	23OCT2020	2/5	2	Yes		NA	R (27OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1090 10901536	MUSC	Injection site pain/ Injection site pain-right arm	1	23OCT2020	2/5	2	Yes		NA	R (27OCT2020)	N/N	
		Myalgia/ Muscle aches	1	23OCT2020	2/5	1	Yes		NA	R (27OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain-Left arm	2	14NOV2020	2/3	1	Yes		NA	R (16NOV2020)	N/N	
		Pyrexia/ Fever	2	14NOV2020	2/3	1	Yes		NA/TC	R (16NOV2020)	N/N	
	SKIN	Rash/ Body rash-all over	2	14NOV2020	2/3	1	Yes		NA/TC	R (16NOV2020)	N/N	
		Pyrexia/ Fever	1	24OCT2020	2/2	1	Yes		NA/TC	R (25OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia	1	24OCT2020	2/2	2	Yes		NA/TC	R (25OCT2020)	N/N	
		Myalgia/ Myalgia	2	14NOV2020	2/3	1	Yes		NA/TC	R (16NOV2020)	N/N	
	INFEC	Pyelonephritis/ pyelonephritis	2	11FEB2021	91/2	2	No	O	NA/TC	R (12FEB2021)	Y/N	
	16-55/ C4591001 1090 10901537	GENRL	Chills/ Chills#	4	09FEB2021	2/2	2	Yes		NA	R (10FEB2021)	N/N
NERV		Headache/ Headache#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
16-55/ C4591001 1090 10901538	GENRL	Fatigue/ Fatigue	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1090 10901544	GENRL	Injection site pain/ Injection site pain-left arm	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N	
		Fatigue/ Fatigue	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N	
	GASTR	Injection site pain/ Injection site pain-left RM	2	14NOV2020	2/3	1	Yes		NA	R (16NOV2020)	N/N	
		Diarrhoea/ Worsening diarrhea	1	24OCT2020	2/3	3	Yes		NA	R (26OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	24OCT2020	2/3	2	Yes		NA	R (26OCT2020)	N/N	
	GENRL	Pyrexia/ Fever	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N	
		Fatigue/ Fatigue	2	14NOV2020	2/4	2	Yes		NA	R (17NOV2020)	N/N	
	GENRL	Injection site pain/ Injection site pain- left arm	2	14NOV2020	2/3	1	Yes		NA	R (16NOV2020)	N/N	
		Pain/ Bodyaches	2	14NOV2020	2/3	1	Yes		NA	R (16NOV2020)	N/N	
		Injection site pain/ Injection site pain-left arm#	3	04MAR2021	2/2	2	Yes		NA	R (05MAR2021)	N/N	
Injection site pain/ Injection site pain- left arm		2	16NOV2020	1/4	2	Yes		NA/TC	R (19NOV2020)	N/N		
16-55/ C4591001 1090 10901548	GENRL	Chills/ Chills	2	17NOV2020	2/3	2	Yes		NA	R (19NOV2020)	N/N	
		Pain/ Body aches	2	17NOV2020	2/3	2	Yes		NA/TC	R (19NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901551	GENRL	Chills/ Chills	2	17NOV2020	1/1	1	Yes		NA	R (17NOV2020)	N/N
		Fatigue/ Fatigue	2	17NOV2020	1/2	1	Yes		NA	R (18NOV2020)	N/N
16-55/ C4591001 1090 10901557	GENRL	Pyrexia/ fever	2	17NOV2020	1/2	1	Yes		NA/TC	R (18NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	17NOV2020	1/2	1	Yes		NA	R (18NOV2020)	N/N
	NERV	Headache/ headache	2	17NOV2020	1/2	2	Yes		NA/TC	R (18NOV2020)	N/N
16-55/ C4591001 1090 10901558	GENRL	Injection site pain/ Injection site pain-	1	27OCT2020	1/4	1	Yes		NA	R (30OCT2020)	N/N
	GENRL	Chills/ Chills	2	19NOV2020	1/2	2	Yes		NA	R (20NOV2020)	N/N
	GENRL	Pyrexia/ Fever	2	20NOV2020	2/1	1	Yes		NA/TC	R (20NOV2020)	N/N
16-55/ C4591001 1090 10901559	GENRL	Injection site pain/ Injection site pain-left arm	1	27OCT2020	1/5	2	Yes		NA/TC	R (31OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain-left arm	2	17NOV2020	1/5	1	Yes		NA	R (21NOV2020)	N/N
	GASTR	Vomiting/ Vomiting	2	18NOV2020	2/2	2	Yes		NA	R (19NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1090 10901565	GENRL	Chills/ Chills	2	18NOV2020	2/1	3	Yes		NA	R (18NOV2020)	N/N	
		Pyrexia/ Fever	2	18NOV2020	2/1	2	Yes		NA/TC	R (18NOV2020)	N/N	
	NERV	Headache/ Headache	2	18NOV2020	2/2	2	Yes		NA/TC	R (19NOV2020)	N/N	
	MUSC	Myalgia/ Myalgia	1	29OCT2020	1/1	1	Yes		NA	R (29OCT2020)	N/N	
	RESP	Nasal congestion/ Stuffy nose	1	29OCT2020	1/1	1	Yes		NA	R (29OCT2020)	N/N	
	INFEC	Hordeolum/ External hordeolum-right eye	1	14NOV2020	17/8	1	No	O	NA/TC	R (21NOV2020)	N/N	
	NERV	Headache/ Headache#	3	21JAN2021	1/2	1	Yes		NA/TC	R (22JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N	
		Fatigue/ Fatigue#	4	11FEB2021	1/3	2	Yes		NA	R (13FEB2021)	N/N	
		Pyrexia/ Fever#	4	11FEB2021	1/2	2	Yes		NA/TC	R (12FEB2021)	N/N	
MUSC	Myalgia/ Myalgia#	4	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N		
16-55/ C4591001 1091 10911008	METAB	Hypercholesterolaemia/ hypercholesterolemia	2	02SEP2020	14/C	1	No	O	NA	N	N/N	
	VASC	Hypertension/ hypertension	2	02SEP2020	14/C	1	No	O	NA/TC	N	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1091 10911011	MUSC	Arthralgia/ generalized joint aches#	4	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N	
	MUSC	Myalgia/ generalized myalgia#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N	
16-55/ C4591001 1091 10911014	GENRL	Chest pain/ chest pain	2	11NOV2020	84/1	2	No	O	NA	R (11NOV2020)	N/N	
	GASTR	Gastroesophageal reflux disease/ Gastroesophageal Reflux	2	25NOV2020	98/1	2	No	O	NA/TC	R (25NOV2020)	N/N	
	GASTR	Haematemesis/ hematemesis	2	27NOV2020	100/1	2	No	O	NA	R (27NOV2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N	
	MUSC	Arthralgia/ generalized joint pain#	4	07JAN2021	2/1	2	Yes		NA/TC	R (07JAN2021)	N/N	
	MUSC	Myalgia/ generalized myalgia#	4	07JAN2021	2/1	2	Yes		NA/TC	R (07JAN2021)	N/N	
16-55/ C4591001 1091 10911022	NERV	Headache/ headache	1	22AUG2020	20/1	1	No	O	NA	R (22AUG2020)	N/N	
16-55/ C4591001 1091 10911032	INFEC	Otitis media/ otitis media	2	07SEP2020	15/9	2	No	O	NA/TC	R (15SEP2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	15FEB2021	1/1	1	Yes		NA	R (15FEB2021)	N/Y	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911052	GENRL	Injection site pain/ injection site pain#	3	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1091 10911061	GENRL	Injection site pain/ injection site pain#	4	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1091 10911062	GENRL	Pyrexia/ fever#	4	06JAN2021	1/3	1	Yes		NA/TC	R (08JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	06JAN2021	1/3	1	Yes		NA/TC	R (08JAN2021)	N/N
	NERV	Headache/ headache#	4	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1091 10911067	GENRL	Injection site pain/ injection pain#	3	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/Y
	GENRL	Chills/ chills#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
		Fatigue/ fatigue#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	MUSC	Arthralgia/ generalized arthralgia#	4	03FEB2021	2/1	2	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911070	MUSC	Myalgia/ Myalgia#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
		Myalgia/ generalized myalgia#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1091 10911072	GENRL	Chills/ chills#	4	11FEB2021	2/5	1	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1091 10911079	NERV	Fatigue/ Fatigue#	4	11FEB2021	2/5	2	Yes		NA	R (15FEB2021)	N/N
		Headache/ Headache#	4	11FEB2021	2/5	1	Yes		NA	R (15FEB2021)	N/N
	GASTR	Nausea/ nausea#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	NERV	Headache/ headache#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	GASTR	Nausea/ nausea#	4	08JAN2021	2/3	2	Yes		NA	R (10JAN2021)	N/N
	GENRL	Vomiting/ vomiting#	4	08JAN2021	2/1	2	Yes		NA	R (08JAN2021)	N/N
		Chills/ chills#	4	08JAN2021	2/3	2	Yes		NA	R (10JAN2021)	N/N
		Pyrexia/ fever#	4	08JAN2021	2/3	2	Yes		NA	R (10JAN2021)	N/N
PSYCH	Insomnia/ insomnia#	4	08JAN2021	2/3	2	Yes		NA	R (10JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Fatigue/ fatigue#	4	09JAN2021	3/2	2	Yes		NA	R (10JAN2021)	N/N	
16-55/ C4591001 1091 10911088	GASTR	Crohn's disease/ Crohn's Disease	2	NOV2020	62/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1091 10911095	MUSC	Myalgia/ myalgia#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N	
16-55/ C4591001 1091 10911113	NERV	Paraesthesia/ paresthesia in left finger tips	1	13AUG2020	1/1	1	No	O	NA	R (13AUG2020)	N/N	
16-55/ C4591001 1091 10911116	GENRL	Chills/ Chills#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N	
		Injection site pain/ Injection site pain#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N	
	METAB	Decreased appetite/ Loss of appetite#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N	
	NERV	Headache/ Headache#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N	
	GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux disease#	4	19FEB2021	3/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1091 10911121	GASTR	Diarrhoea/ diarrhea	1	20AUG2020	8/1	1	Yes		NA	R (20AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1091 10911123	GENRL	Vomiting/ vomitting	1	20AUG2020	8/2	1	Yes		NA	R (21AUG2020)	N/N	
		Chills/ chills	1	20AUG2020	8/1	1	Yes		NA	R (20AUG2020)	N/N	
		Fatigue/ fatigue	1	20AUG2020	8/2	1	Yes		NA	R (21AUG2020)	N/N	
	NERV	Headache/ headache	1	20AUG2020	8/2	1	Yes		NA	R (21AUG2020)	N/N	
	GENRL	Injection site pain/ injection site tenderness	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N	
16-55/ C4591001 1091 10911133	GENRL	Fatigue/ fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N	
	GENRL	Fatigue/ fatigue#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N	
	GENRL	Injection site pain/ injection site pain#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/Y	
	GENRL	Fatigue/ fatigue#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
	MUSC	Arthralgia/ generalized joint aches#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
16-55/ C4591001 1091 10911134	GENRL	Fatigue/ fatigue	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N	
		Injection site pain/ injection site soreness	1	18AUG2020	1/4	1	Yes		NA/TC	R (21AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ muscle aches	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Injection site bruising/ injection site bruising	1	19AUG2020	2/4	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Fatigue/ fatigue	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		Injection site bruising/ injection site bruising	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		Injection site pain/ injection site soreness	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1091 10911140	GENRL	Injection site pain/ injection arm pain (whole limb)#	4	08JAN2021	1/2	2	Yes		NA/TCN	R (09JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	4	08JAN2021	1/2	2	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1091 10911143	GENRL	Injection site pain/ injection site pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001 1091 10911144	MUSC	Myalgia/ myalgia	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1091 10911146	NERV	Headache/ intermittent headaches	1	20AUG2020	2/11	1	Yes		NA/TC	R (30AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Chills/ chills	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N	
		Malaise/ malaise	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N	
		Pain/ body aches	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N	
16-55/ C4591001 1091 10911149	GENRL	Injection site pain/ Injection site pain#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
	NERV	Headache/ headache#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
16-55/ C4591001 1091 10911152	GENRL	Fatigue/ fatigue#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N	
	MUSC	Myalgia/ myalgias#	4	12JAN2021	2/2	2	Yes		NA/TC	R (13JAN2021)	N/N	
	NERV	Headache/ headache#	4	12JAN2021	2/2	2	Yes		NA/TC	R (13JAN2021)	N/N	
16-55/ C4591001 1091 10911156	GENRL	Pain/ body aches	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N	
16-55/ C4591001 1091 10911157	GENRL	Injection site pain/ injection site pain#	3	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911162	GENRL	Injection site pain/ soreness at injection site	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
		Pain/ body aches	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	INJ&P	Muscle strain/ Right bicep muscle strain	2	16OCT2020	33/34	1	No	O	NA/TC	R (18NOV2020)	N/N
16-55/ C4591001 1091 10911164	GENRL	Injection site pain/ injection site pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Chills/ chills#	4	08JAN2021	2/3	1	Yes		NA	R (10JAN2021)	N/N
		Fatigue/ fatigue#	4	08JAN2021	2/3	1	Yes		NA	R (10JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	08JAN2021	2/3	2	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ headache#	4	08JAN2021	2/3	2	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1091 10911169	PSYCH	Anxiety/ anxiety	2	26SEP2020	12/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1091 10911174	GENRL	Injection site pain/ soreness at injection site	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Chills/ chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911175	GENRL	Fatigue/ fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Pain/ body aches	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Fatigue/ fatigue	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ fever	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)
16-55/ C4591001 1091 10911179	NERV	Headache/ headache	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ chills#	4	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	MUSC	Fatigue/ fatigue#	4	02FEB2021	2/2	2	Yes		NA	R (03FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1091 10911182	GENRL	Injection site pain/ injection site pain	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ chills	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911189	MUSC	Injection site pain/ injection site pain	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ fever	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
		Myalgia/ worsening myalgias	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		Headache/ worsening headache	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		Tendonitis/ left bicep tendonitis	2	15SEP2020	1/	1	No	O	NA	RS	N/N
16-55/ C4591001 1091 10911192	GENRL	Fatigue/ fatigue#	4	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1091 10911196	MUSC	Injection site pain/ injection site pain#	4	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
		Myalgia/ myalgia#	4	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Fatigue/ fatigue	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001	MUSC	Myalgia/ generalized muscle pain	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ headaches	2	08OCT2020	22/1	1	No	O	NA	R (08OCT2020)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ Diarrhea	2	17SEP2020	1/17	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1091 10911197	INJ&P	Toxicity to various agents/ poisoning by cocaine	2	26SEP2020	10/2	4	No	O	NA/TC/TCN	R (27SEP2020)	Y/N	
	RESP	Hypoxia/ hypoxia	2	26SEP2020	10/2	3	No	O	NA/TC/TCN	R (27SEP2020)	Y/N	
		Pneumonia aspiration/ Aspiration Pneumonia	2	26SEP2020	10/11	3	No	O	NA/TC	R (06OCT2020)	Y/N	
	RESP	Nasal congestion/ nasal congestion	2	10OCT2020	24/8	1	No	O	NA	R (17OCT2020)	N/N	
16-55/ C4591001 1091 10911202	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N	
	GENRL	Pyrexia/ fever	2	22SEP2020	2/1	2	Yes		NA	R (22SEP2020)	N/N	
	NERV	Headache/ headache	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
16-55/ C4591001 1091 10911207	GENRL	Injection site pain/ soreness at injection site	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 1091 10911208	GENRL	Fatigue/ Fatigue	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N	
		Injection site pain/ Injection site pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Arthralgia/ Joint pain	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
	NERV	Headache/ Headache	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
16-55/ C4591001 1091 10911219	GENRL	Injection site pain/ L arm injection site pain	2	21SEP2020	1/5	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Chills/ Chills	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1091 10911220	GENRL	Fatigue/ Fatigue	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001 1091 10911226	GENRL	Injection site pain/ injection site soreness	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1091 10911232	GENRL	Injection site pain/ left injection-site pain	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ L injection site pain	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1091 10911237	GENRL	Injection site pain/ L arm injection site pain	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Chills/ Chills	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N	
		Fatigue/ Fatigue	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 1091 10911239	MUSC	Myalgia/ Myalgia	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N	
	GENRL	Injection site pain/ soreness at injection site	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N	
16-55/ C4591001 1091 10911250	RESP	Epistaxis/ epistaxis	1	23SEP2020	22/1	1	No	O	NA	R (23SEP2020)	N/N	
	GENRL	Injection site pain/ soreness at injection site	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N	
16-55/ C4591001 1091 10911252	MUSC	Myalgia/ generalized muscle aches	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	29SEP2020	1/4	1	Yes		NA	R (02OCT2020)	N/N	
16-55/ C4591001 1091 10911256	INJ&P	Muscle strain/ worsening back strain	1	09SEP2020	2/8	1	No	O	NA/TC	R (16SEP2020)	N/N	
	GENRL	Injection site pain/ site injection pain	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1091 10911257	NERV	Headache/ Headache	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N	
	GENRL	Fatigue/ fatigue#	4	12JAN2021	2/2	2	Yes		NA	R (13JAN2021)	N/N	
	MUSC	Myalgia/ myalgias#	4	12JAN2021	2/2	2	Yes		NA/TC	R (13JAN2021)	N/N	
16-55/ C4591001 1091 10911260		Pain in extremity/ left arm pain (whole limb)#	4	12JAN2021	2/2	2	Yes		NA/TC	R (13JAN2021)	N/N	
	GENRL	Chills/ Chills	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N	
16-55/ C4591001 1091 10911261		Malaise/ Malaise	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N	
16-55/ C4591001 1091 10911270		Injection site pain/ injection site soreness	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N	
16-55/ C4591001 1091 10911271	GENRL	Chills/ chills#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1091 10911277	GENRL	Fatigue/ fatigue#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N	
		Chills/ chills (without fever)	1	10SEP2020	1/4	1	Yes		NA	R (13SEP2020)	N/N	
	MUSC	Pain in extremity/ left arm pain	1	10SEP2020	1/10	1	Yes		NA	R (19SEP2020)	N/N	
	GENRL	Chills/ chills	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N	
		Injection site pain/ injection site pain	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N	
MUSC	Myalgia/ myalgia	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N		
16-55/ C4591001 1091 10911279	GENRL	Injection site pain/ Injection Site Pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N	
		Malaise/ Malaise	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N	
		Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N	
	GENRL	Chills/ Chills#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N	
		Fatigue/ Fatigue#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1091 10911283	GENRL	Injection site pain/ Injection Site Soreness	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1091 10911284	GASTR	Nausea/ nausea#	4	13JAN2021	2/3	2	Yes		NA	R (15JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	13JAN2021	2/3	2	Yes		NA	R (15JAN2021)	N/N
	METAB	Decreased appetite/ anorexia#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	4	13JAN2021	2/3	2	Yes		NA/TC	R (15JAN2021)	N/N
16-55/ C4591001 1091 10911289	MUSC	Myalgia/ muscle aches	1	14SEP2020	4/1	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Chills/ chills	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/Y
		Fatigue/ fatigue	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/Y
	MUSC	Myalgia/ myalgia	2	01OCT2020	1/3	1	Yes		NA/TC	R (03OCT2020)	N/Y
	NERV	Headache/ headache	2	01OCT2020	1/3	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site soreness	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1091 10911290 16-55/ C4591001	MUSC	Metatarsalgia/ worsening of metatarsalgia	1	21SEP2020	11/16	1	No	O	NA/TC	R (06OCT2020)	N/N	
1091 10911291 16-55/ C4591001	INJ&P	Muscle rupture/ R Deltoid Tear	1	20SEP2020	7/105	2	No	O	NA/TCN	R (02JAN2021)	N/N	
1091 10911293	NEOPL	Lipoma/ Right deltoid lipoma	1	20SEP2020	7/105	1	No	O	NA/TCN	R (02JAN2021)	N/N	
16-55/ C4591001 1091 10911297	INFEC	Vulvovaginal mycotic infection/ vaginal yeast infection	1	02OCT2020	19/4	1	No	O	NA/TC	R (05OCT2020)	N/N	
	INFEC	Fungal infection/ yeast infection	2	13FEB2021	132/7	1	No	O	NA/TC	R (19FEB2021)	N/N	
	GENRL	Fatigue/ fatigue#	3	22FEB2021	1/5	2	Yes		NA/W	R (26FEB2021)	N/N	
		Injection site pain/ injection site pain#	3	22FEB2021	1/3	1	Yes		NA/TC	R (24FEB2021)	N/N	
16-55/ C4591001 1091 10911298	GENRL	Fatigue/ fatigue#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N	
	MUSC	Myalgia/ generalized myalgia#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ soreness at injection site	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1091 10911300	GENRL	Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	INFEC	Appendicitis/ Appendicitis	2	21OCT2020	16/2	4	No	O	NA/TCN	R (22OCT2020)	Y/N
16-55/ C4591001 1091 10911301	GENRL	Chills/ Chills	2	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N
		Fatigue/ Fatigue	2	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N
		Malaise/ Maliase	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
	PSYCH	Insomnia/ Insomnia	2	08OCT2020	1/2	1	No	O	NA	R (09OCT2020)	N/N
16-55/ C4591001 1091 10911306	GENRL	Injection site pain/ pain at injection site	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
		Pyrexia/ Fever	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1091 10911310	GENRL	Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1091 10911311	MUSC	Fatigue/ Fatigue	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N	
		Injection site pain/ Injection Site Pain	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N	
		Myalgia/ Muscle Pain	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N	
	INFEC	Otitis media/ Serous Otitis Media, R ear	2	29OCT2020	23/4	1	No	O	NA	R (01NOV2020)	N/N	
	INJ&P	Tendon rupture/ Tear of bicep tendon	1	23SEP2020	7/C	1	No	O	NA	RG	N/N	
	GENRL	Injection site pain/ left arm injection site pain#	3	18DEC2020	1/4	1	Yes		NA	R (21DEC2020)	N/Y	
	GENRL	Chills/ chills	2	11OCT2020	4/3	2	Yes		NA	R (13OCT2020)	N/N	
	NERV	Fatigue/ fatigue	2	11OCT2020	4/3	2	Yes		NA	R (13OCT2020)	N/N	
		Headache/ headache	2	11OCT2020	4/3	2	Yes		NA	R (13OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1091 10911321	INJ&P	Spinal compression fracture/ worsening of compression fracture in spine	2	OCT2020	1/C	1	No	O	NA	RG	N/N	
	GENRL	Fatigue/ fatigue	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N	
	MUSC	Arthralgia/ Generalized joint pain	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N	
		Myalgia/ muscle pain	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N	
16-55/ C4591001 1091 10911334	GENRL	Fatigue/ fatigue#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N	
	NERV	Headache/ headache#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N	
16-55/ C4591001 1091 10911336	GASTR	Nausea/ Nausea	2	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N	
		Pyrexia/ Fever	2	13OCT2020	2/3	1	Yes		NA/TC	R (15OCT2020)	N/N	
	MUSC	Myalgia/ Myalgias	2	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N	
16-55/ C4591001 1091 10911340	GENRL	Injection site pain/ left arm injection site pain	1	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/Y	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Nerve compression/ pinched nerve in back	2	08DEC2020	55/C	2	No	O	NA/TC	N	N/N
	MUSC	Myalgia/ myalgia#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
		Pain in extremity/ left arm pain (whole limb)#	3	12JAN2021	1/2	2	Yes		NA	R (13JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1091 10911341	GENRL	Injection site pain/ left arm injection site pain	1	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/Y
	GENRL	Chills/ chills	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
		Fatigue/ fatigue	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1091 10911342	GENRL	Pyrexia/ fever	1	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	14OCT2020	1/3	2	Yes		NA/TC	R (16OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
	NERV	Headache/ Headache	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site soreness	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1091 10911343	GASTR	Tooth impacted/ wisdom tooth impaction	2	OCT2020	1/	1	No	O	NA/TCN	R (05NOV2020)	N/N	
	GENRL	Fatigue/ fatigue	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N	
	INFEC	Oral infection/ wisdom socket infection	2	05NOV2020	23/12	2	No	O	NA/TC	R (16NOV2020)	N/N	
16-55/ C4591001 1091 10911344	NERV	Headache/ Headache	1	29SEP2020	1/1	1	Yes		NA	R (29SEP2020)	N/N	
	GASTR	Nausea/ nausea	1	17OCT2020	19/1	1	No	O	NA	R (17OCT2020)	N/N	
	GASTR	Diarrhoea/ Diarrhea	2	21OCT2020	3/2	1	Yes		NA	R (22OCT2020)	N/N	
16-55/ C4591001 1091 10911348	GENRL	Injection site pain/ L arm injection site pain	1	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N	
	INFEC	Gastritis viral/ viral gastritis#	2	24FEB2021	128/C	2	No	O	NA	N	N/N	
16-55/ C4591001 1091 10911350	GENRL	Chills/ Chills#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N	
		Fatigue/ Fatigue#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N	
		Pyrexia/ Fever#	4	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Arthralgia/ Joint aches#	4	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
	NERV	Headache/ Headache#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1091 10911351	GENRL	Injection site pain/ pain at injection site	1	05OCT2020	1/3	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1091 10911353	GENRL	Injection site pain/ injection site pain	1	07OCT2020	2/57	1	Yes		NA	R (02DEC2020)	N/N
16-55/ C4591001 1091 10911355	CARD	Palpitations/ worsening of heart palpitations	2	25NOV2020	28/1	1	No	O	NA	R (25NOV2020)	N/N
16-55/ C4591001 1091 10911356	NERV	Headache/ headache	2	29OCT2020	2/1	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	12FEB2021	1/3	2	Yes		NA	R (14FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
	NERV	Headache/ Headache#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1091 10911357	GENRL	Injection site pain/ injection site pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911360	GENRL	Fatigue/ fatigue	2	28OCT2020	1/2	2	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1091 10911363	GASTR	Diarrhoea/ diarrhea	2	05NOV2020	2/1	1	Yes		NA	R (05NOV2020)	N/N
	GENRL	Chills/ chills	2	05NOV2020	2/1	1	Yes		NA	R (05NOV2020)	N/N
		Pyrexia/ fever	2	05NOV2020	2/1	1	Yes		NA/TC	R (05NOV2020)	N/N
	MUSC	Myalgia/ myalgias	2	05NOV2020	2/1	1	Yes		NA	R (05NOV2020)	N/N
	MUSC	Arthralgia/ worsening of right wrist triangular fibrocartilage complex pain	2	09NOV2020	6/1	2	No	O	NA/TC/TCN	R (09NOV2020)	N/N
16-55/ C4591001 1091 10911372	GENRL	Injection site pain/ pain at injection site#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
	GENRL	Chills/ chills#	4	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N
		Fatigue/ fatigue#	4	05JAN2021	2/2	2	Yes		NA	R (06JAN2021)	N/N
		Pyrexia/ fever#	4	05JAN2021	2/2	2	Yes		NA	R (06JAN2021)	N/N
	MUSC	Myalgia/ worsening of myalgias#	4	05JAN2021	2/2	2	Yes		NA	R (06JAN2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1091 10911375	MUSC	Myalgia/ myalgia	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1091 10911376	NERV	Headache/ headache	2	25NOV2020	1/3	1	Yes		NA	R (27NOV2020)	N/N
	NERV	Headache/ Headache#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1091 10911381	MUSC	Myalgia/ myalgias	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Pyrexia/ fever	1	29OCT2020	3/1	1	Yes		NA	R (29OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	17NOV2020	2/2	1	Yes		NA	R (18NOV2020)	N/N
	GENRL	Pyrexia/ Fever#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
	MUSC	Myalgia/ Generalized myalgia#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1091 10911382	REPRO	Breast mass/ left breast mass	1	11NOV2020	15/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1091 10911383	INFEC	Infectious mononucleosis/ mononucleosis	2	13JAN2021	57/26	2	No	O	NA/TC/TCN	R (07FEB2021)	N/N	
	HEPAT	Hepatic steatosis/ fatty liver	2	27JAN2021	71/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1091 10911386	GENRL	Chills/ Chills	1	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N	
	NERV	Headache/ Headache	1	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N	
	GENRL	Chills/ chills	2	23NOV2020	1/5	1	Yes		NA	R (27NOV2020)	N/N	
	NERV	Headache/ headache	2	23NOV2020	1/5	1	Yes		NA	R (27NOV2020)	N/N	
	MUSC	Myalgia/ myalgia	2	24NOV2020	2/4	1	Yes		NA	R (27NOV2020)	N/N	
16-55/ C4591001 1091 10911387	RESP	Asthma exercise induced/ Exercise induced asthma	1	30JAN2021	87/C	2	No	O	NA	RG	N/N	
	GENRL	Fatigue/ Fatigue#	2	15FEB2021	1/4	2	Yes		NA	R (18FEB2021)	N/N	
		Injection site swelling/ injection site swelling#	2	15FEB2021	1/4	1	Yes		NA	R (18FEB2021)	N/N	
16-55/ C4591001 1091 10911392	GENRL	Oedema peripheral/ left foot edema	1	01DEC2020	2/37	2	No	O	NA/TC	R (06JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911398	MUSC	Arthralgia/ right knee joint pain	2	24DEC2020	3/14	2	No	O	NA/TC	R (06JAN2021)	N/N
16-55/ C4591001 1091 10911398	RESP	Asthma/ asthma attack	1	14DEC2020	12/1	1	No	O	NA	R (14DEC2020)	N/N
16-55/ C4591001 1092 10921002	SKIN	Rash/ Rash on right hand	2	10SEP2020	1/112	1	No	O	NA	R (30DEC2020)	N/N
16-55/ C4591001 1092 10921020	EYE	Scleral discolouration/ Painless erythema of left sclera	1	05SEP2020	17/16	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C4591001 1092 10921027	GASTR	Diarrhoea/ Diarrhea#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1092 10921033	INJ&P	Nausea/ Nausea# Muscle strain/ muscle strain lower back	4 2	23FEB2021 03OCT2020	2/2 26/14	1 2	Yes No		NA NA/TC	R (24FEB2021) R (16OCT2020)	N/N N/N
16-55/ C4591001 1092 10921035	GENRL	Pyrexia/ Fever	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001	GASTR	Dyspepsia/ Heartburn#	3	01FEB2021	1/1	1	Yes		NA	R (01FEB2021)	N/Y

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1092 10921036	INFEC	Herpes zoster/ Herpes Zoster (Shingles)#	3	17FEB2021	17/10	2	No	O	NA/TC	R (26FEB2021)	N/N
	GENRL	Pain/ Body Aches#	4	02MAR2021	1/3	2	Yes		NA	R (04MAR2021)	N/N
	MUSC	Pain in extremity/ Injection arm pain#	4	02MAR2021	1/2	1	Yes		NA	R (03MAR2021)	N/N
16-55/ C4591001 1092 10921045	INFEC	Otitis media/ left otitis media	1	01SEP2020	9/11	1	No	O	NA/TC	R (11SEP2020)	N/N
		Sinusitis/ sinus infection	1	01SEP2020	9/11	1	No	O	NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1092 10921064	GENRL	Injection site pain/ Injection arm soreness#	3	09FEB2021	1/2	2	Yes		NA/TC	R (10FEB2021)	N/N
	GENRL	Injection site pain/ Injection site soreness#	4	02MAR2021	1/2	2	Yes		NA/TC	R (03MAR2021)	N/N
	GENRL	Chills/ Chills#	4	03MAR2021	2/2	2	Yes		NA/TC	R (04MAR2021)	N/N
		Pain/ Body Aches#	4	03MAR2021	2/2	2	Yes		NA/TC	R (04MAR2021)	N/N
16-55/ C4591001 1092 10921065	GENRL	Injection site erythema/ Injection site redness	1	25AUG2020	1/5	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ injection site tenderness	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1092 10921081	MUSC	Pyrexia/ fever	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		Myalgia/ myalgia	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
	EAR	Ear pain/ Earache	2	18SEP2020	3/10	1	No	O	NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1092 10921083	GENRL	Pyrexia/ Fever#	4	13JAN2021	2/2	1	Yes		NA/TC	R (14JAN2021)	N/N
	NERV	Headache/ Headache#	4	13JAN2021	2/2	1	Yes		NA/TC	R (14JAN2021)	N/N
16-55/ C4591001 1092 10921084	GENRL	Chills/ Chills#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
	METAB	Pyrexia/ Fever#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1092 10921085	METAB	Dyslipidaemia/ Dyslipidemia	2	09DEC2020	85/C	2	No	O	NA/TC	N	N/N
	VASC	Hypertension/ hypertension	2	09DEC2020	85/C	1	No	O	NA	N	N/N
16-55/ C4591001 1092 10921098	INFEC	Rhinitis/ Coryza	2	20SEP2020	4/12	1	No	O	NA/TC	R (01OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1092 10921099	VASC	Flushing/ Facial flushing#	4	09MAR2021	16/1	1	No	O	NA	R (09MAR2021)	N/N
	VASC	Flushing/ Facial Flushing#	4	10MAR2021	17/1	1	No	O	NA	R (10MAR2021)	N/N
	GENRL	Chills/ Chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Pain/ Body Aches	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1092 10921106		Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
	INFEC	Urinary tract infection/ urinary tract infection	2	08OCT2020	18/9	1	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1092 10921112	SKIN	Rash/ scattered Rash	2	15OCT2020	25/3	1	No	O	NA	R (17OCT2020)	N/N
	GENRL	Chills/ Chills#	4	02MAR2021	1/C	1	Yes		NA	RG	N/N
		Fatigue/ Fatigue#	4	02MAR2021	1/C	1	Yes		NA	RG	N/N
		Injection site pain/ Injection site soreness#	4	02MAR2021	1/C	1	Yes		NA	RG	N/N
		Pyrexia/ Fever#	4	02MAR2021	1/C	1	Yes		NA	RG	N/N
	NERV	Headache/ Headache#	4	02MAR2021	1/C	2	Yes		NA	RG	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1092 10921122	RESP	Epistaxis/ Nose bleed#	4	02MAR2021	1/1	2	Yes		NA	R (02MAR2021)	N/N
	GENRL	Fatigue/ Fatigue	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
		Injection site pain/ Injection site soreness	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
		Pyrexia/ fever	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001 1092 10921130	RESP	Epistaxis/ intermittent bilateral nose bleed	2	12OCT2020	21/29	1	No	O	NA	R (09NOV2020)	N/N
16-55/ C4591001 1092 10921132	GENRL	Fatigue/ fatigue	1	01SEP2020	1/1	1	Yes		NA	R (01SEP2020)	N/Y
16-55/ C4591001 1092 10921139	NERV	Sciatica/ Sciatica	2	28SEP2020	6/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1092 10921142	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	INV	Blood pressure increased/ Elevated Blood Pressure	2	24SEP2020	1/2	1	No	O	NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1092 10921143	NERV	Lethargy/ Lethargy	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
	GENRL	Injection site pain/ injection site soreness	1	03SEP2020	2/2	1	Yes		NA/TC	R (04SEP2020)	N/N	
		Injection site papule/ Injection site papule	1	03SEP2020	2/C	1	Yes		NA	RG	N/N	
16-55/ C4591001 1092 10921146		Pyrexia/ fever	1	03SEP2020	2/2	1	Yes		NA/TC	R (04SEP2020)	N/N	
	GENRL	Injection site pain/ injection site pain	1	03SEP2020	2/3	1	Yes		NA/TC	R (05SEP2020)	N/N	
16-55/ C4591001 1092 10921153		Pyrexia/ fever	1	03SEP2020	2/3	1	Yes		NA/TC	R (05SEP2020)	N/N	
	MUSC	Back pain/ back ache	1	03SEP2020	2/3	1	Yes		NA/TC	R (05SEP2020)	N/N	
		Myalgia/ myalgia	1	03SEP2020	2/3	1	Yes		NA/TC	R (05SEP2020)	N/N	
16-55/ C4591001 1092 10921153	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
		Pyrexia/ Fever	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection site soreness#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1092 10921162 16-55/ C4591001 1092 10921168	GENRL	Chills/ Chills	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Injection site pain/ Injection site tenderness	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Malaise/ Malaise	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Pyrexia/ Fever	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	NERV	Headache/ Headache	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Chills/ Chills	2	29SEP2020	1/1	1	Yes		NA	R (29SEP2020)	N/N
		Fatigue/ Fatigue	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Pyrexia/ Fever	2	29SEP2020	1/1	1	Yes		NA/TC	R (29SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1092 10921177	INFEC	Localised infection/ Infection on finger	2	15DEC2020	78/11	1	No	O	NA/TC	R (25DEC2020)	N/N
	GENRL	Chills/ Chills#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
		Chills/ Rigors#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1092 10921184		Pyrexia/ Fever#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	NERV	Headache/ Headache#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	SKIN	Acne/ Pimple on vaginal area#	4	08JAN2021	1/3	2	No	O	NA/TC	R (10JAN2021)	N/N
	INFEC	Urinary tract infection/ Urinary Tract Infction#	4	29JAN2021	22/10	2	No	O	NA/TC	R (07FEB2021)	N/N
	GENRL	Chills/ Chills#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/N
		Chills/ Rigors#	4	07JAN2021	1/2	2	Yes		NA/TC	R (08JAN2021)	N/N
	MUSC	Back pain/ Back Pain#	4	07JAN2021	1/2	2	Yes		NA/TC	R (08JAN2021)	N/N
	NERV	Headache/ Headache#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/N
	MUSC	Osteoarthritis/ worsening osteoarthritis	2	02NOV2020	29/57	2	No	O	NA	R (28DEC2020)	N/N
	16-55/ C4591001 1092 10921201	GENRL	Chills/ Chills#	4	25FEB2021	1/2	2	Yes		NA/TC	R (26FEB2021)
		Pyrexia/ Fever#	4	25FEB2021	1/2	2	Yes		NA/TC	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	1/2	2	Yes		NA/TC	R (26FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1092 10921208	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	16JAN2021	81/C		No	O	NA	UNK	N/N
16-55/ C4591001 1092 10921211	GENRL	Chills/ Chills#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
		Fatigue/ Tiredness#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
		Pain/ Body Aches#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1092 10921218	GENRL	Injection site pain/ Injection Site Soreness#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	GASTR	Gastrointestinal sounds abnormal/ Borborygmus#	3	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
		Nausea/ Nausea#	3	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	01MAR2021	1/2	1	Yes		NA	R (02MAR2021)	N/N
		Pain/ Body aches#	4	01MAR2021	1/2	2	Yes		NA/TC	R (02MAR2021)	N/N
	NERV	Headache/ Headache#	4	01MAR2021	1/2	2	Yes		NA/TC	R (02MAR2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection Site pain	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1092 10921223	NERV	Headache/ Headache	1	13OCT2020	2/1	2	Yes		NA	R (13OCT2020)	N/N	
16-55/ C4591001 1092 10921248	GENRL	Injection site pain/ injection site soreness#	3	22DEC2020	2/3	1	Yes		NA	R (24DEC2020)	N/N	
16-55/ C4591001 1092 10921272	GENRL	Pyrexia/ Fever	2	17NOV2020	1/2	1	Yes		NA/TC	R (18NOV2020)	N/N	
	MUSC	Myalgia/ myalgia	2	17NOV2020	1/5	1	Yes		NA/TC	R (21NOV2020)	N/N	
16-55/ C4591001 1093 10931033	MUSC	Bursitis/ BURSITIS LEFT ELBOW	1	28AUG2020	8/11	1	No	O	NA/TC/TCN	R (07SEP2020)	N/N	
16-55/ C4591001 1093 10931039	GASTR	Constipation/ IDIOPATHIC CONSTIPATION	2	01DEC2020	68/C	1	No	O	NA/TC	RG	N/N	
		Gastroesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISEASE	2	01DEC2020	68/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1093 10931042	INFEC	Diverticulitis/ DIVERTICULITIS	2	15JAN2021	106/5	1	No	O	NA/TC	R (19JAN2021)	N/N	
16-55/ C4591001	REPRO	Endometriosis/ ENDOMETRIOSIS	2	26SEP2020	12/47	1	No	O	NA/TC	R (11NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1093 10931053	INFEC	Bacterial vaginosis/ BACTERIAL VAGINOSIS	2	15NOV2020	62/8	1	No	O	NA/TC	R (22NOV2020)	N/N
16-55/ C4591001 1093 10931058	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY*		25AUG2020	1/C		No	O	P	UNK	N/N
16-55/ C4591001 1093 10931066	GENRL	Chills/ CHILLS	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
		Pain/ BODY ACHES	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE ACHES	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1093 10931067	INFEC	Subcutaneous abscess/ Cutaneous abscess of left upper extremity#	2	20FEB2021	158/17	1	No	O	NA/TC	R (08MAR2021)	Y/N
16-55/ C4591001 1093 10931070	MUSC	Osteoarthritis/ WORSENING OF GENERALIZED OSTEOARTHRITIS#	4	08MAR2021	28/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1093 10931078	GASTR	Nausea/ NAUSEA	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	15SEP2020	1/5	1	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Myalgia/ GENERALIZED MILD MUSCLE ACHES	2	15SEP2020	1/5	1	Yes		NA/TC	R (19SEP2020)	N/N	
	INFEC	Gastroenteritis/ GASTROENTERITIS#	2	19FEB2021	158/8	1	No	O	NA	R (26FEB2021)	N/N	
16-55/ C4591001 1093 10931084	MUSC	Arthralgia/ LEFT SHOULDER PAIN#	4	29JAN2021	1/3	1	No	O	NA	R (31JAN2021)	N/N	
16-55/ C4591001 1093 10931095	GASTR	Diarrhoea/ DIARRHEA	1	03SEP2020	4/1	1	Yes		NA	R (03SEP2020)	N/N	
	GENRL	Pain/ MILD BODY ACHES	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N	
16-55/ C4591001 1093 10931111	RESP	Rhinorrhoea/ RUNNY NOSE	1	16SEP2020	9/5	1	No	O	NA/TC	R (20SEP2020)	N/N	
	MUSC	Psoriatic arthropathy/ PSORIATIC ARTHRITIS	2	DEC2020	65/C				NA/TC	RG	N/N	
16-55/ C4591001 1093 10931121	NERV	Headache/ HEADACHE	1	25SEP2020	15/1	1	No	O	NA/TC	R (25SEP2020)	N/N	
	PSYCH	Anxiety/ ANXIETY	2	01FEB2021	120/C	1	No	O	NA/TC	RG	N/N	
		Attention deficit hyperactivity disorder/ EXASERBATION OF ATTENTION DEFICIT DISORDER	2	01FEB2021	120/C	1	No	O	NA/TC	RG	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1093 10931124	GENRL	Pyrexia/ FEVER	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N	
	GENRL	Injection site pain/ LEFT ARM PAIN AT INJECTION SITE#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N	
		Pyrexia/ FEVER 101.5#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N	
	MUSC	Myalgia/ MYALGIA#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N	
16-55/ C4591001 1093 10931133	INJ&P	Tendon injury/ RIGHT THIGH TENDON STRAIN	2	26OCT2020	18/113	1	No	O	NA/TC	R (15FEB2021)	N/N	
16-55/ C4591001 1093 10931134	METAB	Glucose tolerance impaired/ PRE-DIABETES	2	30OCT2020	17/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1093 10931135	GENRL	Chills/ CHILLS	2	12OCT2020	1/4	1	Yes		NA	R (15OCT2020)	N/N	
		Pyrexia/ FEVER	2	12OCT2020	1/4	1	Yes		NA	R (15OCT2020)	N/N	
	MUSC	Myalgia/ MILD MUSCLE ACHES	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N	
	NERV	Headache/ MILD HEADACHE	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1093 10931158	GENRL	Injection site pain/ LEFT ARM PAIN AT INJECTION SITE#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N	
		Pyrexia/ FEVER#	4	08JAN2021	1/3	1	Yes		NA/TC	R (10JAN2021)	N/N	
	MUSC	Myalgia/ MYALGIA#	4	08JAN2021	1/3	1	Yes		NA/TC	R (10JAN2021)	N/N	
	NERV	Headache/ HEADACHE#	4	08JAN2021	1/3	1	Yes		NA/TC	R (10JAN2021)	N/N	
16-55/ C4591001 1093 10931185	INFEC	Oral candidiasis/ ORAL CANDIDIASIS#	4	09MAR2021	7/C	1	No	O	NA/TC	RG	N/N	
		Vulvovaginal candidiasis/ CANDIDAL VULVOVAGINITIS#	4	09MAR2021	7/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1093 10931186	VASC	Hypertension/ WORSENING HYPERTENSION	1	10NOV2020	22/15	1	No	O	NA/TC	R (24NOV2020)	N/N	
16-55/ C4591001 1093 10931195	GENRL	Pyrexia/ LOW-GRADE FEVER	2	12NOV2020	1/3	2	Yes		NA	R (14NOV2020)	N/N	
16-55/ C4591001 1093 10931203	GENRL	Chills/ CHILLS	2	15NOV2020	3/4	2	Yes		NA	R (18NOV2020)	N/N	
		Fatigue/ FATIGUE	2	15NOV2020	3/4	2	Yes		NA	R (18NOV2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1093 10931205	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ HEADACHE	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1093 10931209	GENRL	Injection site pain/ LEFT ARM PAIN AT INJECTION SITE	2	17NOV2020	2/4	1	Yes		NA	R (20NOV2020)	N/N
		Pain/ BODY ACHES	2	17NOV2020	2/4	1	Yes		NA	R (20NOV2020)	N/N
16-55/ C4591001 1093 10931218	PSYCH	Insomnia/ WORSENING INSOMNIA	2	11DEC2020	26/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1093 10931226	INJ&P	Foot fracture/ LEFT FOOT FRACTOR-5TH METATARSAL#	3	30DEC2020	3/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1094 10941010	MUSC	Arthralgia/ left wrist pain	2	30OCT2020	60/C	1	No	O	NA	RG	N/N
		Pain in extremity/ bilateral heel pain	2	30OCT2020	60/C	1	No	O	NA	RG	N/N
	REPRO	Erectile dysfunction/ erectile dysfunction	2	30OCT2020	60/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001	INV	SARS-CoV-2 antibody test positive/ Positive COVID-19 serology test	2	13NOV2020	73/C	1	No	O	NA	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1094 10941016	NERV	Restless legs syndrome/ restless leg syndrome	2	24NOV2020	76/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1094 10941025	MUSC	Back pain/ Back pain	1	21SEP2020	25/5	2	No	O	NA/TC	R (25SEP2020)	N/N	
16-55/ C4591001 1094 10941070	MUSC	Pain in extremity/ Left arm pain	2	30SEP2020	7/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1094 10941077	VASC	Peripheral arterial occlusive disease/ Atherosclerosis of native artery of both lower extremities	2	30DEC2020	99/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1094 10941095	MUSC	Back pain/ Back Pain	2	30SEP2020	3/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1094 10941129	GENRL	Pyrexia/ fever#	3	25FEB2021	2/5	1	Yes		NA	R (01MAR2021)	N/N	
	NERV	Headache/ intermittent headache#	3	25FEB2021	2/5	1	Yes		NA	R (01MAR2021)	N/N	
16-55/ C4591001	SKIN	Hyperhidrosis/ sweat	1	19SEP2020	5/3	2	No	O	NA	R (21SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1094 10941132 16-55/ C4591001 1094 10941155	INJ&P	Colon injury/ colon injury	1	16OCT2020	22/8	3	No	O	NA/TC/TCN	RS (23OCT2020)	Y/N
16-55/ C4591001 1094 10941179	GENRL	Road traffic accident/ motor vehicle accident Pyrexia/ fever#	1 4	16OCT2020 18FEB2021	22/1 1/1	3 1	No Yes	O	NA NA/TC	R (16OCT2020) R (18FEB2021)	N/N N/N
16-55/ C4591001 1095 10951001	MUSC	Arthralgia/ left knee pain	1	17AUG2020	19/1	1	No	O	NA/TC	R (17AUG2020)	N/N
16-55/ C4591001 1095 10951005	MUSC	Arthralgia/ polyarthralgias	1	06AUG2020	8/C	1	No	O	NA	N	N/N
16-55/ C4591001 1095 10951009	INFEC	Gastroenteritis viral/ viral gastroenteritis	2	01SEP2020	15/1	1	No	O	NA	R (01SEP2020)	N/N
16-55/ C4591001 1095 10951009	REPRO	Adnexal torsion/ torsion of right ovary	2	23DEC2020	125/27	3	No	O	NA/TC/TCN	R (18JAN2021)	Y/N
16-55/ C4591001 1095 10951022	GASTR	Diarrhoea/ Diarrhea#	3	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ left arm injection site pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1095 10951023	INFEC	Diverticulitis/ Diverticulitis flare	1	20AUG2020	18/5	1	No	O	NA/TC	R (24AUG2020)	N/N
16-55/ C4591001 1095 10951026	METAB	Decreased appetite/ Loss of appetite	1	13AUG2020	11/C	1	No	O	NA	RG	N/N
	INJ&P	Fall/ Fall	1	23AUG2020	21/1	1	No	O	NA	R (23AUG2020)	N/N
		Skin abrasion/ Left arm abrasions	1	23AUG2020	21/8	1	No	O	NA	R (30AUG2020)	N/N
16-55/ C4591001 1095 10951029	RESP	Rhinitis allergic/ allergic rhinitis	2	03SEP2020	11/2	1	No	O	NA	R (04SEP2020)	N/N
	GASTR	Diarrhoea/ diarrhea	2	04SEP2020	12/2	1	No	O	NA	R (05SEP2020)	N/N
16-55/ C4591001 1095 10951047	INJ&P	Rib fracture/ Rib fracture	2	30AUG2020	6/33	1	No	O	NA/TC	R (01OCT2020)	N/N
	GENRL	Malaise/ idiopathic malaise	2	31AUG2020	7/2	1	No	O	NA	R (01SEP2020)	N/N
16-55/ C4591001 1095 10951055	REPRO	Cervical dysplasia/ ASCUS of cervix	1	10AUG2020	7/18	1	No	O	NA/TC	R (27AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1095 10951058	VASC	Hypertension/ Worsening of Hypertension	2	22JAN2021	150/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1095 10951062	INJ&P	Arthropod bite/ nonvenomous insect bite of right elbow	1	17AUG2020	13/1	1	No	O	NA/TC	R (17AUG2020)	N/N	
	IMMUN	Seasonal allergy/ seasonal allergies	2	14SEP2020	20/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1095 10951066	PSYCH	Insomnia/ Worsening insomnia#	2	15JAN2021	143/C	2	No	O	NA	N	N/N	
16-55/ C4591001 1095 10951087	GENRL	Fatigue/ Fatigue	1	12AUG2020	7/2	1	No	O	NA	R (13AUG2020)	N/N	
16-55/ C4591001 1095 10951095	RESP	Rhinitis allergic/ allergic rhinitis	1	17AUG2020	11/5	1	No	O	NA	R (21AUG2020)	N/N	
	MUSC	Myalgia/ Myalgia#	3	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	04MAR2021	1/1	1	Yes		NA	R (04MAR2021)	N/N	
		Injection site pain/ left arm pain at injection site#	4	04MAR2021	1/C	1	Yes		NA	RG	N/N	
	MUSC	Myalgia/ generalized myalgias#	4	04MAR2021	1/1	1	Yes		NA	R (04MAR2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1095 10951106	MUSC	Arthralgia/ polyarthralgia	2	03SEP2020	7/2	1	No	O	NA	R (04SEP2020)	N/N	
16-55/ C4591001 1095 10951112	GASTR	Nausea/ Nausea	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N	
	MUSC	Myalgia/ Myalgia	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N	
	NERV	Headache/ Headache	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/N	
	GENRL	Injection site pain/ Injection Site Tenderness	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N	
	NERV	Headache/ Headache	2	17SEP2020	2/3	1	Yes		NA/TC	R (19SEP2020)	N/N	
	VASC	Hot flush/ Hot Flashes	2	17SEP2020	2/C	1	Yes		NA	N	N/N	
	NERV	Sinus headache/ Sinus Headache	2	25SEP2020	10/2	1	No	O	NA/TC	R (26SEP2020)	N/N	
16-55/ C4591001 1095 10951116	GENRL	Fatigue/ fatigue	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N	
	MUSC	Myalgia/ Generalized myalgias	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N	
	NERV	Headache/ Headache	2	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1095 10951119	MUSC	Back pain/ mechanical back pain	2	02JAN2021	109/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1095 10951124	SKIN	Dermatitis contact/ Dermatitis-poison ivy	1	12SEP2020	20/5	1	No	O	NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1095 10951129	MUSC	Myalgia/ Myalgia post vaccine	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1095 10951132	INV	Body temperature increased/ Elevated Body Temperature	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	MUSC	Myalgia/ Myalgia post vaccination	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ Headache post vaccination	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1095 10951137	GENRL	Vaccination site pain/ Left arm injection site pain post vaccine #1.#	3	05MAR2021	1/2	1	Yes		NA	R (06MAR2021)	N/N
	GENRL	Chills/ Chills#	3	06MAR2021	2/2	1	Yes		NA	R (07MAR2021)	N/N
16-55/ C4591001 1095 10951138	GENRL	Injection site pain/ left arm (deltoid) injection site pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1095 10951141	SKIN	Diabetic foot/ Diabetic Foot Ulcer R Foot	1	14SEP2020	20/C	1	No	O	P/TCN/W	N	N/N	
16-55/ C4591001 1095 10951143	GASTR	Nausea/ nausea#	3	13JAN2021	1/1	1	Yes		NA	R (13JAN2021)	N/Y	
	GENRL	Injection site pain/ Pain at Injection Site 30 mins after dose#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/Y	
	NERV	Dizziness/ dizziness#	3	13JAN2021	1/1	1	No	O	NA	R (13JAN2021)	N/Y	
16-55/ C4591001 1095 10951144	GENRL	Injection site pain/ pain right shoulder injection site (serapin)	1	09SEP2020	15/5	1	No	O	NA/TC	R (13SEP2020)	N/N	
16-55/ C4591001 1095 10951148	GENRL	Chills/ Chills post vaccination	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue post vaccination	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	
	PSYCH	Anxiety disorder/ Anxiety Disorder	2	NOV2020	46/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1095 10951149	INV	Body temperature increased/ elevated temperature	1	13SEP2020	18/2	1	Yes		NA/TC	R (14SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1095 10951150	NERV	Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
		Headache/ Headache	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1095 10951150	INFEC	Soft tissue infection/ soft tissue infection left leg*		JUN2020		1	No	O	NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1095 10951153	GENRL	Injection site pain/ injection site pain left arm	2	22SEP2020	1/6	1	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1095 10951154	MUSC	Pyrexia/ fever post vaccination	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		Myalgia/ myalgia post vaccination	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		Headache/ headache post vaccination	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1095 10951154	GASTR	Nausea/ nausea post vaccination	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ injection site pain left arm	2	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/Y
16-55/ C4591001 1095 10951156	GENRL	Injection site pain/ Injection site pain left arm	1	29AUG2020	2/4	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Chills/ Post vaccine chills	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1095 10951159	NERV	Fatigue/ Post vaccine fatigue	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
		Pyrexia/ Post vaccine fever	2	16SEP2020	1/2	3	Yes		NA/TC	R (17SEP2020)	N/N	
		Headache/ Post vaccine headache	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain right arm	1	29AUG2020	1/4	1	Yes		NA	R (01SEP2020)	N/Y	
	GENRL	Chills/ Chills	2	18SEP2020	1/2	1	Yes		NA/TC	R (19SEP2020)	N/N	
16-55/ C4591001 1095 10951160	GENRL	Fatigue/ fatigue	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N	
		Injection site pain/ Pain at injection site post vaccination	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001 1095 10951161	GENRL	Injection site warmth/ Warmth at injection site	2	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N	
		Fatigue/ Fatigue post vaccination	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	
	GENRL	Injection site pain/ injection site reaction left arm myalgia	1	29AUG2020	1/3	1	Yes		NA	R (31AUG2020)	N/N	
	GENRL	Injection site pain/ injection site pain left arm	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N	
16-55/ C4591001	MUSC	Arthralgia/ Arthralgia post vaccine	1	29AUG2020	1/3	2	Yes		NA/TC	R (31AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1095 10951168	SOCCI	Menopause/ Perimenopausal	1	14SEP2020	17/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1095 10951169	CONG	Developmental hip dysplasia/ Right Hip dysplasia	2	20FEB2021	153/C	2	No	O	NA	N	N/N	
16-55/ C4591001 1095 10951170	NERV	Headache/ Headache	1	29AUG2020	1/3	1	Yes		NA/TC	R (31AUG2020)	N/N	
	GENRL	Injection site pain/ Injection site pain left arm	1	30AUG2020	2/3	1	Yes		NA/TC	R (01SEP2020)	N/N	
	GENRL	Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N	
	MUSC	Myalgia/ Myalgias	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N	
	NERV	Headache/ Headache	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N	
16-55/ C4591001 1095 10951171	SKIN	Dermatitis contact/ Contact Dermatitis Left Arm	1	29AUG2020	1/2	1	Yes		NA	R (30AUG2020)	N/N	
16-55/ C4591001 1095 10951172	GENRL	Injection site pain/ Left arm injection site pain#	3	02FEB2021	2/2	1	Yes		NA/TC	R (03FEB2021)	N/N	
16-55/ C4591001	CARD	Acute myocardial infarction/ STEMI: ST elevation Myocardial Infarction	1	05SEP2020	8/5	4	No	O	NA/TC/TCN	R (09SEP2020)	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1095 10951173		Coronary artery disease/ Coronary Artery Disease	1	05SEP2020	8/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1095 10951174	MUSC	Myalgia/ Myalgia	1	09SEP2020	10/2	1	Yes		NA	R (10SEP2020)	N/N	
16-55/ C4591001 1095 10951176	GENRL	Injection site pain/ right side injection site pain	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N	
	GENRL	Injection site pain/ injection site pain right arm	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N	
	MUSC	Myalgia/ post vaccination myalgia	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N	
	NERV	Headache/ post vaccination headache	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N	
16-55/ C4591001 1095 10951177	GENRL	Injection site pain/ injection site myalgia left arm	1	03SEP2020	1/7	1	Yes		NA	R (09SEP2020)	N/N	
16-55/ C4591001 1095 10951178	GENRL	Injection site pain/ Pain at injection site left arm	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N	
16-55/ C4591001 1095 10951182	GENRL	Injection site pain/ Injection site pain	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1095 10951183	GENRL	Chills/ Generalized Rigors	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
	INV	Body temperature increased/ elevated temperature	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N	
	MUSC	Myalgia/ generalized myalgia	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
	GENRL	Chills/ chills without fever	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
			Fatigue/ fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N	
	INJ&P	Tendon injury/ left finger tendon injury	2	26SEP2020	6/C	1	No	O	NA	RG	N/N	
	16-55/ C4591001 1095 10951186	GENRL	Pyrexia/ fever	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1095 10951188	MUSC	Myalgia/ myalgia post vaccination	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 1095 10951194	GENRL	Injection site pain/ injection site pain left arm	1	02SEP2020	2/5	1	Yes		NA/TC	R (06SEP2020)	N/N	
	RESP	Rhinitis allergic/ allergic rhinitis	1	02SEP2020	2/5	1	No	O	NA/TC	R (06SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Back pain/ Back Pain	2	15OCT2020	23/2	1	No	O	NA/TC	R (16OCT2020)	N/N	
		Pain in extremity/ Bilateral leg pain	2	15OCT2020	23/2	1	No	O	NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001 1095 10951196	INJ&P	Ligament sprain/ Right wrist sprain	1	08SEP2020	8/29	1	No	O	NA	R (06OCT2020)	N/N	
16-55/ C4591001 1095 10951197	SKIN	Drug eruption/ Fixed drug eruption on feet bilaterally	2	26OCT2020	8/C	2	Yes		NA	N	N/N	
	MUSC	Intervertebral disc degeneration/ exacerbation of Degenerative Disc Disease	2	14JAN2021	88/2	3	No	O	NA/TC/TCN	R (15JAN2021)	Y/N	
16-55/ C4591001 1095 10951198	MUSC	Myalgia/ post vaccination myalgia	1	02SEP2020	2/1	1	Yes		NA/TC	R (02SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N	
		Injection site pain/ Injection Site pain Left Arm	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/Y	
	MUSC	Myalgia/ Myalgia	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N	
16-55/ C4591001 1095 10951199	GENRL	Injection site pain/ injection site reaction myalgia	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1095 10951208	GENRL	Injection site pain/ myalgia due to intramuscular injection into deltoid muscle	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N	
	INFEC	Tooth infection/ tooth infection	1	23SEP2020	22/16	1	No	O	NA/TC	R (08OCT2020)	N/N	
	ENDO	Hypothyroidism/ worsening of hypothyroidism	1	08OCT2020	37/C	1	No	O	NA/TC	UNK	N/N	
16-55/ C4591001 1095 10951218	GENRL	Pyrexia/ Fever	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
	SKIN	Hyperhidrosis/ Diaphoresis	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
16-55/ C4591001 1095 10951225	GENRL	Injection site pain/ injection site left deltoid muscle pain	1	04SEP2020	1/4	1	Yes		NA	R (07SEP2020)	N/N	
	MUSC	Myalgia/ myalgia	1	05SEP2020	2/1	1	Yes		NA/TC	R (05SEP2020)	N/N	
	INV	Body temperature increased/ elevated temperature	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N	
16-55/ C4591001 1095 10951233	GENRL	Pyrexia/ Fever	2	15OCT2020	2/1	2	Yes		NA/TC	R (15OCT2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection site myalgia left arm	1	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1095 10951241	GENRL	Fatigue/ generalized fatigue	1	20OCT2020	21/2	1	No	O	NA	R (21OCT2020)	N/N
	GENRL	Fatigue/ generalized fatigue	1	30OCT2020	31/2	2	No	O	NA	R (31OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain	2	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/Y
1095 10951250	GENRL	Fatigue/ Fatigue	1	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
1095 10951251	MUSC	Myalgia/ Myalgia post vaccination	1	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N
		Injection site pain/ pain at injection site left arm	2	20OCT2020	1/6	1	Yes		NA	R (25OCT2020)	N/N
		Injection site swelling/ swelling at injection site left arm	2	20OCT2020	1/6	1	Yes		NA	R (25OCT2020)	N/N
		Injection site warmth/ warmth at injection site left arm	2	20OCT2020	1/6	1	Yes		NA	R (25OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N
	NERV	Headache/ worsening headache	2	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1095 10951255	GENRL	Injection site pain/ pain at injection site left arm post vaccine	1	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain Left Arm	2	19OCT2020	1/2	1	Yes		NA/TC	R (20OCT2020)	N/N	
16-55/ C4591001 1095 10951257	GENRL	Fatigue/ fatigue	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N	
		Injection site pain/ injection site pain left arm	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N	
	NERV	Headache/ worsening Headache	2	22OCT2020	2/1	1	Yes		NA/TC	R (22OCT2020)	N/N	
16-55/ C4591001 1095 10951259	GENRL	Fatigue/ Fatigue#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N	
	GENRL	Pain/ body aches#	4	12JAN2021	2/2	1	Yes		NA/TC	R (13JAN2021)	N/N	
	GASTR	Umbilical hernia/ Umbilical Hernia#	4	01FEB2021	22/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1095 10951262	MUSC	Myalgia/ myalgia left arm	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N	
	GENRL	Fatigue/ Generalized fatigue	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1095 10951266	GENRL	Malaise/ generalized malaise	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N	
		Injection site pain/ left arm pain at injection site	1	08OCT2020	1/5	1	Yes		NA/TC	R (12OCT2020)	N/N	
		Injection site pain/ injection site pain left arm	2	28OCT2020	1/2	1	Yes		NA/TC	R (29OCT2020)	N/N	
		Diarrhoea/ Diarrhea	2	29OCT2020	2/1	1	Yes		NA	R (29OCT2020)	N/N	
		Fatigue/ fatigue	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N	
16-55/ C4591001 1095 10951267	GENRL	Myalgia/ myalgia	2	29OCT2020	2/2	1	Yes		NA/TC	R (30OCT2020)	N/N	
		Chills/ chills	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N	
		Pyrexia/ Fever	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N	
		Myalgia/ myalgias	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N	
		Headache/ mild headache	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N	
16-55/ C4591001 1095 10951274	NERV	Headache/ headache	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N	
16-55/ C4591001	INJ&P	Ligament rupture/ Right ACL tear	1	19OCT2020	8/C	2	No	O	NA/TC	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1095 10951277		Meniscus injury/ right meniscus tear	1	19OCT2020	8/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1095 10951278	GASTR	Nausea/ Nausea	1	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N	
	INFEC	Abscess limb/ Right leg anterior abscess	1	19OCT2020	8/11	3	No	O	NA/TC	R (29OCT2020)	N/N	
		Infected bite/ Cellulitis due to spider bite right anterior leg	1	19OCT2020	8/11	3	No	O	NA/TC	R (29OCT2020)	N/N	
	PSYCH	Anxiety/ Worsening anxiety	2	03DEC2020	31/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1095 10951280	NERV	Headache/ Headache	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/Y	
	MUSC	Pain in extremity/ Left Hand Pain	2	20NOV2020	17/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1095 10951281	GENRL	Injection site pain/ Injection site pain left arm	1	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N	
	METAB	Hyperlipidaemia/ Hyperlipidemia	1	19OCT2020	8/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1095 10951282	GENRL	Injection site pain/ injection site pain right arm	1	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1095 10951284	INJ&P	Ligament sprain/ left fifth toe sprain	1	21OCT2020	10/11	1	No	O	NA	R (31OCT2020)	N/N
	MUSC	Myalgia/ left deltoid myalgia	1	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1095 10951285	NERV	Headache/ headache	1	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/Y
16-55/ C4591001 1095 10951286	GENRL	Injection site pain/ injection site pain left arm	1	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
	GENRL	Chills/ chills	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
		Injection site pain/ injection site pain left arm	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
		Pyrexia/ Fever	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N
	GENRL	Injection site pain/ injection site pain left arm	1	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/N
	NERV	Headache/ Headache	1	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/Y
	GENRL	Chills/ chills	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
		Injection site pain/ injection site pain right arm	2	03NOV2020	1/3	1	Yes		NA	R (05NOV2020)	N/N
	Pyrexia/ Fever	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1095 10951288	MUSC	Myalgia/ Myalgias	1	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
	MUSC	Arthralgia/ Arthralgia	1	15OCT2020	2/4	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1095 10951290	GENRL	Asthenia/ Weakness	2	05NOV2020	2/3	1	Yes		NA	R (07NOV2020)	N/N
		Chills/ Chills	2	05NOV2020	2/3	1	Yes		NA	R (07NOV2020)	N/N
	INV	Heart rate increased/ Elevated Heart Rate	2	05NOV2020	2/1	1	Yes		NA	R (05NOV2020)	N/N
	NERV	Headache/ Headache	2	05NOV2020	2/3	1	Yes		NA	R (07NOV2020)	N/N
	GASTR	Aphthous ulcer/ aphthous ulcers to soft palate	2	25NOV2020	22/C	1	Yes		NA	N	N/N
16-55/ C4591001 1095 10951291	GENRL	Injection site pain/ Pain at injection site L arm#	3	12FEB2021	1/2	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1095 10951293	GENRL	Chills/ Chills Post Vaccine	2	05NOV2020	2/1	1	Yes		NA/TC	R (05NOV2020)	N/N
		Fatigue/ Fatigue Post Vaccine	2	05NOV2020	2/1	1	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ diarrhea	1	16OCT2020	1/1	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1095 10951294	INJ&P	Fall/ Fall	2	28NOV2020	25/15	1	No	O	NA/TC	R (12DEC2020)	N/N	
	MUSC	Pain in extremity/ left leg pain	2	28NOV2020	25/15	1	No	O	NA/TC	R (12DEC2020)	N/N	
16-55/ C4591001 1095 10951295	GENRL	Injection site pain/ Pain at injection site left arm*		16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N	
	MUSC	Synovial cyst/ Ganglion cyst right wrist	1	02NOV2020	18/4	1	No	O	NA	R (05NOV2020)	N/N	
16-55/ C4591001 1095 10951304	GENRL	Injection site pain/ injection site pain left arm	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N	
		Injection site pain/ pain at injection site left arm	2	11NOV2020	1/3	1	Yes		NA/TC	R (13NOV2020)	N/N	
	MUSC	Myalgia/ generalized myalgia	2	11NOV2020	1/3	1	Yes		NA/TC	R (13NOV2020)	N/N	
	MUSC	Systemic lupus erythematosus/ lupus	2	27NOV2020	17/C	2	No	O	NA	N	N/N	
16-55/ C4591001 1095 10951306	GASTR	Diarrhoea/ Diarrhea	2	18NOV2020	2/4	1	Yes		NA	R (21NOV2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	18NOV2020	2/4	1	Yes		NA	R (21NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1095 10951307	MUSC	Myalgia/ Generalized myalgia	2	18NOV2020	2/4	1	Yes		NA/TC	R (21NOV2020)	N/N	
	GENRL	Chills/ chills	2	21NOV2020	2/2	1	Yes		NA	R (22NOV2020)	N/N	
	INV	Body temperature increased/ elevated temperature	2	21NOV2020	2/2	1	Yes		NA	R (22NOV2020)	N/N	
16-55/ C4591001 1095 10951308	MUSC	Myalgia/ generalized myalgia	2	21NOV2020	2/2	1	Yes		NA	R (22NOV2020)	N/N	
	PSYCH	Depression/ worsening of depression	2	DEC2020	1/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1095 10951310	PSYCH	Attention deficit hyperactivity disorder/ ADHD diagnosed by Psychiatrist	2	25JAN2021	42/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1095 10951317	GENRL	Fatigue/ Fatigue	2	15DEC2020	1/1	1	Yes		NA	R (15DEC2020)	N/Y	
16-55/ C4591001 1095 10951319	INJ&P	Joint dislocation/ L Patellar Dislocation	2	02JAN2021	6/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1096 10961031	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	14AUG2020	1/40		No	O	P	R (22SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1096 10961035 16-55/ C4591001 1096 10961036 16-55/ C4591001 1096 10961042 16-55/ C4591001 1096 10961059 16-55/ C4591001 1096 10961062	RESP	Oropharyngeal pain/ Sore throat	1	05OCT2020	53/3	1	No	O	NA	R (07OCT2020)	N/N	
	INFEC	Urinary tract infection/ urinary tract infection	1	22JAN2021	162/C	1	No	O	NA/TC	N	N/N	
	GENRL	Injection site pain/ injection pain	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N	
	PSYCH	Depression suicidal/ worsening of depression with suicidal ideation	2	OCT2020	23/	3	No	O	P/TC	RS (14NOV2020)	Y/N	
	GENRL	Pyrexia/ Fever	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N	
	GASTR	Diarrhoea/ DIARRHEA	1	25AUG2020	7/4	2	Yes		NA/TC	R (28AUG2020)	N/N	
	METAB	Hypokalaemia/ HYPOKALEMIA	2	SEP2020	1/	3	No	O	NA/TC	R	Y/N	
	VASC	Hypertension/ worsening of hypertension	2	14SEP2020	6/C	1	No	O	NA/TC	N	N/N	
	MUSC	Muscular weakness/ bilateral lower extremity weakness	2	04OCT2020	26/2	3	No	O	NA	R (05OCT2020)	Y/N	
	MUSC	Muscle spasms/ left upper arm Muscle spasms	1	22AUG2020	4/2	1	Yes		NA	R (23AUG2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1096 10961063 16-55/ C4591001 1096 10961078	RESP	Cough/ Cough	1	01SEP2020	13/4	1	No	O	NA	R (04SEP2020)	N/N	
16-55/ C4591001 1096 10961083	MUSC	Osteoarthritis/ osteoarthritis	2	NOV2020	52/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1096 10961088	GASTR	Dyspepsia/ Indigestion	2	12SEP2020	2/3	2	Yes		NA/TC	R (14SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	
	MUSC	Arthralgia/ Joint pain in both elbows and knees	2	12SEP2020	2/2	2	Yes		NA	R (13SEP2020)	N/N	
16-55/ C4591001 1096 10961090	INJ&P	Limb injury/ Right arm injury	2	19SEP2020	9/1	2	No	O	NA/TC	R (19SEP2020)	N/N	
		Road traffic accident/ motor vehicle accident	2	19SEP2020	9/1	2	No	O	NA/TC	R (19SEP2020)	N/N	
	MUSC	Pain in extremity/ Right arm pain	2	19SEP2020	9/78	2	No	O	NA	R (05DEC2020)	N/N	
16-55/ C4591001 1096 10961093	GASTR	Flatulence/ Gassiness	2	18FEB2021	161/14	2	No	O	NA	R (03MAR2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1096 10961097	NERV	Headache/ Intermittent headaches	2	13SEP2020	2/3	1	Yes		NA/TC	R (15SEP2020)	N/N
	SKIN	Rash/ generalized rash on body	2	13SEP2020	2/6	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1096 10961098	PSYCH	Insomnia/ Insomnia	2	06OCT2020	25/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1096 10961115	RESP	Oropharyngeal pain/ Sore throat	1	12SEP2020	20/8	1	No	O	NA	R (19SEP2020)	N/N
16-55/ C4591001 1096 10961130	NERV	Tension headache/ stress headaches	1	26AUG2020	2/23	1	No	O	NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1096 10961137	INJ&P	Concussion/ concussion	1	13SEP2020	19/5	2	No	O	NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1096 10961138	METAB	Vitamin D deficiency/ VITAMIN D DEFICIENCY	2	06OCT2020	21/C	1	No	O	NA/TC	N	N/N
	PSYCH	Anxiety/ worsening of anxiety	2	06OCT2020	21/133	1	No	O	NA/TC	R (15FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	27AUG2020	2/4	1	Yes		NA	R (30AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1096 10961141	INFEC	Ear infection/ Right ear infection	1	13SEP2020	18/5	1	No	O	NA/TC	R (17SEP2020)	N/N
1096 10961150	NERV	Tension headache/ stress headache	2	22FEB2021	159/16	1	No	O	NA/TC	R (09MAR2021)	N/N
1096 10961168	GASTR	Flatulence/ gassiness	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
1096 10961169	GENRL	Chills/ chills	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
		Fatigue/ fatigue	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
		Injection site pain/ injection site tenderness	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
		Pyrexia/ fever	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
	NERV	Headache/ headache	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
	GASTR	Abdominal pain upper/ upper abdominal pain	2	15FEB2021	152/1	2	No	O	NA	R (15FEB2021)	N/N
	GASTR	Abdominal pain upper/ Upper abdominal pain	2	20FEB2021	157/1	2	No	O	NA	R (20FEB2021)	N/N
16-55/ C4591001	SKIN	Rash/ rash around right elbow#	3	19JAN2021	2/C	1	No	O	NA	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1096 10961170	GENRL	Injection site pain/ injection site soreness*		29AUG2020	1/3	2	Yes		NA	R (31AUG2020)	N/N	
1096 10961186	NERV	Headache/ Intermittent Headaches	1	02SEP2020	2/38	1	Yes		NA	R (09OCT2020)	N/N	
1096 10961206	INJ&P	Epicondylitis/ lateral epicondylitis of the left elbow	1	09SEP2020	9/C	1	No	O	NA	N	N/N	
1096 10961207	SKIN	Dermatitis contact/ Contact dermatitis on left arm	1	19SEP2020	19/17	1	No	O	NA/TC	R (05OCT2020)	N/N	
1096 10961208	SKIN	Hyperhidrosis/ Sweating	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N	
1096 10961209	RESP	Nasal congestion/ Nasal congestion	1	16SEP2020	16/5	1	No	O	NA	R (20SEP2020)	N/N	
		Oropharyngeal pain/ Sore throat	1	16SEP2020	16/3	1	No	O	NA	R (18SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site soreness	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/Y	
1096 10961209	GENRL	Fatigue/ Fatigue	1	02SEP2020	1/3	2	Yes		NA	R (04SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1096 10961213		Injection site pain/ Injection site soreness	1	02SEP2020	1/3	2	Yes		NA	R (04SEP2020)	N/N
	MUSC	Myalgia/ Generalized muscle pain	1	02SEP2020	1/3	2	Yes		NA/TC	R (04SEP2020)	N/N
	GENRL	Injection site pain/ Injection site soreness	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ Fever	2	24SEP2020	1/2	2	Yes		NA/TC	R (25SEP2020)	N/N
	MUSC	Myalgia/ Generalized muscle pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001	GASTR	Nausea/ Nausea	1	07SEP2020	6/9	1	No	O	NA/TC	R (15SEP2020)	N/N
1096 10961215											
16-55/ C4591001	GENRL	Chills/ CHILLS	1	03SEP2020	2/1	1	Yes		NA/TC	R (03SEP2020)	N/N
1096 10961219											
		Pain/ BODY ACHES	1	03SEP2020	2/2	1	Yes		NA/TC	R (04SEP2020)	N/N
		Pyrexia/ FEVER	1	03SEP2020	2/1	1	Yes		NA/TC	R (03SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE SORENESS	1	04SEP2020	3/3	1	Yes		NA/TC	R (06SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site soreness*		03SEP2020	1/4	1	Yes		NA	R (06SEP2020)	N/N
1096 10961226											

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1096 10961236	GENRL	Injection site pain/ Injection site soreness	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Chills/ Chills	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Chills/ Chills	2	26SEP2020	1/2	1	Yes		NA	R (27SEP2020)	N/N
		Pyrexia/ Fever (102F max)	2	26SEP2020	1/2	2	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1096 10961240	MUSC	Myalgia/ Generalized muscle aches	2	26SEP2020	1/2	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ Headache	2	27SEP2020	2/2	1	Yes		NA	R (28SEP2020)	N/N
	NERV	Presyncope/ presyncope	1	04SEP2020	1/1	1	Yes		NA	R (04SEP2020)	N/Y
	GASTR	Nausea/ Nausea	2	30SEP2020	8/3	1	No	O	NA	R (02OCT2020)	N/N
		Vomiting/ Vomiting	2	30SEP2020	8/3	1	No	O	NA	R (02OCT2020)	N/N
16-55/ C4591001	NERV	Headache/ Headache	2	30SEP2020	8/3	1	No	O	NA	R (02OCT2020)	N/N
	EAR	Vertigo/ Vertigo	2	09DEC2020	78/1	2	No	O	NA/TC	R (09DEC2020)	N/N
	INFEC	Conjunctivitis/ left eye conjunctivitis	2	17OCT2020	25/8	1	No	O	NA/TC	R (24OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1096 10961244 16-55/ C4591001 1096 10961255	GENRL	Injection site pain/ Injection site pain	1	23SEP2020	20/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1096 10961256	PSYCH	Anxiety/ Worsening of anxiety	2	08OCT2020	16/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1096 10961256	NERV	Dizziness/ Lightheaded*		04SEP2020	1/1	1	No	O	NA	R (04SEP2020)	N/N
16-55/ C4591001 1096 10961262	GENRL	Injection site erythema/ Injection site redness on left arm (3 units on sponsor's caliper)	1	05SEP2020	1/1	1	Yes		NA	R (05SEP2020)	N/Y
	GENRL	Fatigue/ Fatigue	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N
		Injection site pain/ Injection site pain	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N
	MUSC	Myalgia/ Generalized muscle aches	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1096 10961264	INJ&P	Road traffic accident/ motor vehicle accident	2	24OCT2020	30/1	1	No	O	NA	R (24OCT2020)	N/N
	MUSC	Back pain/ Lower Back Pain	2	24OCT2020	30/61	2	No	O	NA/TC	R (23DEC2020)	N/N
	GENRL	Pain/ generalized body aches	2	26OCT2020	32/6	1	No	O	NA/TC	R (31OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1096 10961265	GENRL	Injection site erythema/ injection site redness left upper arm	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N	
		Injection site pain/ Injection site pain left upper arm	2	24SEP2020	1/5	2	Yes		NA	R (28SEP2020)	N/N	
	MUSC	Myalgia/ General muscle aches	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N	
	NERV	Headache/ Headache	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1096 10961267	GENRL	Injection site pain/ Injection site soreness (left arm)	1	06SEP2020	2/2	1	Yes		NA	R (07SEP2020)	N/N	
16-55/ C4591001 1096 10961271	GASTR	Nausea/ NAUSEA	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
	GENRL	Chills/ CHILLS	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
		Pain/ BODY ACHE	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
	VASC	Hot flush/ INTERMITTENT HOT FLAHERS	2	25SEP2020	2/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1096 10961275	GENRL	Injection site pain/ Injection site soreness	1	05SEP2020	1/3	1	Yes		NA	R (07SEP2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	05SEP2020	1/3	1	Yes		NA	R (07SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1096 10961277	BLOOD	Lymphadenopathy/ Right swollen lymph node under jaw	1	13SEP2020	9/4	1	No	O	NA	R (16SEP2020)	N/N	
16-55/ C4591001 1096 10961278	INFEC	Sialoadenitis/ Sialadenitis	1	13SEP2020	9/4	1	No	O	NA	R (16SEP2020)	N/N	
	RESP	Oropharyngeal pain/ Sore throat	1	13SEP2020	9/2	1	No	O	NA/TC	R (14SEP2020)	N/N	
	MUSC	Myalgia/ Generalized muscle aches due to exercise	1	22SEP2020	18/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1096 10961280	GENRL	Chills/ Chills	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N	
		Injection site pain/ Injection site soreness	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N	
16-55/ C4591001 1096 10961299	GENRL	Injection site swelling/ Injection site swelling	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/Y	
	INFEC	Tooth infection/ Canine Tooth Infection#	3	29JAN2021	17/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1096 10961301	INFEC	Tooth infection/ tooth infection	1	15SEP2020	8/16	1	No	O	NA/TC	R (30SEP2020)	N/N	
16-55/ C4591001	INJ&P	Epicondylitis/ right tennis elbow	2	15DEC2020	78/C	2	No	O	NA/TC	N	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1096 10961305	INFEC	Ear infection/ left ear infection	2	03JAN2021	97/8	1	No	O	NA/TC	R (10JAN2021)	N/N
16-55/ C4591001 1096 10961307	GENRL	Fatigue/ fatigue	2	07OCT2020	6/4	1	No	O	NA	R (10OCT2020)	N/N
16-55/ C4591001 1096 10961331	GASTR	Diarrhoea/ Diarrhea	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ Injection Pain	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Injection Pain	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	18SEP2020	4/2	1	Yes		NA	R (19SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	20SEP2020	6/2	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	20SEP2020	6/2	2	Yes		NA	R (21SEP2020)	N/N
	NERV	Headache/ Headache	1	20SEP2020	6/3	2	Yes		NA	R (22SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1096 10961336	GENRL	Fatigue/ Fatigue	1	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ Injection Pain	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ Headache*		15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	17SEP2020	3/2	2	Yes		NA	R (18SEP2020)	N/N
	GENRL	Chills/ Chills	1	19SEP2020	5/2	1	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ Headache	1	19SEP2020	5/2	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	20SEP2020	6/2	2	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1096 10961343	GENRL	Injection site pain/ Injection Site pain left arm#	3	31DEC2020	2/4	1	Yes		NA	R (03JAN2021)	N/N
16-55/ C4591001 1096 10961348	GENRL	Injection site pain/ Injection site soreness	1	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
	MUSC	Myalgia/ Generalized muscle aches	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1096 10961350	INFEC	Sinusitis/ sinus infection	1	01OCT2020	15/3	1	No	O	NA/TC	R (03OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1096 10961362	INJ&P	Meniscus injury/ left meniscus tear	1	19SEP2020	3/137	2	No	O	NA	R (02FEB2021)	N/N	
16-55/ C4591001 1096 10961375	GENRL	Injection site pain/ Site injection pain	1	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N	
16-55/ C4591001 1096 10961376	GENRL	Injection site pain/ Injection site soreness	1	07OCT2020	1/2	2	Yes		NA/TC	R (08OCT2020)	N/N	
		Injection site pruritus/ Injection site pruritus	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N	
		Injection site swelling/ Injection site swelling	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N	
16-55/ C4591001 1096 10961378	GENRL	Injection site pain/ Injection site soreness	1	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N	
	GENRL	Fatigue/ FATIGUE	2	30OCT2020	1/3	2	Yes		NA	R (01NOV2020)	N/N	
		Injection site pain/ INJECTION SITE PAIN IN LEFT ARM	2	30OCT2020	1/3	2	Yes		NA	R (01NOV2020)	N/N	
	GENRL	Pyrexia/ FEVER	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N	
	MUSC	Myalgia/ GENERALIZED MUSCLE ACHES	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Diarrhoea/ DIARRHEA	2	01NOV2020	3/3	1	Yes		NA	R (03NOV2020)	N/N
16-55/ C4591001 1096 10961382	GENRL	Injection site pain/ Injection site soreness	1	09OCT2020	1/1	1	Yes		NA	R (09OCT2020)	N/Y
16-55/ C4591001 1096 10961385	GENRL	Chills/ CHILLS	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
		Fatigue/ FATIGUE	1	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	1	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
		Pain/ BODY ACHES	1	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
		Pyrexia/ FEVER	1	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	31OCT2020	2/4	2	Yes		NA	R (03NOV2020)	N/N
		Pyrexia/ FEVER	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N
16-55/ C4591001 1098 10981009	CARD	Coronary artery disease/ Coronary Artery Disease#	2	01JAN2021	115/C	1	No	O	NA/TC	RG	N/N
	VASC	Hypertension/ Hypertension#	2	01JAN2021	115/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001	RESP	Dry throat/ Dry Throat	1	29AUG2020	9/1	1	No	O	NA	R (29AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1098 10981025 16-55/ C4591001 1098 10981054	GASTR	Diarrhoea/ Diarrhea	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001 1098 10981091	METAB	Obesity/ Obesity	2	21OCT2020	29/C	1	No	O	NA	RG	N/N	
		Type 2 diabetes mellitus/ Type 2 Diabetes	2	21OCT2020	29/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1098 10981101	GENRL	Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N	
16-55/ C4591001 1098 10981137	GENRL	Chills/ Chills	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N	
	GENRL	Asthenia/ Weakness	1	12SEP2020	3/1	1	Yes		NA/TC	R (12SEP2020)	N/N	
16-55/ C4591001 1098 10981140	GENRL	Pain/ Bodyache	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N	
16-55/ C4591001 1098 10981141	GENRL	Pain/ Bodyache	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1098 10981152	GENRL	Chills/ Chills	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N	
		Pain/ Bodyache	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N	
		Pyrexia/ Fever	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N	
16-55/ C4591001 1098 10981161	MUSC	Back pain/ BackPain	1	20SEP2020	7/1	1	No	O	NA	R (20SEP2020)	N/N	
16-55/ C4591001 1098 10981163	GENRL	Chills/ Chills	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N	
		Pyrexia/ Fever	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N	
16-55/ C4591001 1098 10981176	GASTR	Nausea/ Nausea	1	30SEP2020	15/1	1	Yes		NA/TC	R (30SEP2020)	N/N	
	MUSC	Myalgia/ Muscle Pain	1	30SEP2020	15/1	1	Yes		NA/TC	R (30SEP2020)	N/N	
16-55/ C4591001 1098 10981177	INV	Body temperature increased/ Elevated Temperature	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001	GENRL	Chills/ Chills	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1098 10981180	GENRL	Pyrexia/ Fever	1	16SEP2020	1/4	1	Yes		NA/TC	R (19SEP2020)	N/N
1098 10981183	GENRL	Pyrexia/ Fever	1	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
1098 10981188	GENRL	Peripheral swelling/ Swelling of Right and left arms	1	28SEP2020	8/1	1	No	O	NA	R (28SEP2020)	N/N
1098 10981196	SKIN	Erythema/ Redness of right arms and left arms	1	28SEP2020	8/1	1	No	O	NA	R (28SEP2020)	N/N
1098 10981207	GENRL	Injection site pain/ Left injection site pain	1	23SEP2020	2/3	1	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Pyrexia/ Fever	1	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Chills/ Chills	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
		Injection site pain/ Left arm injection site pain	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
	INV	Body temperature increased/ Elevated Temperature	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	14OCT2020	3/1	2	Yes		NA/TC	R (14OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1098 10981217	GENRL	Pyrexia/ Fever	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Pain/ Bodyache	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N
		Pyrexia/ Fever	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 1098 10981229	GENRL	Chills/ Chills	1	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
		Injection site pain/ Injection site Pain	1	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
		Pain/ Bodyaches	1	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
		Pyrexia/ Fever	1	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1098 10981243	GENRL	Chills/ Chills	1	03OCT2020	2/4	1	Yes		NA/TC	R (06OCT2020)	N/N
		Pyrexia/ Fever	1	03OCT2020	2/4	1	Yes		NA/TC	R (06OCT2020)	N/N
	MUSC	Myalgia/ Muscle Ache	1	03OCT2020	2/4	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1101 11011004	GENRL	Injection site erythema/ injection site redness	1	02SEP2020	2/2	2	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1101 11011005	NERV	Injection site pain/ arm soreness in injection arm	1	02SEP2020	2/2	2	Yes		NA	R (03SEP2020)	N/N	
		Injection site pain/ pain at the injection site	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N	
		Pyrexia/ fever	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N	
		Headache/ headache	1	02SEP2020	2/2	2	Yes		NA/TC	R (03SEP2020)	N/N	
		GASTR	Nausea/ nausea	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
			Pyrexia/ fever	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
		GENRL	Pyrexia/ fever#	4	14JAN2021	2/2	2	Yes		NA	R (15JAN2021)	N/N
		NERV	Headache/ headache#	4	14JAN2021	2/3	1	Yes		NA	R (16JAN2021)	N/N
16-55/ C4591001 1101 11011007	GENRL	Chills/ chills#	3	21JAN2021	2/1	1	Yes		NA	R (21JAN2021)	N/N	
	MUSC	Myalgia/ muscle aches#	3	21JAN2021	2/1	1	Yes		NA	R (21JAN2021)	N/N	
16-55/ C4591001	MUSC	Myalgia/ muscle aches#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1101 11011010	GENRL	Injection site pain/ pain at injection site	1	03SEP2020	1/2	2	Yes		NA	R (04SEP2020)	N/N
1101 11011012	GENRL	Injection site pain/ pain at injection site	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1101 11011013	GENRL	Injection site warmth/ injection site warmth	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
	NERV	Headache/ headache	1	04SEP2020	2/1	1	Yes		NA/TC	R (04SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ headache#	4	16FEB2021	2/2	2	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1101 11011016	GENRL	Injection site pain/ injection site pain#	3	05MAR2021	2/C	1	Yes		NA	N	N/N
16-55/ C4591001 1101 11011029	GENRL	Injection site pain/ injection site pain#	4	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/Y

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1101 11011030	GENRL	Pain/ generalized body aches#	4	18JAN2021	1/2	2	Yes		NA	R (19JAN2021)	N/N
		Pyrexia/ fever#	4	18JAN2021	1/2	2	Yes		NA	R (19JAN2021)	N/N
		Pyrexia/ fever	1	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		Cough/ cough	1	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		Upper respiratory tract congestion/ head congestion	1	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1101 11011033	GENRL	Chills/ chills	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ injection site pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1101 11011034	GENRL	Pyrexia/ fever	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Chills/ chills	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ pain at injection site	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
		Decreased appetite/ decreased appetite	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
	METAB										
	NERV	Headache/ headache	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1101 11011038	GASTR	Nausea/ nausea	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N	
	GENRL	Chills/ chills	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N	
		Fatigue/ fatigue	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N	
	NERV	Headache/ headache	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N	
	GENRL	Pain/ generalized body aches#	4	13JAN2021	1/2	2	Yes		NA/TC	R (14JAN2021)	N/N	
	NERV	Headache/ headache#	4	13JAN2021	1/2	2	Yes		NA/TC	R (14JAN2021)	N/N	
	16-55/ C4591001 1101 11011039	GENRL	Injection site pain/ injection site pain	1	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	02OCT2020	2/1	2	Yes		NA	R (02OCT2020)	N/N	
	16-55/ C4591001 1101 11011040	GENRL	Injection site pain/ injection site pain#	3	09FEB2021	1/3	2	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ headache#	3	10FEB2021	2/2	2	Yes		NA	R (11FEB2021)	N/N	
GENRL	Injection site pain/ injection site pain#	4	02MAR2021	1/C	1	Yes		NA/TC	RG	N/N		
GENRL	Pyrexia/ fever#	4	03MAR2021	2/C	1	Yes		NA	RG	N/N		

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache#	4	03MAR2021	2/C	1	Yes		NA/TC	RG	N/N
16-55/ C4591001 1101 11011041	GENRL	Injection site pain/ injection site pain#	3	19FEB2021	1/C	1	Yes		NA	RG	N/N
		Pyrexia/ fever#	3	19FEB2021	1/2	2	Yes		NA	R (20FEB2021)	N/Y
	GENRL	Pain/ generalized body aches#	3	20FEB2021	2/1	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1101 11011045	GENRL	Injection site pain/ injection site pain	1	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
16-55/ C4591001 1101 11011048	GENRL	Pyrexia/ fever	2	05OCT2020	1/3	2	Yes		NA/TC	R (07OCT2020)	N/N
	MUSC	Muscle fatigue/ muscle fatigue	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
	RESP	Oropharyngeal pain/ sore throat	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
		Sinus congestion/ sinus congestion	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1101 11011052	GENRL	Pyrexia/ fever	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1101 11011056	GENRL	Chills/ chills	1	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1101 11011059	GASTR	Diarrhoea/ diarrhea	1	17SEP2020	3/1	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	20JAN2021	1/1	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Pyrexia/ low grade fever#	3	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1101 11011060	INFEC	Gastroenteritis/ GASTROENTERITIS	1	18SEP2020	4/1	1	No	O	NA	R (18SEP2020)	N/N
	REPRO	Adenomyosis/ adenomyosis	2	16OCT2020	11/81	2	No	O	NA	R (04JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	3	20JAN2021	1/2	2	Yes		NA	R (21JAN2021)	N/N
		Pain/ general body aches#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	CARD	Tachycardia/ tachycardia#	4	08FEB2021	1/2	2	Yes		NA	R (09FEB2021)	N/N
	GENRL	Pain/ body aches#	4	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N
		Pyrexia/ fever#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1101 11011061	GASTR	Nausea/ nausea	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1101 11011062	EYE	Eye pain/ bilateral eye soreness	2	08OCT2020	2/3	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	08OCT2020	2/8	1	Yes		NA	R (15OCT2020)	N/N
	MUSC	Myalgia/ muscle aches	2	08OCT2020	2/3	2	Yes		NA/TC	R (10OCT2020)	N/N
	NERV	Headache/ headache	2	08OCT2020	2/3	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1101 11011065	GENRL	Chills/ chills#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	MUSC	Myalgia/ generalized muscle aches#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1101 11011067	GASTR	Diarrhoea/ diarrhea	2	14OCT2020	8/1	1	No	O	NA	R (14OCT2020)	N/N
	GENRL	Chills/ chills#	4	11MAR2021	2/1	2	Yes		NA	R (11MAR2021)	N/N
		Pyrexia/ fever#	4	11MAR2021	2/1	2	Yes		NA	R (11MAR2021)	N/N



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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache#	4	11MAR2021	2/1	1	Yes		NA	R (11MAR2021)	N/N
16-55/ C4591001 1101 11011069	INJ&P	Road traffic accident/ motor vehicle accident/subject was the driver	2	19OCT2020	11/1	2	No	O	NA	R (19OCT2020)	N/N
	MUSC	Myalgia/ muscle pain post-traumatic	2	19OCT2020	11/7	2	No	O	NA/TC	R (25OCT2020)	N/N
16-55/ C4591001 1101 11011070	GENRL	Injection site pain/ injection site pain	1	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1101 11011072	GENRL	Injection site pain/ injection site pain	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1101 11011073	GENRL	Injection site pain/ injection site pain#	3	09JAN2021	2/1	2	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1101 11011075	GENRL	Effusion/ fluid near spine	1	26SEP2020	10/C	2	No	O	NA/TC	RG	N/N
	INJ&P	Contusion/ left thigh bruise	1	26SEP2020	10/11	1	No	O	NA	R (06OCT2020)	N/N
		Road traffic accident/ motor vehicle accident	1	26SEP2020	10/1	2	No	O	NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1101 11011079	GENRL	Injection site erythema/ injection site redness	1	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1101 11011080	GENRL	Injection site pain/ injection site pain#	4	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
		Pyrexia/ fever#	4	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1101 11011085	GENRL	Chills/ chills#	3	20JAN2021	1/4	1	Yes		NA	R (23JAN2021)	N/N
		Fatigue/ fatigue#	3	20JAN2021	1/4	1	Yes		NA	R (23JAN2021)	N/N
		Injection site pain/ injection site pain#	3	20JAN2021	1/4	2	Yes		NA	R (23JAN2021)	N/N
	MUSC	Myalgia/ muscle aches#	3	20JAN2021	1/4	2	Yes		NA	R (23JAN2021)	N/N
	GENRL	Chills/ Chills#	4	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N
		Fatigue/ Fatigue#	4	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	4	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N

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1101 11011094 16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	1/4	1	Yes		NA/TC	R (30JAN2021)	N/N
1101 11011097	GASTR	Abdominal pain upper/ stomach pain#	3	29JAN2021	3/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Chills/ Chills#	3	29JAN2021	3/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Chills/ chills#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
		Injection site pain/ injection site pain#	4	19FEB2021	1/5	1	Yes		NA	R (23FEB2021)	N/N
		Pyrexia/ fever#	4	19FEB2021	1/4	2	Yes		NA	R (22FEB2021)	N/N
	GENRL	Non-cardiac chest pain/ non-cardiac chest pain#	4	21FEB2021	3/4	1	Yes		NA	R (24FEB2021)	N/N
	MUSC	Myalgia/ generalized muscle aches#	4	21FEB2021	3/2	1	Yes		NA	R (22FEB2021)	N/N
	NERV	Headache/ worsening headache#	4	21FEB2021	3/2	1	Yes		NA/TC	R (22FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain	1	13OCT2020	1/4	1	Yes		NA/TC	R (16OCT2020)	N/N
1101 11011107 16-55/ C4591001	NERV	Headache/ headache	1	21OCT2020	2/3	1	Yes		NA/TC	R (23OCT2020)	N/N
1101 11011115											

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	RESP	Sinus congestion/ sinus congestion	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N	
	INFEC	Genital herpes/ genital herpes	1	09NOV2020	21/C	2	No	O	NA/TC	N	N/N	
	INFEC	Coxsackie viral infection/ infection of coxsackievirus	2	06DEC2020	25/10	2	No	O	NA	R (15DEC2020)	N/N	
	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	19DEC2020	38/C		No	O	NA	UNK	N/N	
	PREG	Abortion spontaneous/ spontaneous abortion#	2	20FEB2021	101/1	3	No	O	NA	R (20FEB2021)	Y/N	
16-55/ C4591001 1107 11071003	GASTR	Tongue discomfort/ BURNT SENSATION ON TONGUE	1	11AUG2020	14/35	1	Yes		NA	R (14SEP2020)	N/N	
16-55/ C4591001 1107 11071010	INFEC	Vulvovaginal mycotic infection/ YEAST INFECTION VAGINAL	1	11AUG2020	13/7	1	No	O	NA/TC	R (17AUG2020)	N/N	
	GENRL	Pain/ BODYACHES#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N	
		Pyrexia/ FEVER#	3	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N	
	NERV	Dizziness/ DIZZINESS#	3	18FEB2021	1/1	1	Yes		NA	R (18FEB2021)	N/Y	
		Headache/ HEADACHE#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N	
16-55/ C4591001 1107 11071015	MUSC	Pain in extremity/ LEFT ARM PAIN	1	16AUG2020	14/8	1	Yes		NA	R (23AUG2020)	N/N	

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	GASTR	Haematochezia/ POSSIBLE BLOOD STREAKED STOOL	2	22SEP2020	28/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1107 11071020	INV	Blood testosterone decreased/ LOW TESTOSTERONE#	4	24FEB2021	17/C	1	No	O	NA/TC	N	N/N	
	VASC	Hypertension/ HYPERTENSION#	4	24FEB2021	17/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1107 11071031	GASTR	Colitis/ ASCENDING COLITIS	2	25NOV2020	73/19	3	No	O	NA/TC	R (13DEC2020)	Y/N	
16-55/ C4591001 1107 11071054	MUSC	Muscle twitching/ LEFT LOWER LIP TWITCH	1	06AUG2020	1/5	1	Yes		NA	R (10AUG2020)	N/N	
	PSYCH	Anxiety/ ANXIETY	2	SEP2020	6/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1107 11071059	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE#	3	29JAN2021	2/2	1	Yes		NA/TC	R (30JAN2021)	N/N	
16-55/ C4591001 1107 11071065	BLOOD	Microcytic anaemia/ MICROCYTIC ANEMIA	2	09NOV2020	75/C	3	No	O	NA/TC/TCN	N	Y/N	
	INV	Red blood cell morphology abnormal/ ABNORMAL RBC MORPHOLOGY INCLUDING SICKLE CELLS	2	09NOV2020	75/C	3	No	O	NA	N	Y/N	

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16-55/ C4591001 1107 11071102	INFEC	Tooth abscess/ TOOTH ABSCESS#	4	07FEB2021	21/8	1	No	O	NA/TC	R (14FEB2021)	N/N	
16-55/ C4591001 1107 11071112	MUSC	Neck pain/ CERVICALGIA	1	29AUG2020	17/32	1	No	O	NA/TC	R (29SEP2020)	N/N	
	GENRL	Chills/ CHILLS#	4	25FEB2021	4/2	1	Yes		NA	R (26FEB2021)	N/N	
		Pyrexia/ FEVER#	4	25FEB2021	4/2	1	Yes		NA	R (26FEB2021)	N/N	
16-55/ C4591001 1107 11071114	INFEC	Otitis media/ SEROUS OTITIS MEDIA#	4	03MAR2021	24/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1107 11071118	RENAL	Renal atrophy/ RIGHT KIDNEY ATROPHY	2	OCT2020	24/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1107 11071122	INFEC	Abscess oral/ ORAL ABSCESS	2	17DEC2020	101/11	1	No	O	NA/TC	R (27DEC2020)	N/N	
16-55/ C4591001 1107 11071123	GENRL	Chills/ CHILLS	2	14SEP2020	1/4	2	Yes		NA	R (17SEP2020)	N/N	
		Fatigue/ FATIGUE	2	14SEP2020	1/4	2	Yes		NA	R (17SEP2020)	N/N	

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16-55/ C4591001 1107 11071129	MUSC	Pyrexia/ FEVER	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N	
		Myalgia/ MUSCLE PAIN	2	14SEP2020	1/4	2	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001 1107 11071129	GASTR	Nausea/ NAUSEA	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N	
	RESP	Dyspnoea/ SHORTNESS OF BREATH	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N	
16-55/ C4591001 1107 11071134	INFEC	Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	1	31AUG2020	14/23	1	No	O	NA/TC	R (22SEP2020)	N/N	
16-55/ C4591001 1107 11071146	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N	
16-55/ C4591001 1107 11071151	METAB	Vitamin D deficiency/ VITAMIN D DEFICIENCY	2	11JAN2021	124/C	1	No	O	NA/TC	N	N/N	
	VASC	Hypertension/ HYPERTENSION	2	11JAN2021	124/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1107 11071156	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE LEFT ARM	1	20AUG2020	1/3	1	Yes		NA/TC	R (22AUG2020)	N/N	
	GENRL	Fatigue/ FATIGUE	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N	

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16-55/ C4591001 1107 11071171	NERV	Injection site pain/ PAIN AT THE INJECTION SITE (LEFT ARM)	2	10SEP2020	1/3	1	Yes		NA/TC	R (12SEP2020)	N/N	
		Headache/ HEADACHE	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N	
	REPRO	Prostatitis/ ACUTE PROSTATITIS	1	11SEP2020	18/104	1	No	O	NA/TC	R (23DEC2020)	N/N	
16-55/ C4591001 1107 11071190	GENRL	Chills/ CHILLS#	3	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N	
		Pyrexia/ FEVER#	3	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N	
	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE#	3	12JAN2021	1/6	2	Yes		NA/TC	R (17JAN2021)	N/N	
	GENRL	Chills/ CHILLS#	3	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N	
		Fatigue/ FATIGUE#	3	13JAN2021	2/5	1	Yes		NA	R (17JAN2021)	N/N	
		Pain/ BODYACHES#	3	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N	
16-55/ C4591001 1107 11071193	NERV	Headache/ HEADACHE#	3	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N	
	RESP	Nasal congestion/ NASAL CONGESTION	1	15SEP2020	14/11	1	No	O	NA/TC	R (25SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1107 11071195	INJ&P	Muscle rupture/ PARTIAL TEAR-LEFT CALF MUSCLE	1	16SEP2020	14/38	1	No	O	NA/TC	R (23OCT2020)	N/N	
16-55/ C4591001 1107 11071200	GENRL	Chills/ CHILLS	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N	
		Injection site pain/ LEFT ARM PAIN (INJECTION PAIN)	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N	
	NERV	Headache/ HEADACHE	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N	
16-55/ C4591001 1107 11071204	GENRL	Chills/ CHILLS	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
		Injection site pain/ PAIN AT THE INJECTION SITE (LEFT ARM)	1	08SEP2020	1/3	2	Yes		NA	R (10SEP2020)	N/N	
	NERV	Headache/ HEADACHE	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
	GENRL	Chills/ CHILLS	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
		Injection site pain/ PAIN AT THE INJECTION SITE (LEFT ARM)	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N	
	NERV	Headache/ HEADACHE	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1109 11091001	NERV	Headache/ HEADACHE#	4	19FEB2021	1/4	1	Yes		NA	R (22FEB2021)	N/N	
16-55/ C4591001 1109 11091002	GENRL	Injection site pain/ Injection site tenderness	1	29JUL2020	1/1	1	Yes		NA	R (29JUL2020)	N/N	
16-55/ C4591001 1109 11091010	GENRL	Injection site pain/ injection site tenderness	1	29JUL2020	1/3	2	Yes		NA/TC	R (31JUL2020)	N/N	
16-55/ C4591001 1109 11091011	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	11MAR2021	2/3	1	Yes		NA	R (13MAR2021)	N/N	
16-55/ C4591001 1109 11091016	INJ&P	Contusion/ contusion of right hip	1	13AUG2020	15/C	1	No	O	NA	N	N/N	
		Contusion/ contusion to pelvis	1	13AUG2020	15/C	1	No	O	NA	N	N/N	
		Fall/ FALL FROM STEP	1	13AUG2020	15/1	1	No	O	NA	RS (13AUG2020)	N/N	
	INFEC	Tooth abscess/ DENTAL ABSCCESS#	3	23FEB2021	2/9	2	No	O	NA/TC	R (03MAR2021)	N/N	
16-55/ C4591001 1109 11091021	GASTR	Vomiting/ EMESIS#	4	05MAR2021	1/1	1	Yes		NA	R (05MAR2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1109 11091028	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	05MAR2021	1/3	1	Yes		NA	R (07MAR2021)	N/N
16-55/ C4591001 1109 11091030	GENRL	Injection site erythema/ Injection Site Redness	1	30JUL2020	1/2	1	Yes		NA	R (31JUL2020)	N/N
16-55/ C4591001 1109 11091043	GENRL	Pyrexia/ FEVER#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
	MUSC	Myalgia/ MYALGIA#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1109 11091060	PSYCH	Bipolar disorder/ WORSENING OF BIPOLAR DISORDER	2	04SEP2020	16/77	1	No	O	NA/TC	R (19NOV2020)	N/N
16-55/ C4591001 1109 11091080	GENRL	Chills/ CHILLS	1	02AUG2020	2/1	1	Yes		NA	R (02AUG2020)	N/N
16-55/ C4591001 1109 11091110	GENRL	Chills/ CHILLS#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
		Fatigue/ FATIGUE#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
		Pyrexia/ FEVER 101.0 F#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	INJ&P	Tooth fracture/ FRACTURE TOOTH#	3	27JAN2021	9/7	2	No	O	NA/TC/TCN	R (02FEB2021)	N/N	
	GENRL	Chills/ CHILLS#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N	
	MUSC	Myalgia/ MYALGIA#	4	09FEB2021	1/30	1	Yes		NA	R (10MAR2021)	N/N	
16-55/ C4591001 1109 11091122	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	13FEB2021	1/4	1	Yes		NA	R (16FEB2021)	N/N	
16-55/ C4591001 1109 11091159	MUSC	Myalgia/ LEFT ARM MYALGIA	1	04AUG2020	1/5	1	Yes		NA	R (08AUG2020)	N/N	
16-55/ C4591001 1109 11091180	GENRL	Fatigue/ FATIGUE#	4	14FEB2021	2/1	1	Yes		NA	R (14FEB2021)	N/N	
		Pyrexia/ FEVER#	4	14FEB2021	2/1	1	Yes		NA	R (14FEB2021)	N/N	
16-55/ C4591001 1109 11091204	INFEC	Appendicitis/ ACUTE APPENDICITIS	1	17AUG2020	7/17	4	No	O	NA/TC	R (02SEP2020)	Y/N	
		Peritoneal abscess/ Peritoneal Abscess	1	17AUG2020	7/17	4	No	O	NA/TC	R (02SEP2020)	Y/N	
16-55/ C4591001 1109 11091223	GENRL	Pyrexia/ FEVER#	4	15FEB2021	1/C	1	Yes		NA	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1109 11091242	NERV	Headache/ HEADACHE#	4	15FEB2021	1/C	1	Yes		NA	N	N/N
	GENRL	Fatigue/ FATIGUE#	4	14FEB2021	2/C	1	Yes		NA	N	N/N
16-55/ C4591001 1109 11091246	NERV	Headache/ HEADACHE#	4	14FEB2021	2/2	1	Yes		NA	R (15FEB2021)	N/N
	SKIN	URTICARIA CHEST/STOMACH Urticaria/ URTICARIA CHEST/STOMACH	2	12SEP2020	5/24	1	Yes		NA/TC	R (05OCT2020)	N/N
16-55/ C4591001 1109 11091258	SKIN	Dermatitis contact/ allergic contact dermatitis on all extremities and trunk	1	25AUG2020	10/16	2	No	O	NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1109 11091266	GENRL	Chills/ CHILLS#	3	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
	SKIN	INJECTION SITE PAIN# Injection site pain/ INJECTION SITE PAIN#	3	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001 1109 11091287	SKIN	Rash/ Rash on both hands	1	05SEP2020	16/4	1	No	O	NA/TC	R (08SEP2020)	N/N
16-55/ C4591001 1109 11091304	GENRL	Pyrexia/ Fever 101#	4	23FEB2021	1/2	2	Yes		NA	R (24FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1109 11091309	NERV	Headache/ HEADACHE#	4	23FEB2021	1/2	2	Yes		NA	R (24FEB2021)	N/N
	GENRL	Fatigue/ FATIGUE#	3	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
		Injection site pain/ INJECTION SITE PAIN#	3	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1109 11091320	INV	Body temperature increased/ ELEVATED TEMPERATURE 102.0	1	24AUG2020	2/2	1	Yes		NA	R (25AUG2020)	N/N
16-55/ C4591001 1109 11091331	GENRL	Injection site pain/ INJECTION SITE PAIN LEFT ARM*		26AUG2020	1/3	2	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001 1109 11091343	GENRL	Fatigue/ FATIGUE	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C4591001 1109 11091361	NERV	Headache/ HEADACHE	1	29AUG2020	2/2	1	Yes		NA/TC/TCN	R (30AUG2020)	N/N
	INFEC	Urinary tract infection/ URINARY TRACT INFECTION#	2	02MAR2021	161/4	1	No	O	NA/TC	R (05MAR2021)	N/N
16-55/ C4591001 1109 11091362	GENRL	Chills/ CHILLS#	4	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1109 11091397	EYE	Dry eye/ DRY EYES	1	09SEP2020	8/8	1	Yes		NA	R (16SEP2020)	N/N
	EYE	Dry eye/ DRY EYES	1	20SEP2020	19/18	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1109 11091415	NERV	Syncopal episode	2	29DEC2020	95/C	3	No	O	NA/TC	RG	N/N
16-55/ C4591001 1109 11091425	INFEC	Sinusitis/ SINUSITIS#	3	08MAR2021	10/5	2	No	CD	NA	R (12MAR2021)	N/N
16-55/ C4591001 1109 11091444	GASTR	Diverticulum intestinal haemorrhagic/ BLOOD IN STOOL DIVERTICULOSIS	2	10OCT2020	12/11	2	No	O	NA	R (20OCT2020)	N/N
16-55/ C4591001 1109 11091448	NERV	Hemiplegic migraine/ Hemiplegic Migraine	2	20OCT2020	23/C	4	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1109 11091453	MUSC	Pain in extremity/ right leg pain#	2	10MAR2021	164/C	1	No	O	NA/TCN	N	N/N
16-55/ C4591001 1109 11091455	GENRL	Chills/ CHILLS#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Pyrexia/ FEVER 101.3#	4	18FEB2021	2/C	2	Yes		NA	N	N/N
16-55/ C4591001 1109 11091466	MUSC	Muscle spasms/ muscle spasm upper right abdomen	2	19OCT2020	20/6	3	No	O	NA	R (24OCT2020)	N/N
16-55/ C4591001 1109 11091473	GENRL	Pyrexia/ FEVER 101F	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1109 11091488	EAR	Ear pain/ Earache(bilateral)	1	18SEP2020	9/11	1	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C4591001 1109 11091492	MUSC	Back pain/ LOW BACK PAIN	2	16OCT2020	16/58	2	Yes		NA	R (12DEC2020)	N/N
16-55/ C4591001 1109 11091557	GENRL	Injection site pain/ Injection Site Pain	2	26OCT2020	3/1	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C4591001 1110 11101002	MUSC	Neck pain/ neck pain	1	06AUG2020	7/8	1	No	O	NA	R (13AUG2020)	N/N
	HEPAT	Cholelithiasis/ Cholelithiasis	2	04DEC2020	107/2	1	No	O	NA	R (05DEC2020)	N/N
	NERV	Headache/ Headache#	3	17DEC2020	2/1	1	Yes		NA	R (17DEC2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1110 11101013	GENRL	Fatigue/ fatigue	1	07AUG2020	7/4	1	Yes		NA	R (10AUG2020)	N/N
	GENRL	Injection site pain/ Pain at the site of injection.#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	INV	Body temperature increased/ Elevated temperature 98.5 F#	4	13JAN2021	2/1	1	Yes		NA/TC	R (13JAN2021)	N/N
	NERV	Headache/ Headache.#	4	13JAN2021	2/1	1	Yes		NA/TC	R (13JAN2021)	N/N
16-55/ C4591001 1110 11101019	INFEC	Helicobacter infection/ Helicobacter Pylori Infection	2	11JAN2021	144/C	1	No	O	NA/TC	RG	N/N
	INFEC	Cellulitis/ Cellulitis Left hand	2	13JAN2021	146/16	1	No	O	NA/TC	R (28JAN2021)	N/N
16-55/ C4591001 1110 11101020	NERV	Headache/ Headache	1	07AUG2020	5/3	1	Yes		NA/TC	R (09AUG2020)	N/N
16-55/ C4591001 1110 11101021	GASTR	Diarrhoea/ diarrhea	1	25AUG2020	23/1	1	No	O	NA	R (25AUG2020)	N/N
	GENRL	Injection site pain/ Pain at the Site of Injection Left Deltoid#	3	25JAN2021	1/C	1	Yes		NA/TC	N	N/N
	INV	Body temperature increased/ Elevated Temperature (99.9F)#	3	25JAN2021	1/2	1	Yes		NA/TC	R (26JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	4	21FEB2021	7/1	1	Yes		NA	R (21FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1110 11101022	GENRL	Injection site pain/ Pain at site injection (Left Deltoid)#	4	03FEB2021	1/3	1	Yes		NA/TC	R (05FEB2021)	N/N
	GASTR	Nausea/ Nausea#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Chills/ Chills#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1110 11101025	GASTR	Diarrhoea/ Diarrhea (1 episode)#	4	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Chills/ Chills#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
		Pain/ Body Aches#	4	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N
	NERV	Headache/ Headache#	4	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1110 11101027	GENRL	Fatigue/ FATIGUE	1	03AUG2020	1/10	2	Yes		NA	R (12AUG2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	1	04AUG2020	2/9	2	Yes		NA	R (12AUG2020)	N/N
	NERV	Headache/ HEADACHE	1	04AUG2020	2/9	2	Yes		NA/TCN	R (12AUG2020)	N/N
16-55/ C4591001 1110 11101045	GENRL	Injection site pain/ PAIN AT SITE INJECTION	1	12AUG2020	7/4	1	No	O	NA	R (15AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1110 11101050	VASC	Hypertension/ Hypertension	2	12NOV2020	78/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1110 11101057	GENRL	Injection site pain/ Pain at the site of injection.#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N	
16-55/ C4591001 1110 11101058	GENRL	Injection site pain/ pain at site injection (left deltoid)#	3	02MAR2021	1/4	1	Yes		NA	R (05MAR2021)	N/N	
16-55/ C4591001 1110 11101059	METAB	Hypertriglyceridaemia/ HYPERTRIGLYCERIDEMIA	1	12AUG2020	6/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1110 11101064	RESP	Rhinorrhoea/ runny nose	1	19AUG2020	10/8	1	No	O	NA	R (26AUG2020)	N/N	
16-55/ C4591001 1110 11101072	GASTR	Diarrhoea/ Diarrhea#	3	25JAN2021	1/6	1	Yes		NA	R (30JAN2021)	N/N	
	GENRL	Injection site pain/ Pain at site of injection (Right deltoid)#	3	25JAN2021	1/6	1	Yes		NA	R (30JAN2021)	N/N	
	GASTR	Diarrhoea/ Diarrhea#	4	15FEB2021	1/6	1	Yes		NA	R (20FEB2021)	N/N	
	GENRL	Injection site pain/ Pain at the site of injection (Right deltoid)#	4	15FEB2021	1/4	1	Yes		NA/TC	R (18FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1110 11101076	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N	
	GENRL	Fatigue/ fatigue#	3	02MAR2021	1/1	1	Yes		NA	R (02MAR2021)	N/N	
		Injection site pain/ pain at the site of injection (left deltoid)#	3	02MAR2021	1/4	1	Yes		NA	R (05MAR2021)	N/N	
16-55/ C4591001 1110 11101078	NERV	Headache/ headache#	3	02MAR2021	1/1	1	Yes		NA	R (02MAR2021)	N/N	
	GASTR	Toothache/ toothache	2	28SEP2020	28/23	1	No	O	NA/TC	R (20OCT2020)	N/N	
16-55/ C4591001 1110 11101082	GENRL	Chills/ chills#	4	08MAR2021	1/2	1	Yes		NA	R (09MAR2021)	N/N	
	NERV	Headache/ Headache#	4	09MAR2021	2/C	1	Yes		NA/TC	RG	N/N	
	INJ&P	Joint injury/ right knee injury	2	29SEP2020	29/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1110 11101091	SKIN	Rash maculo-papular/ Maculopapular rash to abdomen, chest, back and upper arms	1	30AUG2020	18/3	1	No	O	NA/TC	R (01SEP2020)	N/N	
16-55/ C4591001	RESP	Rhinorrhoea/ Runny nose	2	08OCT2020	37/1	1	No	O	NA	R (08OCT2020)	N/N	
	GENRL	Fatigue/ fatigue#	3	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1110 11101092		Injection site pain/ pain at site of injection (left deltoid)#	3	24FEB2021	2/4	1	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1110 11101106	GENRL	Injection site pain/ pain at the site of injection (left deltoid)#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1110 11101117	MUSC	Bursitis/ Bursitis of Left Foot	2	30SEP2020	22/71	2	No	O	NA/TC	R (09DEC2020)	N/N
		Plantar fasciitis/ Left Plantar Fasciitis	2	30SEP2020	22/71	2	No	O	NA/TC	R (09DEC2020)	N/N
16-55/ C4591001 1110 11101122	GENRL	Injection site pain/ pain at the injection site left arm#	3	26FEB2021	1/4	1	Yes		NA	R (01MAR2021)	N/N
	GENRL	Chills/ chills#	3	27FEB2021	2/4	1	Yes		NA	R (02MAR2021)	N/N
	INV	Body temperature increased/ elevated temperature 100.0 degrees Fahrenheit#	3	27FEB2021	2/4	1	Yes		NA	R (02MAR2021)	N/N
	NERV	Headache/ headache#	3	27FEB2021	2/4	1	Yes		NA	R (02MAR2021)	N/N
16-55/ C4591001 1110 11101131	INJ&P	Limb injury/ Right Shoulder Injury	2	03OCT2020	20/	2	No	O	NA/TC	R	N/N
	MUSC	Arthritis/ Arthritis on Right Shoulder	2	NOV2020	49/C	1	No	O	NA	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1110 11101145	MUSC	Muscle spasms/ Cramp on right foot.	2	26JAN2021	133/3	1	No	O	NA	R (28JAN2021)	N/N	
16-55/ C4591001 1110 11101151	MUSC	Myalgia/ mild muscle pain	1	08SEP2020	12/9	1	Yes		NA/TC	R (16SEP2020)	N/N	
	NERV	Headache/ Headache	2	19SEP2020	2/8	2	Yes		NA/TC	R (26SEP2020)	N/N	
	EYE	Vitreous floaters/ Right eye visual floaters	2	14OCT2020	27/10	2	No	O	NA	R (23OCT2020)	N/N	
	NERV	Headache/ Headache	2	14OCT2020	27/13	1	No	O	NA/TC	R (26OCT2020)	N/N	
16-55/ C4591001 1110 11101158	GENRL	Injection site pain/ pain at injection site#	3	22FEB2021	1/8	1	Yes		NA	R (01MAR2021)	N/N	
16-55/ C4591001 1110 11101162	MUSC	Rotator cuff syndrome/ right bicep tendon rotator cuff tear	2	20DEC2020	91/C	2	No	O	NA/TC/TCN	RG	N/N	
16-55/ C4591001 1110 11101164	INJ&P	Exposure during pregnancy/ exposure during pregnancy#	2	25FEB2021	161/C		No	O	NA	UNK	N/N	
16-55/ C4591001 1110 11101165	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	25FEB2021	161/C		No	O	NA	UNK	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1110 11101167	GASTR	Dental caries/ dental cavity	1	04SEP2020	7/1	2	No	O	NA/TC	R (04SEP2020)	N/N	
	SKIN	Acne/ acne	2	14JAN2021	119/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1110 11101168	GENRL	Injection site pain/ Pain at the injection site left arm#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N	
	MUSC	Myalgia/ muscle aches#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N	
16-55/ C4591001 1110 11101175	VASC	Hypertension/ Hypertension	2	06JAN2021	107/C	1	No	O	NA/TC/TCN	N	N/N	
16-55/ C4591001 1110 11101181	GENRL	Chills/ chills#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N	
		Injection site pain/ pain at site of injection#	3	18FEB2021	1/1	1	Yes		NA	R (18FEB2021)	N/N	
16-55/ C4591001 1110 11101186	GENRL	Chills/ chills#	4	12MAR2021	1/C	2	Yes		NA/TC	N	N/N	
		Fatigue/ fatigue#	4	12MAR2021	1/C	2	Yes		NA	N	N/N	
		Pyrexia/ fever 101.0 degrees Fahrenheit#	4	12MAR2021	1/C	2	Yes		NA/TC	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1110 11101187	MUSC	Swelling/ painful swelling on the left side of the neck#	4	12MAR2021	1/2	1	Yes		NA/TC	R (13MAR2021)	N/N	
		Myalgia/ muscle pain#	4	12MAR2021	1/C	2	Yes		NA/TC	N	N/N	
	GASTR	Colitis ulcerative/ Ulcerative Colitis	2	07DEC2020	77/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1110 11101189	INFEC	Gastritis/ Gastritis	2	07DEC2020	77/C	1	No	O	NA/TC/TCN	RG	N/N	
		Appendicitis/ Acute Appendicitis	2	07DEC2020	77/4	3	No	O	NA/TC/TCN	R (10DEC2020)	Y/N	
	GENRL	Injection site pain/ Pain at site injection (left deltoid)#	3	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N	
16-55/ C4591001 1110 11101189	RESP	Oropharyngeal pain/ sore throat	1	15SEP2020	5/2	1	No	O	NA	R (16SEP2020)	N/N	
16-55/ C4591001 1110 11101198	GENRL	Injection site pain/ pain at the injection site left arm#	3	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N	
16-55/ C4591001 1110 11101199	GENRL	Injection site pain/ Pain at the Site of Injection on left Arm#	3	05JAN2021	1/3	1	Yes		NA/TC	R (07JAN2021)	N/N	
16-55/ C4591001	NERV	Headache/ Headache#	3	05JAN2021	1/1	1	Yes		NA/TC	R (05JAN2021)	N/N	
	GENRL	Chills/ chills#	3	26FEB2021	2/1	1	Yes		NA	R (26FEB2021)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1110 11101203		Pain/ body aches#	3	26FEB2021	2/1	1	Yes		NA	R (26FEB2021)	N/N	
16-55/ C4591001 1110 11101211	GASTR	Irritable bowel syndrome/ Irritable Bowel Syndrome	1	22SEP2020	19/C	1	No	O	NA/TC	N	N/N	
	METAB	Hypocholesterolaemia/ hypocholesteremia	1	22SEP2020	19/C	1	No	O	NA/TC	RS	N/N	
	GENRL	Injection site pain/ Pain at the site of injection (Right deltoid)#	3	17FEB2021	2/3	1	Yes		NA/TC	R (19FEB2021)	N/N	
	NERV	Headache/ headache#	4	09MAR2021	1/C	1	Yes		NA/TC	RG	N/N	
16-55/ C4591001 1110 11101212	INFEC	Helicobacter infection/ Helicobacter Pylori Infection	2	04FEB2021	134/18	1	No	O	NA/TC	R (21FEB2021)	N/N	
16-55/ C4591001 1110 11101213	INFEC	Urinary tract infection/ urinary tract infection#	3	12MAR2021	16/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1110 11101219	GENRL	Pain/ Body Aches#	4	17FEB2021	1/C	1	Yes		NA	N	N/N	
		Pyrexia/ Fever (100.2 degrees Fahrenheit)#	4	17FEB2021	1/1	1	Yes		NA/TC	R (17FEB2021)	N/N	
16-55/ C4591001	BLOOD	Lymphadenopathy/ Bilateral axillary adenopathy	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1110 11101220	GENRL	Injection site pain/ Pain at the site of injection (right deltoid)#	3	03MAR2021	2/3	1	Yes		NA	R (05MAR2021)	N/N	
1110 11101227	REPRO	Vaginal haemorrhage/ Vaginal Bleeding (prolonged)	1	14DEC2020	96/31	2	No	O	NA/TCN	R (13JAN2021)	N/N	
1110 11101229	GENRL	Swelling/ swelling left deltoid area#	3	24FEB2021	2/15	2	Yes		NA/TC	R (10MAR2021)	N/N	
16-55/ C4591001 1110 11101235	GENRL	Fatigue/ fatigue#	3	25FEB2021	1/3	1	Yes		NA	R (27FEB2021)	N/N	
	INV	Injection site pain/ pain at injection site (left deltoid)#	3	25FEB2021	1/4	1	Yes		NA	R (28FEB2021)	N/N	
	INV	Body temperature increased/ elevated temperature#	3	25FEB2021	1/3	1	Yes		NA	R (27FEB2021)	N/N	
16-55/ C4591001 1110 11101236	SKIN	Rash/ rash to legs	2	08OCT2020	7/149	1	No	O	NA	R (05MAR2021)	N/N	
	MUSC	Back pain/ back pain	2	31OCT2020	30/9	1	No	O	NA/TC	R (08NOV2020)	N/N	
	EYE	Eye pruritus/ Bilateral Eye Itchiness	2	14NOV2020	44/3	1	No	O	NA	R (16NOV2020)	N/N	
		Ocular hyperaemia/ Bilateral Eye redness	2	14NOV2020	44/3	1	No	O	NA	R (16NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Abdominal discomfort/ Abdominal Discomfort	2	14NOV2020	44/3	1	No	O	NA	R (16NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	14NOV2020	44/80	1	No	O	NA	R (01FEB2021)	N/N
	RESP	Throat irritation/ Throat Itchiness	2	14NOV2020	44/3	1	No	O	NA	R (16NOV2020)	N/N
	EYE	Visual impairment/ change in vision	2	06DEC2020	66/2	2	No	O	NA	R (07DEC2020)	Y/N
	SKIN	Rash/ Generalize Rash	2	05JAN2021	96/2	1	No	O	NA	R (06JAN2021)	N/N
16-55/ C4591001 1110 11101237	GENRL	Injection site pain/ MILD INJECTION PAIN	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1110 11101246	GENRL	Injection site pain/ Pain at injection site left deltoid	1	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N
		Malaise/ malaise	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1110 11101264	GENRL	Chills/ chills	2	07OCT2020	1/2	2	Yes		NA/TC	R (08OCT2020)	N/N
		Pyrexia/ fever	2	07OCT2020	1/2	3	Yes		NA/TC	R (08OCT2020)	N/N
	NERV	Headache/ headache	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001	GASTR	Gastroesophageal reflux disease/ Acid reflux	2	19FEB2021	137/2	1	No	O	NA/TC	R (20FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1110 11101268 16-55/ C4591001	GENRL	Chills/ chills	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
1110 11101269	MUSC	Arthralgia/ Left Shoulder pain	2	01JAN2021	87/C	1	No	O	NA	N	N/N
16-55/ C4591001 1110 11101271	GENRL	Chills/ Chills#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
		Pyrexia/ Fever#	4	06JAN2021	1/2	1	Yes		NA/TC	R (07JAN2021)	N/N
	NERV	Headache/ Headache#	4	07JAN2021	2/C	1	Yes		NA	N	N/N
	BLOOD	Lymphadenopathy/ Adenopathy (left armpit)#	4	08FEB2021	34/C	1	Yes		NA	N	N/N
16-55/ C4591001 1110 11101274	GENRL	Injection site pain/ Pain at site of injection#	3	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1110 11101275	CONG	Factor II mutation/ prothrombin gene mutation#	3	MAR2021	1/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ pain at site of injection (left deltoid)#	3	04MAR2021	2/C	1	Yes		NA	N	N/N
	GENRL	Injection site haemorrhage/ ecchymosis at site of injection 2 cm#	3	07MAR2021	5/C	1	Yes		NA	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INV	Body temperature increased/ elevated temperature 99.6 degrees Fahrenheit#	3	07MAR2021	5/C	1	Yes		NA/TC	N	N/N
	VASC	Haematoma/ hematoma at mid left arm 10 cm#	3	07MAR2021	5/C	2	Yes		NA	N	N/N
	INV	Blood pressure increased/ elevated blood pressure#	3	12MAR2021	10/C	2	No	O	NA	N	N/N
16-55/ C4591001 1110 11101278	GASTR	Dental caries/ Left side molar cavity	2	10FEB2021	125/17	1	No	O	NA/TC	R (26FEB2021)	N/N
16-55/ C4591001 1110 11101282	BLOOD	Iron deficiency anaemia/ iron deficiency anemia	1	02OCT2020	12/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1110 11101286	GENRL	Injection site pain/ Pain at the site of injection (Left Deltoid)#	4	05JAN2021	1/4	1	Yes		NA/TC	R (08JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
		Pain/ Body Aches#	4	06JAN2021	2/2	1	Yes		NA/TC	R (07JAN2021)	N/N
16-55/ C4591001 1110 11101290	GENRL	Chills/ Chills#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Pain at site injection (Left Deltoid)#	4	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
	INV	Body temperature increased/ Elevated temperature#	4	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1110 11101293	NERV	Headache/ Headache#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Pain at the site of injection (Right deltoid)#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site right arm#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Injection site swelling/ swelling of injection site right arm#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1110 11101294	GASTR	Dental caries/ Toothache (Dental Cavity)	1	01OCT2020	9/1	2	No	O	NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1110 11101298	SKIN	Papule/ Papule left upper arm	1	24SEP2020	2/	1	Yes		NA	R	N/N
	GENRL	Injection site pain/ Pain at site injection	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1110 11101308	GENRL	Injection site pain/ Site injection pain#	3	21DEC2020	1/2	1	Yes		NA/TC	R (22DEC2020)	N/N
16-55/ C4591001 1110 11101311	PSYCH	Attention deficit hyperactivity disorder/ attention deficit hyperactivity disorder#	4	02MAR2021	20/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at site injection	1	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1110 11101313	NERV	Headache/ headache	1	01OCT2020	4/2	2	No	O	NA/TC	R (02OCT2020)	N/N	
16-55/ C4591001 1110 11101319	RENAL	Dysuria/ Dysuria	2	28OCT2020	10/21	1	No	O	NA/TC	R (17NOV2020)	N/N	
16-55/ C4591001 1110 11101320	GENRL	Asthenia/ Generalized weakness#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N	
		Chills/ Chills#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N	
		Injection site pain/ Injection Site pain#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N	
16-55/ C4591001 1110 11101321	BLOOD	Lymphadenopathy/ Lymphadenopathy to left neck	2	21OCT2020	2/C	1	Yes		NA	RG	N/N	
	BLOOD	Neutropenia/ Neutropenia	2	26OCT2020	7/C	3	Yes		NA	N	N/N	
16-55/ C4591001 1110 11101323	METAB	Hypercholesterolaemia/ hypercholesterolemia	2	30OCT2020	11/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1110 11101325	GENRL	Fatigue/ Fatigue	2	23OCT2020	2/23	1	Yes		NA	R (14NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1110 11101337	GASTR	Irritable bowel syndrome/ Irritable Bowel Syndrome	2	02NOV2020	12/C	2	No	O	NA/TC	N	N/N
	GASTR	Gastritis/ Gastritis	2	03NOV2020	13/15	2	No	O	NA/TC	R (17NOV2020)	N/N
16-55/ C4591001 1110 11101338	GENRL	Chills/ chills	2	22OCT2020	1/2	1	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1110 11101343	GENRL	Chills/ Chills	2	27OCT2020	1/5	2	Yes		NA	R (31OCT2020)	N/N
		Pyrexia/ Fever	2	27OCT2020	1/5	2	Yes		NA/TC	R (31OCT2020)	N/N
	RESP	Cough/ Cough	2	27OCT2020	1/18	1	No	O	NA	R (13NOV2020)	N/N
16-55/ C4591001 1110 11101346	GENRL	Fatigue/ Fatigue	2	04NOV2020	6/3	2	No	O	NA	R (06NOV2020)	N/N
	NERV	Headache/ Headache	2	04NOV2020	6/3	1	No	O	NA/TC	R (06NOV2020)	N/N
	GENRL	Injection site pain/ Pain at site injection#	3	31DEC2020	3/3	1	Yes		NA/TC	R (02JAN2021)	N/N
	MUSC	Back pain/ Back pain#	3	01JAN2021	4/2	1	No	O	NA/TC	R (02JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the site of injection.#	4	18JAN2021	1/8	1	Yes		NA/TC	R (25JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache#	4	18JAN2021	1/3	1	Yes		NA/TC	R (20JAN2021)	N/N
		Paraesthesia/ Tingling Left forearm.#	4	18JAN2021	1/1	1	Yes		NA	R (18JAN2021)	N/Y
	GENRL	Chills/ Chills#	4	19JAN2021	2/2	1	Yes		NA/TC	R (20JAN2021)	N/N
		Pain/ Body aches#	4	19JAN2021	2/2	1	Yes		NA/TC	R (20JAN2021)	N/N
		Pyrexia/ Fever (100.2)#	4	19JAN2021	2/2	1	Yes		NA/TC	R (20JAN2021)	N/N
	GENRL	Injection site rash/ Rash Left Deltoid below injection site#	4	22JAN2021	5/6	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1110 11101349	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/2	2	Yes		NA/TC	R (23DEC2020)	N/N
16-55/ C4591001 1110 11101354	RESP	Rhinorrhoea/ Rhinorrea	1	16OCT2020	2/8	1	No	O	NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1110 11101356	GENRL	Pyrexia/ fever	2	07NOV2020	2/1	1	Yes		NA/TC	R (07NOV2020)	N/N
16-55/ C4591001 1110 11101361	GENRL	Injection site pain/ pain at injection site	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
	GENRL	Chills/ chills	2	11NOV2020	2/1	2	Yes		NA/TC	R (11NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1110 11101372	NERV	Headache/ headache	2	11NOV2020	2/1	2	Yes		NA/TC	R (11NOV2020)	N/N	
	GENRL	Pyrexia/ Fever#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N	
16-55/ C4591001 1110 11101377	MUSC	Myalgia/ Myalgia#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N	
	GASTR	Gastritis/ Gastritis	1	03NOV2020	6/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1110 11101379	GENRL	Fatigue/ Fatigue	1	14NOV2020	2/1	2	Yes		NA	R (14NOV2020)	N/N	
	MUSC	Arthralgia/ Joint Pain (Generalized)	1	14NOV2020	2/1	1	Yes		NA	R (14NOV2020)	N/N	
16-55/ C4591001 1111 11111072	GENRL	Chills/ Chills	2	01SEP2020	2/2	2	Yes		NA/TCN	R (02SEP2020)	N/N	
	GENRL	Pain/ Body aches Injection site pain/ Injection site soreness#	2 3	01SEP2020 29JAN2021	2/2 1/4	3 2	Yes Yes		NA/TCN NA	R (02SEP2020) RS (01FEB2021)	N/N N/N	
16-55/ C4591001	MUSC	Pain in extremity/ Left sore arm#	3	30JAN2021	2/4	1	Yes		NA	R (02FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1111 11111082 16-55/ C4591001	SKIN	Angioedema/ ANGIO-EDEMA BOTH EYES	1	23AUG2020	13/C	1	No	O	NA/TC	RG	N/N	
1111 11111099 16-55/ C4591001	GENRL	Injection site pain/ Soreness (pain) at injection site#	3	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N	
1111 11111101 16-55/ C4591001	NERV	Headache/ headache	2	05SEP2020	2/1	1	Yes		NA/TC	R (05SEP2020)	N/N	
1111 11111115 16-55/ C4591001	NERV	Subarachnoid haemorrhage/ Subarachnoid hemorrhage	1	26AUG2020	9/9	2	No	O	NA/TC/TCN	R (03SEP2020)	Y/N	
1111 11111130 16-55/ C4591001	BLOOD	Lymphadenopathy/ Left axillary lymph node swelling#	4	13JAN2021	3/4	1	Yes		NA	R (16JAN2021)	N/N	
1111 11111139 16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N	
1111 11111143		Injection site pain/ Left sore arm at injection site#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N	
	NERV	Dizziness/ Lightheadedness#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1111 11111155	GASTR	Nausea/ Nausea	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
		Pain/ Body aches	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1111 11111159	MUSC	Neck pain/ Neck pain#	4	04FEB2021	25/5	2	No	O	NA/TC	R (08FEB2021)	N/N
16-55/ C4591001 1111 11111169	RESP	Dyspnoea/ Air Huunger	1	02SEP2020	1/2	2	No	CD	NA/TC	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Left sore arm at injection site#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1111 11111172	GENRL	Injection site pain/ Injection site soreness#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1111 11111176	SKIN	Rash/ Rash on right side of neck	1	14SEP2020	7/21	2	No	CD	NA/TC	R (04OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1111 11111200	MUSC	Pain in extremity/ Right sore arm#	3	22JAN2021	1/2	1	Yes		NA/TCN	R (23JAN2021)	N/N
	GENRL	Injection site erythema/ Redness at injection site#	4	12FEB2021	1/C	1	Yes		NA	RG	N/N
		Injection site swelling/ Swelling at injection site#	4	12FEB2021	1/C	1	Yes		NA	RG	N/N
	MUSC	Pyrexia/ Low grade fever#	4	12FEB2021	1/2	1	Yes		NA/TCN	R (13FEB2021)	N/N
16-55/ C4591001 1112 11121012	MUSC	Pain in extremity/ Right sore arm#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	2	18DEC2020	120/2	2	Yes		NA/TC	R (19DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1112 11121018	MUSC	Myalgia/ Muscle Aches#	4	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	06JAN2021	1/3	2	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ Headache#	4	06JAN2021	1/3	2	Yes		NA/TC	R (08JAN2021)	N/N
16-55/ C4591001 1112 11121021	PSYCH	Anxiety/ Worsening of anxiety	1	20AUG2020	21/35	2	No	O	NA/TC	R (23SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1112 11121026	GENRL	Injection site pain/ Injection site pain#	4	07JAN2021	1/3	2	Yes		NA/TC	R (09JAN2021)	N/N	
	MUSC	Myalgia/ Muscle aches#	4	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N	
16-55/ C4591001 1112 11121047	INJ&P	Hand fracture/ Broken finger, left middle finger	1	12AUG2020	10/21	3	No	O	NA/TC	R (01SEP2020)	N/N	
16-55/ C4591001 1112 11121064	GENRL	Fatigue/ Fatigue#	3	28JAN2021	1/5	2	Yes		NA	R (01FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/5	2	Yes		NA	R (01FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	1/5	2	Yes		NA	R (20FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	1/5	2	Yes		NA	R (20FEB2021)	N/N	
16-55/ C4591001 1112 11121069	GENRL	Fatigue/ Fatigue#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N	
	MUSC	Pyrexia/ Fever#	4	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N	
	MUSC	Myalgia/ Muscle Aches#	4	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N	
16-55/ C4591001	INFEC	Urinary tract infection/ Urinary tract infection	1	10AUG2020	6/13	1	No	O	NA/TC	R (22AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1112 11121071 16-55/ C4591001	INFEC	Pharyngitis streptococcal/ Strep Throat	1	24AUG2020	20/12	1	No	O	NA/TC	R (04SEP2020)	N/N	
1112 11121078 16-55/ C4591001	NERV	Headache/ Headache, mild#	2	16DEC2020	86/2	2	Yes		NA/TC	R (17DEC2020)	N/N	
1112 11121081 16-55/ C4591001	VASC	Haematoma/ Hematoma	1	12AUG2020	3/12	1	No	O	NA/TC	R (23AUG2020)	N/N	
1112 11121087 16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	04JAN2021	1/3	1	Yes		NA	R (06JAN2021)	N/N	
1112 11121090		Injection site pain/ Injection site pain#	4	04JAN2021	1/3	1	Yes		NA	R (06JAN2021)	N/N	
	MUSC	Myalgia/ Muscle Aches#	4	04JAN2021	1/3	1	Yes		NA	R (06JAN2021)	N/N	
	VASC	Hypertension/ Worsening of Hypertension#	4	25JAN2021	22/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001	MUSC	Pain in extremity/ Leg pain	2	06SEP2020	7/1	1	No	O	NA/TC	R (06SEP2020)	N/N	
1112 11121091 16-55/ C4591001	NEOPL	Transitional cell carcinoma/ Urothelial Carcinoma	2	14OCT2020	45/C	3	No	O	NA/TC	RG	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1112 11121100 16-55/ C4591001	SKIN	Dermatitis contact/ Allergic reaction to poison ivy	1	25AUG2020	16/10	2	No	O	NA/TC	R (03SEP2020)	N/N
1112 11121101	MUSC	Bursitis/ Bursitis, left shoulder	2	22OCT2020	21/19	2	No	O	NA/TC	R (09NOV2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever#	4	07JAN2021	1/4	2	Yes		NA/TC	R (10JAN2021)	N/N
1112 11121102	MUSC	Myalgia/ Myalgia#	4	07JAN2021	1/4	2	Yes		NA/TC	R (10JAN2021)	N/N
	GENRL	Chills/ Chills#	4	08JAN2021	2/3	2	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	16DEC2020	1/3	1	Yes		NA	R (18DEC2020)	N/N
1112 11121105	MUSC	Myalgia/ Muscle Aches#	4	07JAN2021	1/3	2	Yes		NA/TC	R (09JAN2021)	N/N
1112 11121109	NERV	Headache/ Headache#	4	07JAN2021	1/3	1	Yes		NA/TC	R (09JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
1112 11121110											



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1112 11121117	GENRL	Fatigue/ Fatigue#	4	06JAN2021	1/2	2	Yes		NA	R (07JAN2021)	N/N	
	MUSC	Myalgia/ Muscle Aches#	4	06JAN2021	1/2	2	Yes		NA	R (07JAN2021)	N/N	
	GENRL	Chills/ Chills#	3	23JAN2021	2/2	2	Yes		NA	R (24JAN2021)	N/N	
		Fatigue/ Fatigue#	3	23JAN2021	2/2	2	Yes		NA	R (24JAN2021)	N/N	
	MUSC	Myalgia/ Muscle Aches#	3	23JAN2021	2/2	2	Yes		NA/TC/TCN	R (24JAN2021)	N/N	
	NERV	Headache/ Headache#	3	23JAN2021	2/2	1	Yes		NA/TC	R (24JAN2021)	N/N	
16-55/ C4591001 1112 11121122	NEOPL	Uterine leiomyoma/ Worsening INTRAMURAL AND SUBSEROUS LEIOMYOMA OF UTERUS	2	14SEP2020	14/66	3	No	O	NA/TCN	R (18NOV2020)	Y/N	
	REPRO	Uterine haemorrhage/ Worsening of Abnormal Uterine Bleeding	2	14SEP2020	14/66	3	No	O	NA/TCN	R (18NOV2020)	N/N	
16-55/ C4591001 1112 11121123	GENRL	Injection site pain/ Injection site pain#	4	08JAN2021	2/3	1	Yes		NA	R (10JAN2021)	N/N	
	NERV	Headache/ Headache#	4	08JAN2021	2/3	1	Yes		NA	R (10JAN2021)	N/N	
16-55/ C4591001 1112 11121125	INFEC	Tinea infection/ Ringworm	1	19AUG2020	3/31	2	No	O	NA/TC	R (18SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1112 11121128	MUSC	Myalgia/ Muscle Aches#	3	26JAN2021	1/3	2	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	18DEC2020	1/4	1	Yes		NA	R (21DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	2/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	08JAN2021	1/6	2	Yes		NA/TC	R (13JAN2021)	N/N
	GENRL	Chills/ Chills#	4	09JAN2021	2/2	2	Yes		NA	R (10JAN2021)	N/N
		Fatigue/ Fatigue#	4	09JAN2021	2/2	2	Yes		NA	R (10JAN2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	09JAN2021	2/3	2	Yes		NA/TC	R (11JAN2021)	N/N
	NERV	Headache/ Headache#	4	09JAN2021	2/3	2	Yes		NA/TC	R (11JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/2	2	Yes		NA/TC	R (23DEC2020)	N/N
	1112 11121151		Pyrexia/ Fever#	3	22DEC2020	1/2	2	Yes		NA/TC	R (23DEC2020)
	NERV	Headache/ Headache#	3	22DEC2020	1/2	1	Yes		NA/TC	R (23DEC2020)	N/N
	GENRL	Pyrexia/ Fever#	4	13JAN2021	1/2	2	Yes		NA/TC	R (14JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1112 11121156	GENRL	Injection site paraesthesia/ Paresthesia, injection site, left arm	2	14SEP2020	4/2	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1112 11121158	GENRL	Fatigue/ Fatigue#	4	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1112 11121160	GENRL	Injection site pain/ Injection site pain#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Pyrexia/ Fever#	4	13JAN2021	1/2	2	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ Headache#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1112 11121171	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/3	2	Yes		NA	R (24DEC2020)	N/N
16-55/ C4591001 1112 11121173	INFEC	Urinary tract infection/ Urinary Tract Infection	2	09OCT2020	25/6	3	No	O	NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1112 11121183	GENRL	Injection site pain/ Injection site Pain	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1112 11121184	GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux disease	2	29SEP2020	15/38	3	No	O	NA/TC	R (05NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	23DEC2020	2/1	2	Yes		NA/TC	R (23DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1112 11121188	INFEC	Urinary tract infection/ Urinary tract infection	1	13SEP2020	18/4	1	No	O	NA/TC	R (16SEP2020)	N/N
	GENRL	Chills/ Chills#	4	08JAN2021	2/2	3	Yes		NA	R (09JAN2021)	N/N
		Pyrexia/ Fever#	4	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N
16-55/ C4591001 1112 11121190	GENRL	Chills/ Chills	2	17SEP2020	2/2	2	Yes		NA/TC/TCN	R (18SEP2020)	N/N
		Pyrexia/ Fever	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1112 11121191	GENRL	Injection site pain/ Injection site pain	1	29AUG2020	2/4	2	Yes		NA	R (01SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches	1	29AUG2020	2/4	2	Yes		NA/TC	R (01SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1112 11121192	GENRL	Fatigue/ Fatigue	1	30AUG2020	3/2	1	Yes		NA	R (31AUG2020)	N/N
16-55/ C4591001 1112 11121193	BLOOD	Lymph node pain/ Lymph node pain, under left arm	2	18SEP2020	2/5	3	Yes		NA/TC	R (22SEP2020)	N/N
		Lymphadenopathy/ Lymph node swelling (under left arm)	2	18SEP2020	2/6	3	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/5	3	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1112 11121194	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1112 11121197	GENRL	Injection site pain/ Injection site pain, post vaccine	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
16-55/ C4591001 1112 11121198	GASTR	Diarrhoea/ Diarrhea, post vaccination	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain, post vaccination	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches, post vaccination	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	18DEC2020	1/4	2	Yes		NA/TC	R (21DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1112 11121199	MUSC	Myalgia/ myalgia#	4	09JAN2021	2/2	1	Yes		NA/TC	R (10JAN2021)	N/N	
	NERV	Headache/ Headache#	4	09JAN2021	2/1	1	Yes		NA/TC	R (09JAN2021)	N/N	
16-55/ C4591001 1112 11121200	GENRL	Fatigue/ Fatigue	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N	
		Injection site erythema/ Redness at injection site	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N	
		Injection site pain/ Injection site pain	1	01SEP2020	2/3	1	Yes		NA/TC	R (03SEP2020)	N/N	
	NERV	Headache/ Headache	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	23SEP2020	1/3	2	Yes		NA/TC	R (25SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue#	4	09JAN2021	2/3	1	Yes		NA	R (11JAN2021)	N/N	
		Pyrexia/ Fever#	4	09JAN2021	2/3	1	Yes		NA/TC	R (11JAN2021)	N/N	
	MUSC	Myalgia/ Muscle aches#	4	09JAN2021	2/3	2	Yes		NA/TC	R (11JAN2021)	N/N	
16-55/ C4591001 1112 11121204	GENRL	Injection site pain/ Injection site soreness, left arm, post vaccine	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	NERV	Headache/ Headache	1	02SEP2020	2/1	1	Yes		NA/TC	R (02SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	2/3	2	Yes		NA	R (26SEP2020)	N/N	
	GENRL	Pain/ Pain, left side neck and upper arm	2	30SEP2020	8/13	2	Yes		NA/TC	R (12OCT2020)	N/N	
16-55/ C4591001 1112 11121207	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/3	2	Yes		NA/TC	R (24DEC2020)	N/N	
16-55/ C4591001 1112 11121208	MUSC	Myalgia/ Muscle aches(all over)	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 1112 11121214	GENRL	Peripheral swelling/ Arm swelling, left arm	2	28SEP2020	5/3	2	Yes		NA/TC	R (30SEP2020)	N/N	
16-55/ C4591001 1112 11121215	MUSC	Myalgia/ Muscle aches, post vaccine	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N	
16-55/ C4591001 1112 11121216	GENRL	Injection site pain/ Injection site pain, post vaccination	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N	
	MUSC	Myalgia/ Muscle Ache	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001	GENRL	Chills/ Chills	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1112 11121226	MUSC	Myalgia/ Muscle Pain	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N	
16-55/ C4591001 1112 11121234	GENRL	Fatigue/ Fatigue#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N	
	MUSC	Myalgia/ Muscle Aches#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N	
	NERV	Headache/ Headache#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N	
16-55/ C4591001 1112 11121237	GENRL	Injection site pain/ Injection site pain (post vaccination)	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N	
16-55/ C4591001 1112 11121242	MUSC	Myalgia/ Muscle aches	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	02OCT2020	1/1	1	Yes		NA	R (02OCT2020)	N/N	
16-55/ C4591001 1112 11121249	GENRL	Injection site pain/ Injection site pain, post vaccination	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N	
16-55/ C4591001 1112 11121253	GENRL	Chills/ Chills#	3	18DEC2020	2/2	1	Yes		NA	R (19DEC2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1112 11121254	MUSC	Myalgia/ Myalgia#	3	18DEC2020	2/2	1	Yes		NA/TC	R (19DEC2020)	N/N
	NERV	Headache/ Headache#	3	18DEC2020	2/2	1	Yes		NA/TC	RS (19DEC2020)	N/N
	NERV	Headache/ Headache#	4	06JAN2021	1/2	2	Yes		NA/TC	R (07JAN2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	07JAN2021	2/2	2	Yes		NA/TC	R (08JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ Headache	1	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001 1112 11121256	NERV	Headache/ Headache	2	26OCT2020	1/2	1	Yes		NA/TC	R (27OCT2020)	N/N
	GASTR	Diarrhoea/ Mild Diarrhea	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	2/8	2	Yes		NA/TC	R (14OCT2020)	N/N
	GENRL	Injection site swelling/ Injection site swelling	1	07OCT2020	2/22	2	Yes		NA/TC	R (28OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1112 11121261	MUSC	Arthralgia/ Joint pain, generalized	2	28OCT2020	1/2	1	Yes	NA	NA	R (29OCT2020)	N/N	
		Myalgia/ Muscle Aches	2	28OCT2020	1/2	1	Yes	NA/TC	NA/TC	R (29OCT2020)	N/N	
16-55/ C4591001	MUSC	Myalgia/ Muscle Ache	1	19OCT2020	1/2	1	Yes	NA	NA	R (20OCT2020)	N/N	
1112 11121266	GENRL	Fatigue/ Fatigue#	3	16DEC2020	1/2	1	Yes	NA	NA	R (17DEC2020)	N/N	
1112 11121268	GENRL	Injection site pain/ Injection site pain#	3	16DEC2020	1/4	1	Yes	NA	NA	R (19DEC2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	04JAN2021	1/2	1	Yes	NA	NA	R (05JAN2021)	N/N	
16-55/ C4591001	MUSC	Myalgia/ Muscle Aches	1	08OCT2020	1/2	1	Yes	NA	NA	R (09OCT2020)	N/N	
1112 11121269	GENRL	Fatigue/ Fatigue	1	09OCT2020	1/2	1	Yes	NA	NA	R (10OCT2020)	N/N	
1112 11121282	MUSC	Myalgia/ Muscle Aches	1	09OCT2020	1/2	2	Yes	NA	NA	R (10OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain, post injection	2	28OCT2020	1/2	2	Yes	NA	NA	R (29OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1112 11121284	GENRL	Fatigue/ Fatigue	2	29OCT2020	2/2	2	Yes		NA	R (30OCT2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	29OCT2020	2/2	2	Yes		NA	R (30OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	2/3	1	Yes		NA	RS (19DEC2020)	N/N
	MUSC	Myalgia/ Myalgia#	3	17DEC2020	2/2	1	Yes		NA/TC	R (18DEC2020)	N/N
	NERV	Headache/ Headache#	3	17DEC2020	2/2	1	Yes		NA/TC	R (18DEC2020)	N/N
	MUSC	Myalgia/ Muscle Aches	1	13OCT2020	2/2	2	Yes		NA/TC	R (14OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	20JAN2021	1/3	2	Yes		NA/TC	R (22JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/2	2	Yes		NA	R (09FEB2021)	N/N
	GASTR	Nausea/ Nausea	1	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
	MUSC	Myalgia/ Muscle Aches	1	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1112 11121297	GENRL	Fatigue/ Fatigue	1	14OCT2020	3/2	1	Yes		NA	R (15OCT2020)	N/N
	NERV	Headache/ Headache	1	14OCT2020	3/2	1	Yes		NA	R (15OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	03NOV2020	2/1	1	Yes		NA	R (03NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N
		Pyrexia/ Fever	2	03NOV2020	2/1	2	Yes		NA/TC	R (03NOV2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	03NOV2020	2/2	2	Yes		NA/TC	R (04NOV2020)	N/N
	NERV	Headache/ Headache	2	03NOV2020	2/2	2	Yes		NA/TC	R (04NOV2020)	N/N
16-55/ C4591001 1112 11121298	GENRL	Injection site pain/ Injection Site Pain, left arm	1	12OCT2020	1/1	1	Yes		NA/TC	R (12OCT2020)	N/N
16-55/ C4591001 1112 11121299	GENRL	Pyrexia/ Fever	1	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1112 11121305	GENRL	Injection site pain/ Pain at the injection site	1	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	03NOV2020	1/3	2	Yes		NA	R (05NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1112 11121308	MUSC	Injection site pain/ Injection site Pain	2	03NOV2020	1/3	2	Yes		NA	R (05NOV2020)	N/N
		Pyrexia/ Fever	2	03NOV2020	1/3	1	Yes		NA	R (05NOV2020)	N/N
	Myalgia/ Myalgia	2	03NOV2020	1/3	2	Yes		NA/TC	R (05NOV2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	04NOV2020	1/1	1	Yes		NA/TC	R (04NOV2020)	N/N
16-55/ C4591001 1112 11121315	GENRL	Injection site pain/ Injection site pain, (post vaccination)	1	20OCT2020	2/2	1	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C4591001 1112 11121318†	GENRL	Fatigue/ Fatigue	2	11NOV2020	1/2	2	Yes		NA	R (12NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	11NOV2020	1/2	2	Yes		NA/TC	R (12NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1112 11121319	GENRL	Fatigue/ Fatigue#	4	05JAN2021	1/3	2	Yes		NA	R (07JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	05JAN2021	1/3	2	Yes		NA	R (07JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1112 11121328	NERV	Headache/ Headache#	4	05JAN2021	1/3	1	Yes		NA/TC	R (07JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	1	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
	MUSC	Myalgia/ Muscle Aches	1	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1112 11121332	GENRL	Injection site pain/ Injection site pain#	3	04JAN2021	1/3	2	Yes		NA/TC	R (06JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ Headache	2	13NOV2020	2/1	1	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1112 11121342	MUSC	Patellofemoral pain syndrome/ Chondromalacia Patallae	2	18JAN2021	68/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1114 11141008	GENRL	Chills/ CHILLS#	3	30JAN2021	1/2	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1114 11141009	GENRL	Injection site pain/ ARM PAIN AT INJECTION SITE#	3	30JAN2021	1/2	1	Yes		NA	R (31JAN2021)	N/N
		Fatigue/ FATIGUE#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1114 11141041	NERV	Injection site pain/ Injection site pain#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
		Headache/ exacerbation of headaches	1	25AUG2020	8/3	1	No	O	NA	R (27AUG2020)	N/N
16-55/ C4591001 1114 11141053	GENRL	Pyrexia/ Fever	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
16-55/ C4591001 1114 11141063	MUSC	Myalgia/ Myalgia	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
	METAB	Glucose tolerance impaired/ Prediabetes	2	SEP2020	1/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1114 11141065	SKIN	Dermatitis contact/ Poison Ivy Rash Back	1	07SEP2020	19/8	1	No	O	NA	R (14SEP2020)	N/N
16-55/ C4591001 1114 11141076	GASTR	Diarrhoea/ Diarrhea#	3	04FEB2021	1/1	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Chills/ Chills#	4	25FEB2021	1/3	1	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1114 11141076	PSYCH	Anxiety/ Anxiety	2	01OCT2020	18/C	1	No	O	NA	N	N/N
16-55/ C4591001	GASTR	Diarrhoea/ Diarrhea#	4	22FEB2021	1/4	1	Yes		NA	R (25FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1114 11141093		Nausea/ Nausea#	4	22FEB2021	1/4	1	Yes		NA	R (25FEB2021)	N/N	
	GENRL	Chills/ Chills#	4	22FEB2021	1/4	1	Yes		NA	R (25FEB2021)	N/N	
		Pyrexia/ Fever#	4	22FEB2021	1/4	1	Yes		NA	R (25FEB2021)	N/N	
	MUSC	Myalgia/ Generalized Muscle Soreness#	4	22FEB2021	1/4	1	Yes		NA	R (25FEB2021)	N/N	
16-55/ C4591001 1116 11161002	GENRL	Injection site pain/ arm pain at injection site#	3	22JAN2021	1/5	1	Yes		NA	R (26JAN2021)	N/N	
16-55/ C4591001 1116 11161023	INFEC	Cellulitis/ Cellulitis Located On Lower Right Leg	2	18OCT2020	31/12	1	No	O	NA/TC	R (29OCT2020)	N/N	
16-55/ C4591001 1116 11161036	GENRL	Fatigue/ fatigue#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N	
		Pain/ generalized body aches#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N	
16-55/ C4591001 1116 11161047	NERV	Headache/ Headaches	1	01SEP2020	5/25	1	No	O	NA/TC	R (25SEP2020)	N/N	
16-55/ C4591001	GENRL	Pain/ generalized body aches#	3	05MAR2021	1/8	1	Yes		NA	R (12MAR2021)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1116 11161049	NERV	Headache/ Headache#	3	05MAR2021	1/8	1	Yes		NA	R (12MAR2021)	N/N	
16-55/ C4591001 1116 11161059	GASTR	Obstructive pancreatitis/ Gall Stone Pancreatitis	1	13SEP2020	14/6	3	No	O	NA/TC/TCN	R (18SEP2020)	Y/N	
	HEPAT	Bile duct stone/ Cholelithiasis	1	13SEP2020	14/7	3	No	O	NA/TC/TCN	R (19SEP2020)	Y/N	
	INJ&P	Maternal exposure before pregnancy/ maternal exposure before pregnancy	2	09NOV2020	49/C	1	No	O	NA	UNK	N/N	
	SOCCI	High risk sexual behaviour/ unprotected, heterosexual intercourse	2	23NOV2020	63/1	1	No	O	NA	RS (23NOV2020)	N/N	
16-55/ C4591001 1116 11161083	GASTR	Abdominal hernia/ Upper Abdominal Hernia	1	SEP2020	1/	1	No	O	NA/TCN	R (21OCT2020)	N/N	
		Umbilical hernia/ Umbilical Hernia	1	SEP2020	1/	1	No	O	NA/TCN	R (21OCT2020)	N/N	
	GENRL	Chills/ chills#	3	04MAR2021	2/5	1	Yes		NA	R (08MAR2021)	N/N	
		Fatigue/ fatigue#	3	04MAR2021	2/5	1	Yes		NA	R (08MAR2021)	N/N	
	NERV	Headache/ headache#	3	04MAR2021	2/5	1	Yes		NA	R (08MAR2021)	N/N	
16-55/ C4591001 1116 11161099	INFEC	Urinary tract infection/ Urinary Tract Infection	2	18OCT2020	24/12	1	No	O	NA/TC	R (29OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1116 11161115	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1116 11161140	INFEC	Tooth infection/ Wisdom tooth infection#	2	12MAR2021	171/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1116 11161148	GENRL	Injection site pain/ Arm pain at injection site#	3	30JAN2021	2/4	1	Yes		NA	R (02FEB2021)	N/N
	GASTR	Abdominal pain/ abdominal cramps#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
	GENRL	Chills/ chills#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
		Injection site pain/ injection site pain#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
		Malaise/ malaise#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
		Pyrexia/ low grade temperature#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
	METAB	Decreased appetite/ lack of appetite#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
	MUSC	Back pain/ back pain#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
	MUSC	Arthralgia/ generalized joint pain#	4	21FEB2021	3/2	1	Yes		NA	R (22FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1116 11161154	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection-unspecified type	2	17JAN2021	110/26	1	No	O	NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1116 11161186	GENRL	Fatigue/ fatigue#	3	30JAN2021	2/2	2	Yes		NA	R (31JAN2021)	N/N
	INFEC	Herpes zoster/ shingles#	3	30JAN2021	2/28	2	No	O	NA	R (26FEB2021)	N/N
16-55/ C4591001 1116 11161200	GENRL	Chills/ Chills	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		Fatigue/ Fatigue	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		Pain/ Body Aches	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		Fatigue/ Fatigue	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ Pain @ Injection Site	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/Y
	MUSC	Arthralgia/ Joint Pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		Myalgia/ Muscle Pains	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1116 11161204	MUSC	Tenosynovitis stenosaurs/ DeQuervain's Tendinosis	1	24SEP2020	14/C	1	No	O	NA/TC	RG	N/N	
	GENRL	Fatigue/ fatigue#	3	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N	
	INV	Body temperature increased/ elevated body temperature#	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N	
16-55/ C4591001 1116 11161228	NERV	Presyncope/ Presyncope during blood draw	2	06NOV2020	30/1	1	No	O	NA	R (06NOV2020)	N/N	
16-55/ C4591001 1116 11161252	GENRL	Chills/ Chills	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N	
		Fatigue/ Fatigue	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N	
	GENRL	Injection site pain/ tenderness at injection site- left deltoid#	3	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N	
	GENRL	Injection site pruritus/ Itching at injection site- left deltoid muscle#	3	13JAN2021	6/1	1	Yes		NA	R (13JAN2021)	N/N	
16-55/ C4591001 1116 11161260	GENRL	Fatigue/ fatigue#	3	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N	
	GENRL	Chills/ chills#	4	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N	
		Pyrexia/ fever#	4	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1116 11161261	NERV	Headache/ headache#	4	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site- left deltoid muscle#	3	16JAN2021	2/3	1	Yes		NA	R (18JAN2021)	N/N
16-55/ C4591001 1116 11161276	INV	Body temperature increased/ elevated body temperature 99.0 to 100.1#	4	05FEB2021	3/1	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site mass/ Knot at Injection Site	2	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1116 11161305	GENRL	Chills/ Body Chills	2	15OCT2020	1/1	1	Yes		NA	R (15OCT2020)	N/N
	16-55/ C4591001 1116 11161308		Fatigue/ Fatigue	2	15OCT2020	1/1	1	Yes		NA	R (15OCT2020)
		Injection site pain/ Pain @ Injection Site	2	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
		Chills/ chills#	4	20FEB2021	2/1	1	Yes		NA	R (20FEB2021)	N/N
		Pain/ generalized body aches#	4	20FEB2021	2/1	1	Yes		NA	R (20FEB2021)	N/N
		Pyrexia/ fever#	4	20FEB2021	2/1	1	Yes		NA	R (20FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1116 11161310	IMMUN	Drug hypersensitivity/ allergic reaction to concomitant medication	2	18OCT2020	3/2	1	No	CD	NA	R (19OCT2020)	N/N	
16-55/ C4591001 1116 11161320	PSYCH	Anxiety/ Anxiety	1	01OCT2020	7/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1117 11171011	INJ&P	Fall/ FALL#	4	06FEB2021	25/1	2	No	O	NA/TCN	R (06FEB2021)	N/N	
		Fibula fracture/ BROKEN BONE, FIBULA, RIGHT, DISTAL#	4	06FEB2021	25/C	2	No	O	NA/TCN	RG	N/N	
16-55/ C4591001 1117 11171015	MUSC	Arthralgia/ KNEE PAIN, LEFT, WORSENING	2	OCT2020	23/C	2	No	O	NA/TC/TCN	N	N/N	
	INJ&P	Tooth fracture/ BROKEN TOOTH	2	NOV2020	54/	2	No	O	NA/TC/TCN	R	N/N	
16-55/ C4591001 1117 11171036	MUSC	Rhabdomyolysis/ RHABDOMYOLYSIS	1	26AUG2020	7/5	1	No	O	NA/TC	R (30AUG2020)	N/N	
	NERV	Syncope/ Syncope Episode	1	26AUG2020	7/5	4	No	O	NA	R (30AUG2020)	Y/N	
	RENAL	Acute kidney injury/ ACUTE KIDNEY INJURY	1	26AUG2020	7/5	1	No	O	NA/TC	R (30AUG2020)	N/N	
	PSYCH	Suicidal ideation/ Suicidal ideation	1	27AUG2020	8/4	4	No	O	NA/TC	R (30AUG2020)	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	METAB	Hypocalcaemia/ HYPOCALCEMIA	2	SEP2020	1/C	2	No	O	NA/TC	N	N/N
	PSYCH	Insomnia/ WORSENING INSOMNIA	2	SEP2020	1/C	2	No	O	NA	RG	N/N
	RESP	Snoring/ SNORING	2	SEP2020	1/C	2	No	O	NA	N	N/N
	VASC	Hypertension/ WORSENING HYPERTENSION	2	SEP2020	1/C	2	No	O	NA/TC	N	N/N
	MUSC	Musculoskeletal stiffness/ NECK STIFFNESS	2	21SEP2020	12/34	1	No	O	NA	R (24OCT2020)	N/N
	MUSC	Pain in extremity/ ARM SORENESS, LEFT	2	22SEP2020	13/11	2	No	O	NA	R (02OCT2020)	N/N
	METAB	Diabetes mellitus/ WORSENING DIABETES MELLITUS TYPE 2	2	10NOV2020	62/C	2	No	O	NA/TC	RG	N/N
	PSYCH	Suicidal ideation/ SUICIDAL IDEATION	2	20NOV2020	72/6	4	No	O	NA/TC/TCN	R (25NOV2020)	Y/N
	PSYCH	Major depression/ MODERATE EPISODE OF MAJOR DEPRESSIVE DISORDER W/ PSYCHOSIS	2	30DEC2020	112/3	3	No	O	NA/TC/TCN	R (01JAN2021)	Y/N
	RENAL	Chronic kidney disease/ CHRONIC KIDNEY DISEASE, STAGE 2, WORSENING	2	31DEC2020	113/C	2	No	O	NA	RG	N/N
16-55/ C4591001 1117 11171058	BLOOD	Lymphadenopathy/ SUPRACLAVICULAR LYMPHADENOPATHY, RIGHT*		25AUG2020	1/C	1	No	O	NA	N	N/N
	NERV	Headache/ Headache	1	27AUG2020	3/3	1	Yes		NA/TC	R (29AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1117 11171066	NERV	Dizziness/ LIGHT HEADEDNESS#	4	01FEB2021	1/1	1	Yes		NA/TCN	R (01FEB2021)	N/N
16-55/ C4591001 1117 11171070	SKIN	Rash maculo-papular/ Maculopapular Rash, Generalized	1	07SEP2020	13/19	2	No	O	NA	R (25SEP2020)	N/N
	INJ&P	Skin laceration/ Laceration, Left Thumb	1	09SEP2020	15/21	2	No	O	NA/TC/TCN	R (29SEP2020)	N/N
16-55/ C4591001 1117 11171091	INFEC	Localised infection/ INFECTION, LEFT THUMB	2	09DEC2020	76/14	2	No	O	NA/TC	R (22DEC2020)	N/N
		Localised infection/ INFECTION, RIGHT GREAT TOE	2	09DEC2020	76/42	2	No	O	NA/TC	R (19JAN2021)	N/N
	SKIN	Ingrowing nail/ INGROWN TOE NAIL, RIGHT GREAT TOE	2	12JAN2021	110/1	2	No	O	NA/TC/TCN	R (12JAN2021)	N/N
16-55/ C4591001 1117 11171100	NERV	Headache/ HEADACHE	1	11SEP2020	8/4	2	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001 1117 11171102	PSYCH	Attention deficit hyperactivity disorder/ ADHD, WORSENING	1	17SEP2020	14/126	1	No	O	NA/TC	R (20JAN2021)	N/N
16-55/ C4591001 1117 11171121	SKIN	Angioedema/ ANGIOEDEMA	2	31OCT2020	26/4	1	No	O	NA/TC	R (03NOV2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1117 11171156	VASC	Hypertension/ HYPERTENSION*		24SEP2020	1/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1117 11171174	INJ&P	Concussion/ CEREBRALCONCUSSION	2	01JAN2021	80/C	2	No	O	NA	RG	N/N
		Head injury/ HEAD TRAUMA	2	01JAN2021	80/C	2	No	O	NA	RG	N/N
	INFEC	Herpes zoster/ SHINGLES, SINGLE DERMATOME	2	03JAN2021	82/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1117 11171178	GENRL	Non-cardiac chest pain/ CHEST PAIN, NON CARDIAC#	2	27JAN2021	100/2	2	No	O	NA	R (28JAN2021)	N/N
16-55/ C4591001 1117 11171186	PSYCH	Suicide attempt/ SUICIDAL IDEATION WITH ATTEMPT	1	19OCT2020	14/8	3	No	O	P/TC/TCN	R (26OCT2020)	Y/N
	GASTR	Gastritis/ ACUTE GASTRITIS W/O HEMMORRHAGE	1	23OCT2020	18/39	2	No	O	NA/TC/TCN	R (30NOV2020)	N/N
		Vomiting/ BILIOUS VOMITING	1	23OCT2020	18/5	3	No	O	NA/TC/TCN	R (27OCT2020)	N/N
	GASTR	Abdominal pain/ ABDOMINAL PAIN	1	26OCT2020	21/2	2	No	O	NA/TC	R (27OCT2020)	N/N
16-55/ C4591001 1117 11171187	EAR	Tinnitus/ EAR RINGING, LEFT	2	27OCT2020	1/1	1	No	O	NA	R (27OCT2020)	N/Y

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1117 11171192	INFEC	Ear infection/ EAR INFECTION#	4	02MAR2021	12/9	2	No	O	NA/TC	R (10MAR2021)	N/N	
16-55/ C4591001 1117 11171197	MUSC	Exostosis/ BONE SPUR, LEFT HEEL, WORSENING	2	06DEC2020	24/1	2	No	O	NA/TC/TCN	R (06DEC2020)	N/N	
16-55/ C4591001 1118 11181003	INJ&P	Concussion/ CONCUSSION	2	03DEC2020	95/16	2	No	O	NA/TC	R (18DEC2020)	N/N	
		Fall/ fall	2	03DEC2020	95/1	2	No	O	NA	R (03DEC2020)	N/N	
		Rib fracture/ LEFT SIDE FRACTURE RIBS	2	03DEC2020	95/16	2	No	O	NA/TC	R (18DEC2020)	N/N	
16-55/ C4591001 1118 11181009	NERV	Headache/ mild headache#	3	31JAN2021	2/5	1	Yes		NA	R (04FEB2021)	N/N	
	GENRL	Pain/ body aches#	3	02FEB2021	4/3	1	Yes		NA	R (04FEB2021)	N/N	
	RESP	Sinus congestion/ sinus congestion#	3	02FEB2021	4/3	1	Yes		NA	R (04FEB2021)	N/N	
16-55/ C4591001 1118 11181028	MUSC	Back pain/ WORSENING OF CHRONIC LOWER BACK PAIN#	3	10FEB2021	12/10	2	No	O	NA/TCN	R (19FEB2021)	N/N	
16-55/ C4591001	MUSC	Muscle spasms/ back spasms	1	21AUG2020	8/C	2	No	O	NA/TC	RG	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1118 11181030 16-55/ C4591001 1118 11181040	INFEC	Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	2	12OCT2020	34/3	1	No	CD	NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1118 11181089	INFEC	Sinusitis/ sinus infection	2	25JAN2021	139/10	1	No	O	NA/TC	R (03FEB2021)	N/N
16-55/ C4591001 1118 11181089	RESP	Epistaxis/ epistaxis#	4	17FEB2021	3/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1118 11181100	RENAL	Nephrolithiasis/ NEPHROLITHIASIS	2	25SEP2020	9/14	1	No	O	NA/TCN	R (08OCT2020)	N/N
16-55/ C4591001 1118 11181110	INJ&P	Tooth fracture/ BROKEN RIGHT UPPER QUADRANT MOLAR#	3	31JAN2021	2/26	2	No	O	NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1118 11181110	GENRL	Oedema peripheral/ left foot edema	1	08NOV2020	21/C	1	No	O	NA	N	N/N
16-55/ C4591001 1118 11181117	PSYCH	Anxiety/ worsening of anxiety	1	24OCT2020	4/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1118 11181121	INJ&P	Road traffic accident/ motor vehicle accident	1	31OCT2020	10/1	1	No	O	NA	R (31OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1120 11201028	MUSC	Musculoskeletal chest pain/ muscular chest pain	1	31OCT2020	10/10	1	No	O	NA	R (09NOV2020)	N/N	
	MUSC	Pain in extremity/ R hand pain	2	15DEC2020	114/C	2	No	O	NA	N	N/N	
16-55/ C4591001 1120 11201044	GASTR	Diarrhoea/ Diarrhea	2	09SEP2020	15/1	1	No	O	NA/TC	R (09SEP2020)	N/N	
16-55/ C4591001 1120 11201082	NERV	Hypersomnia/ HYPERMORNOLENCE	2	28NOV2020	96/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1120 11201103		Migraine/ MIGRAINES	2	28NOV2020	96/1	1	No	O	NA	R (28NOV2020)	N/N	
	INFEC	Bacterial vulvovaginitis/ BACTERIAL VAGINITIS	2	14DEC2020	112/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1120 11201103	INFEC	Folliculitis/ folliculitis back of neck	2	26AUG2020	2/6	2	No	O	NA	R (31AUG2020)	N/N	
16-55/ C4591001 1120 11201104	MUSC	Plantar fasciitis/ Worsening of plantar fasciitis	1	18AUG2020	13/6	1	No	O	NA/TC	R (23AUG2020)	N/N	
16-55/ C4591001 1120 11201148	GENRL	Fatigue/ Fatigue	1	15AUG2020	4/2	3	Yes		NA	R (16AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1120 11201154	METAB	Vitamin D deficiency/ vitamin d deficiency	2	FEB2021	152/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1120 11201198	SKIN	Rash/ RASH TO LEFT FOREARM	2	02SEP2020	1/2	2	No	O	NA	R (03SEP2020)	N/N	
	SKIN	Rash/ RASH TO RIGHT FOREARM	2	09SEP2020	8/1	1	No	O	NA	R (09SEP2020)	N/N	
16-55/ C4591001 1120 11201220	METAB	Hyperlipidaemia/ hyperlipidemia#	2	25FEB2021	171/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1120 11201250	SKIN	Rash/ Rash torso and legs	1	27AUG2020	7/16	1	No	O	NA/TC	R (11SEP2020)	N/N	
	NERV	Burning sensation/ Burning sensation in palm of left hand	2	16SEP2020	6/1	2	No	O	NA	R (16SEP2020)	N/N	
16-55/ C4591001 1120 11201266	EYE	Blindness unilateral/ LOSS OF VISION LEFT EYE	2	04DEC2020	67/C	4	No	O	NA	N	Y/N	
	NEOPL	Lung cancer metastatic/ Metastatic Lung cancer	2	04DEC2020	67/47	4	No	O	NA/TC/W	F (19JAN2021)	Y/N	
16-55/ C4591001 1120 11201299	INFEC	Otitis media/ otitis media	1	06OCT2020	14/C	1	Yes		NA/TC	RG	N/N	

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16-55/ C4591001 1120 11201334	GASTR	Diarrhoea/ Diarrhea	1	28OCT2020	13/2	1	No	O	NA	R (29OCT2020)	N/N
	MUSC	Neck pain/ NECK PAIN	1	04NOV2020	20/C	2	No	CND	NA/TC	RG	N/N
16-55/ C4591001 1120 11201346	MUSC	Neck pain/ Neck Pain	2	12NOV2020	3/2	1	No	CND	NA/TC/TCN	R (13NOV2020)	N/N
16-55/ C4591001 1121 11211085	NERV	Headache/ Headache	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1121 11211112	INFEC	COVID-19/ COVID-19	2	24OCT2020	26/C	3	No	O	NA/TC	RS	Y/N
16-55/ C4591001 1122 11221005	GENRL	Chest pain/ chest aches	1	06SEP2020	4/26	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Arthralgia/ joint pain	1	07SEP2020	5/5	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Feeling hot/ sensation of hotness	2	26SEP2020	3/6	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1122 11221008	GENRL	Chills/ CHILLS#	4	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1122 11221009	MUSC	Fatigue/ FATIGUE#	4	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N	
		Myalgia/ GENERALIZED MUSCLE PAIN#	4	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N	
	NERV	Headache/ HEADACHE#	4	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N	
	NERV	Paraesthesia/ tingling of fingers in right hand	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/Y	
16-55/ C4591001 1122 11221012	GENRL	Fatigue/ fatigue	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	
	METAB	Decreased appetite/ loss of appetite	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	
	MUSC	Myalgia/ muscle pain	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	
	NERV	Headache/ headache	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	
	GASTR	Nausea/ Nausea	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N	
	GENRL	Chills/ Chills	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N	
		Fatigue/ fatigue	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N	
		Injection site pain/ injection site arm pain	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N	
	Pyrexia/ Fever	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N		

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1122 11221014	MUSC	Myalgia/ myalgia	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N	
	GENRL	Fatigue/ fatigue, excessive	1	11SEP2020	3/4	1	Yes		NA	R (14SEP2020)	N/N	
	GASTR	Gingival bleeding/ bleeding gums	2	01OCT2020	2/89	1	Yes		NA	R (28DEC2020)	N/N	
		Loose tooth/ loose tooth	2	01OCT2020	2/89	1	Yes		NA	R (28DEC2020)	N/N	
	GENRL	Fatigue/ fatigue	2	01OCT2020	2/128	1	Yes		NA	R (05FEB2021)	N/N	
	SKIN	Alopecia/ hair loss	2	01OCT2020	2/128	1	Yes		NA	R (05FEB2021)	N/N	
	16-55/ C4591001 1122 11221016	GENRL	Injection site paraesthesia/ tingling at injection site	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
	16-55/ C4591001 1122 11221024	GASTR	Diarrhoea/ Diarrhea	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Pain/ Body Aches	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N	
	MUSC	Pain in extremity/ right upper arm dull ache#	3	01FEB2021	1/4	2	Yes		NA/TC	R (04FEB2021)	N/N	
GENRL	Chills/ chills#	4	23FEB2021	2/4	1	Yes		NA/TC	R (26FEB2021)	N/N		
	Fatigue/ fatigue#	4	23FEB2021	2/4	1	Yes		NA/TC	R (26FEB2021)	N/N		



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1122 11221025	MUSC	Injection site pain/ injection site pain#	4	23FEB2021	2/C	1	Yes		NA/TC	N	N/N	
		Myalgia/ muscle aches#	4	23FEB2021	2/4	1	Yes		NA/TC	R (26FEB2021)	N/N	
	INFEC	Oral herpes/ worsening of cold sore	1	15SEP2020	6/4	1	No	O	NA	R (18SEP2020)	N/N	
	GENRL	Fatigue/ fatigue#	3	22DEC2020	2/2	1	Yes		NA/TC	R (23DEC2020)	N/N	
	MUSC	Injection site pain/ Injection site pain# Myalgia/ Generalized muscle aches#	3	22DEC2020	2/3	1	Yes		NA/TC	R (24DEC2020)	N/N	
16-55/ C4591001 1122 11221026	GASTR	Vomiting/ vomiting*		11SEP2020	/1	1	No	O	NA/W	R (11SEP2020)	N/N	
	NERV	Presyncope/ pre-syncope*		11SEP2020	/1	1	No	O	NA/W	R (11SEP2020)	N/N	
16-55/ C4591001 1122 11221028	GENRL	Fatigue/ fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N	
	MUSC	Injection site pain/ injection site pain	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N	
		Pyrexia/ Fever	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N	
		Arthralgia/ joint soreness at the shoulders	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1122 11221030	GENRL	Malaise/ Malaise	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N	
		Pyrexia/ Fever	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N	
16-55/ C4591001 1122 11221032	NERV	Dizziness/ Dizziness (Loss of Balance)	1	28SEP2020	15/5	2	No	CD	NA	R (02OCT2020)	N/N	
	GASTR	Hypoaesthesia oral/ tongue numbness#	3	04FEB2021	1/1	1	Yes		NA	R (04FEB2021)	N/Y	
16-55/ C4591001 1122 11221033	GENRL	Fatigue/ fatigue#	4	06JAN2021	1/3	1	Yes		NA/TC	R (08JAN2021)	N/N	
	GENRL	Chills/ chills#	4	07JAN2021	2/2	1	Yes		NA/TC	R (08JAN2021)	N/N	
		Injection site pain/ injection site pain#	4	07JAN2021	2/2	1	Yes		NA/TC	R (08JAN2021)	N/N	
		Pyrexia/ fever#	4	07JAN2021	2/2	1	Yes		NA/TC	R (08JAN2021)	N/N	
16-55/ C4591001 1122 11221040	NERV	Headache/ headaches	1	12OCT2020	8/38	1	Yes		NA	R (18NOV2020)	N/N	
	GENRL	Chills/ chills#	3	18DEC2020	2/1	1	Yes		NA/TC	R (18DEC2020)	N/N	
		Malaise/ general malaise#	3	18DEC2020	2/1	1	Yes		NA/TC	R (18DEC2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1122 11221042	MUSC	Pyrexia/ Fever 100.3F#	3	18DEC2020	2/1	1	Yes		NA/TC	R (18DEC2020)	N/N	
		Back pain/ body aches (back)#	3	18DEC2020	2/1	1	Yes		NA/TC	R (18DEC2020)	N/N	
	GENRL	Chills/ chills#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N	
		Fatigue/ fatigue#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N	
		Pain/ generalized body aches#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N	
			Pyrexia/ fever#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
		CONG	Benign familial pemphigus/ exacerbation Haley-Haley disease#	2	24JAN2021	88/C	2	No	O	NA	RG	N/N
16-55/ C4591001 1122 11221045	GENRL	Injection site pain/ pain at injection site	2	28OCT2020	1/1	1	Yes		NA	R (28OCT2020)	N/Y	
	NERV	Hypoaesthesia/ numbness in hand of injection arm	2	28OCT2020	1/1	1	Yes		NA	R (28OCT2020)	N/Y	
		Paraesthesia/ tingling sensation in injection arm	2	28OCT2020	1/1	1	Yes		NA	R (28OCT2020)	N/Y	
	GENRL	Chills/ chills#	3	23DEC2020	2/1	1	Yes		NA/TC	R (23DEC2020)	N/N	
		Fatigue/ Fatigue#	3	23DEC2020	2/9	1	Yes		NA	R (31DEC2020)	N/N	
		Pyrexia/ fever 100.4F#	3	23DEC2020	2/1	1	Yes		NA/TC	R (23DEC2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1122 11221047	MUSC	Arthralgia/ Generalized joint pain (aches)#	3	23DEC2020	2/1	1	Yes		NA/TC	R (23DEC2020)	N/N	
		Myalgia/ muscle pain#	3	23DEC2020	2/1	1	Yes		NA/TC	R (23DEC2020)	N/N	
		Neck pain/ neck pain#	3	23DEC2020	2/1	1	Yes		NA/TC	R (23DEC2020)	N/N	
		Pain in extremity/ injection arm pain#	3	23DEC2020	2/1	1	Yes		NA/TC	R (23DEC2020)	N/N	
	NERV	Headache/ Headache#	3	23DEC2020	2/1	1	Yes		NA/TC	R (23DEC2020)	N/N	
	GENRL	Chills/ shaking chills#	4	14JAN2021	2/2	1	Yes		NA/TC	R (15JAN2021)	N/N	
		Fatigue/ fatigue#	4	14JAN2021	2/2	1	Yes		NA/TC	R (15JAN2021)	N/N	
		Injection site pain/ injection site pain#	4	14JAN2021	2/2	1	Yes		NA/TC	R (15JAN2021)	N/N	
		Pain/ generalized body aches#	4	14JAN2021	2/2	1	Yes		NA/TC	R (15JAN2021)	N/N	
		Pyrexia/ fever#	4	14JAN2021	2/2	1	Yes		NA/TC	R (15JAN2021)	N/N	
	MUSC	Neck pain/ neck pain#	4	14JAN2021	2/2	2	Yes		NA/TC	R (15JAN2021)	N/N	
		Pain in extremity/ bilateral calf pain#	4	14JAN2021	2/2	2	Yes		NA/TC	R (15JAN2021)	N/N	
	NERV	Headache/ headache behind eyes#	4	14JAN2021	2/2	1	Yes		NA/TC	R (15JAN2021)	N/N	
		Diarrhoea/ diarrhea#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1122 11221048	GENRL	Chills/ chills#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	3	26JAN2021	1/4	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ generalized muscle aches#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1122 11221051	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	25NOV2020	29/C		No	O	NA	UNK	N/N
16-55/ C4591001 1122 11221052	GENRL	Non-cardiac chest pain/ Acute Illness non cardiac chest pain	1	10OCT2020	2/3	2	Yes		NA	R (12OCT2020)	N/N
16-55/ C4591001 1122 11221053	GENRL	Injection site pain/ injection site pain#	4	13JAN2021	1/5	1	Yes		NA	R (17JAN2021)	N/N
	NERV	Headache/ Headache#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Paraesthesia/ Paresthesia in bilateral nostrils#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	MUSC	Arthralgia/ Bilateral shoulder pain#	4	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N
	SKIN	Eczema/ flare up of eczema	1	20OCT2020	8/24	1	No	O	NA	R (12NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	07NOV2020	4/6	1	Yes		NA	R (12NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1122 11221059	GENRL	Fatigue/ very mild fatigue	2	08NOV2020	5/7	1	Yes		NA	R (14NOV2020)	N/N
	SKIN	Pruritus/ mild body itching-specific region: lateral aspect of right forearm and left side of neck	2	08NOV2020	5/7	1	No	O	NA	R (14NOV2020)	N/N
	INFEC	Cellulitis/ Cellulitis groin	2	15DEC2020	42/11	2	No	O	NA/TC/TCN	R (25DEC2020)	N/N
	BLOOD	Lymph node pain/ Tender lymph node right jaw#	2	31DEC2020	58/3	1	No	O	NA	R (02JAN2021)	N/N
		Lymphadenopathy/ Swollen lymph node right jaw#	2	31DEC2020	58/3	1	No	O	NA	R (02JAN2021)	N/N
	INFEC	Wound infection/ Infected laceration right thumb#	2	02JAN2021	60/3	1	No	O	NA/TC/TCN	R (04JAN2021)	N/N
	GENRL	Injection site pain/ injection site soreness#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
		Pain/ generalized body aches#	4	11JAN2021	1/4	2	Yes		NA	R (14JAN2021)	N/N
	GENRL	Chills/ rigors#	4	12JAN2021	2/1	2	Yes		NA	R (12JAN2021)	N/N
	16-55/ C4591001 1123 11231009	REPRO	Dysmenorrhoea/ Worsening of dysmenorrhea	1	05AUG2020	7/13	1	No	O	NA/TC/TCN	R (17AUG2020)
	CONG	Congenital cystic kidney disease/ Polycystic kidney disease	1	17AUG2020	19/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001	PSYCH	Attention deficit hyperactivity disorder/ Attention deficit disorder	2	08SEP2020	16/C	2	No	O	NA/TC	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1123 11231019	INJ&P	Chillblains/ Chilblains of fingers and toes	2	01NOV2020	70/C	2	No	O	NA	N	N/N	
16-55/ C4591001 1123 11231041	GENRL	Fatigue/ FATIGUE	1	11AUG2020	7/2	1	Yes		NA	R (12AUG2020)	N/N	
16-55/ C4591001 1123 11231043	GENRL	Fatigue/ FATIGUE	1	12AUG2020	7/3	1	No	O	NA	R (14AUG2020)	N/N	
16-55/ C4591001 1123 11231046	SKIN	Erythema/ Mild erythema bilateral nares	2	25AUG2020	1/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1123 11231046	GENRL	Injection site pain/ Pain at injection site#	3	22DEC2020	2/3	1	Yes		NA	R (24DEC2020)	N/N	
16-55/ C4591001 1123 11231064	GENRL	Chills/ Chills#	4	13JAN2021	2/1	1	Yes		NA	R (13JAN2021)	N/N	
		Pyrexia/ Fever#	4	13JAN2021	2/2	1	Yes		NA/TC	R (14JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	13JAN2021	2/1	1	Yes		NA	R (13JAN2021)	N/N	
	NERV	Headache/ Headache#	4	13JAN2021	2/1	1	Yes		NA	R (13JAN2021)	N/N	
16-55/ C4591001 1123 11231064	GASTR	Hiatus hernia/ hiatal hernia	1	13AUG2020	4/C	1	No	O	NA/TCN	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1123 11231067	METAB	Hyperlipidaemia/ Hyperlipidemia	2	25JAN2021	145/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1123 11231074	MUSC	Myalgia/ myalgia	1	16AUG2020	6/4	1	Yes		NA	R (19AUG2020)	N/N	
	MUSC	Arthralgia/ knee pain	1	29AUG2020	19/9	1	No	O	NA/TC	R (06SEP2020)	N/N	
16-55/ C4591001 1123 11231094	GENRL	Fatigue/ FATIGUE	1	14AUG2020	2/8	1	No	O	NA	R (21AUG2020)	N/N	
	MUSC	Arthralgia/ JOINT PAIN	1	19AUG2020	7/3	1	No	O	NA	R (21AUG2020)	N/N	
16-55/ C4591001 1123 11231102	MUSC	Myalgia/ myalgia#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
	NERV	Headache/ headache#	4	09FEB2021	2/2	1	Yes		NA/TC	R (10FEB2021)	N/N	
16-55/ C4591001 1123 11231114	NEOPL	Lipoma/ Right axilla lipoma	2	23SEP2020	16/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1123 11231116	GENRL	Pyrexia/ Fever	2	09SEP2020	2/1	1	Yes		NA/TC	R (09SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Myalgia/ full body myalgias	2	09SEP2020	2/1	1	Yes		NA/TC	R (09SEP2020)	N/N	
16-55/ C4591001 1123 11231117	MUSC	Periarthritis/ Worsening of right adhesive capsulitis shoulder	2	14SEP2020	7/23	1	No	O	NA/TC	R (06OCT2020)	N/N	
16-55/ C4591001 1123 11231124	GENRL	Chills/ CHILLS	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N	
		Pyrexia/ FEVER	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N	
	MUSC	Myalgia/ FULL BODY MYALGIA	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N	
	NERV	Headache/ HEADACHE	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N	
16-55/ C4591001 1123 11231128	GENRL	Pyrexia/ Fever	2	09SEP2020	2/2	1	Yes		NA/TC	R (10SEP2020)	N/N	
16-55/ C4591001 1123 11231143	MUSC	Myalgia/ Full body myalgia	2	12SEP2020	3/2	1	Yes		NA/TC	R (13SEP2020)	N/N	
16-55/ C4591001 1123 11231164	PSYCH	Anxiety/ Worsening of anxiety	2	03OCT2020	19/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1123 11231172 16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site, left arm	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
1123 11231176 16-55/ C4591001	RENAL	Nephrolithiasis/ Nephrolithiasis#	3	28JAN2021	15/C	2	No	O	NA/TC	RG	N/N
1123 11231183 16-55/ C4591001	GENRL	Pyrexia/ Fever	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
1123 11231187	NERV	Headache/ Headache	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1123 11231191	EAR	Cerumen impaction/ Right Cerumen impaction	2	11NOV2020	56/C	1	No	O	NA	N	N/N
16-55/ C4591001 1123 11231194	SKIN	Rash/ Rash on both feet	2	17SEP2020	2/36	1	No	O	NA	R (22OCT2020)	N/N
16-55/ C4591001 1123 11231197	GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1123 11231200	GENRL	Injection site pain/ Pain at left injection site	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
		Chills/ Chills	2	16SEP2020	1/3	1	Yes		NA/TC	R (18SEP2020)	N/N
	MUSC	Injection site pain/ Injection site pain	2	16SEP2020	1/5	1	Yes		NA/TC	R (20SEP2020)	N/N
		Myalgia/ Full body myalgia	2	16SEP2020	1/3	1	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	1/3	1	Yes		NA/TC	R (18SEP2020)	N/N
	REPRO	Menometrorrhagia/ Worsening of menometrorrhagia	2	01OCT2020	16/21	1	No	O	NA	R (21OCT2020)	N/N
	HEPAT	Biliary colic/ Worsening of biliary colic	2	03OCT2020	18/1	2	No	O	NA	R (03OCT2020)	N/N
	GENRL	Chills/ Chills#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	MUSC	Fatigue/ Fatigue#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
		Pyrexia/ fever#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N
Arthralgia/ Generalized arthralgia#		4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N	
NERV	Headache/ Headache#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N	
16-55/ C4591001 1123 11231204	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	22OCT2020	38/C		No	O	NA	UNK	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1123 11231208	INJ&P	Fall/ Fall	1	18SEP2020	22/1	2	No	O	NA	R (18SEP2020)	N/N
		Foot fracture/ Left foot fracture	1	18SEP2020	22/12	1	No	O	NA/TC/TCN	R (29SEP2020)	N/N
16-55/ C4591001 1123 11231210	GENRL	Fatigue/ fatigue	2	26SEP2020	2/4	1	No	O	NA	R (29SEP2020)	N/N
	MUSC	Myalgia/ myalgia	2	26SEP2020	2/4	1	Yes		NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 1123 11231215	METAB	Vitamin D deficiency/ Vitamin D Deficiency	2	20OCT2020	22/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1123 11231216	GENRL	Chills/ Chills	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
	MUSC	Myalgia/ Full body myalgia	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
	METAB	Type 2 diabetes mellitus/ type II diabetes#	2	06MAR2021	159/C				NA/TC	N	/N
16-55/ C4591001	GENRL	Chills/ Chills	2	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1123 11231217	MUSC	Arthralgia/ joint pain	2	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N	
		Myalgia/ Full body myalgia	2	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N	
	NERV	Dizziness/ Dizziness	2	28SEP2020	1/4	1	Yes		NA	R (01OCT2020)	N/N	
16-55/ C4591001	PSYCH	Depression/ worsening of depression	2	12NOV2020	43/C	2	No	O	NA/TC	N	N/N	
1123 11231220	GENRL	Chills/ chills	2	29SEP2020	1/4	1	Yes		NA/TC	R (02OCT2020)	N/N	
16-55/ C4591001	MUSC	Myalgia/ myalgia	2	29SEP2020	1/4	1	Yes		NA/TC	R (02OCT2020)	N/N	
1123 11231233	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N	
	MUSC	Arthralgia/ Joint pain	1	13SEP2020	4/3	1	Yes		NA/TC	R (15SEP2020)	N/N	
	GENRL	Pyrexia/ Fever	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N	
16-55/ C4591001	GASTR	Teething/ Wisdom tooth eruption with pain	1	30SEP2020	20/22	1	No	O	NA/TC	R (21OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1123 11231237	GENRL	Injection site pain/ Pain at injection site	1	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
1123 11231252	VASC	Hypertension/ Hypertension#	3	29JAN2021	2/C	1	No	CD	NA/TC	RG	N/N
1123 11231253	GASTR	Diarrhoea/ Diarrhea	2	08OCT2020	3/3	1	Yes		NA	R (10OCT2020)	N/N
1123 11231264	GENRL	Chills/ Chills	2	08OCT2020	3/1	1	Yes		NA	R (08OCT2020)	N/N
		Pyrexia/ Fever	2	08OCT2020	3/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	08OCT2020	3/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1123 11231289	GENRL	Chills/ Chills	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ Injection site pain	1	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ Headache	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
	GASTR	Nausea/ nausea	2	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1123 11231294	GENRL	Chills/ Chills	2	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
		Malaise/ malaise	2	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
	NERV	Headache/ Headache	2	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	15OCT2020	2/3	1	Yes		NA	R (17OCT2020)	N/N
	NERV	Headache/ Headache	1	29SEP2020	7/2	1	No	O	NA/TC	R (30SEP2020)	N/N
	GENRL	Chills/ Chills	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
		Fatigue/ Fatigue	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
	GASTR	Nausea/ nausea	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1123 11231305	NERV	Headache/ headache	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1123 11231307											

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1123 11231309 16-55/ C4591001 1123 11231313 16-55/ C4591001 1123 11231317 16-55/ C4591001 1123 11231322 16-55/ C4591001 1123 11231327	MUSC	Myalgia/ Myalgia	2	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/N	
	NERV	Headache/ Headache	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N	
	GENRL	Pyrexia/ Fever	2	15OCT2020	2/3	1	Yes		NA	R (17OCT2020)	N/N	
	NERV	Headache/ Headache	1	06OCT2020	13/2	1	No	O	NA/TC	R (07OCT2020)	N/N	
	PSYCH	Bruxism/ Bruxism	2	27OCT2020	14/C	1	No	O	NA/TC	N	N/N	
	GASTR	Haemorrhoids/ Hemorrhoids	1	04OCT2020	10/5	1	No	O	NA/TC	R (08OCT2020)	N/N	
	INFEC	Vulvovaginal candidiasis/ Vulvovaginal candidiasis	1	02OCT2020	8/4	1	No	O	NA/TC	R (05OCT2020)	N/N	
	INFEC	Acute sinusitis/ Acute sinusitis	2	30OCT2020	17/7	1	No	O	NA/TC	R (05NOV2020)	N/N	
	INJ&P	Cartilage injury/ left labral tear#	2	11FEB2021	121/1	1	No	O	NA/TC/TCN	R (11FEB2021)	N/N	
16-55/ C4591001	MUSC	Myalgia/ FULL BODY MYALGIA	1	26SEP2020	2/3	1	Yes		NA/TC	R (28SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1123 11231328	GENRL	Chills/ Chills	2	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N	
16-55/ C4591001 1123 11231334	INFEC	Cystitis/ Acute cystitis	1	01OCT2020	7/5	1	No	O	NA/TC	R (05OCT2020)	N/N	
16-55/ C4591001 1123 11231338	GENRL	Chills/ Chills	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N	
		Injection site pain/ Pain at injection site	1	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N	
16-55/ C4591001 1123 11231350	MUSC	Myalgia/ Muscle pain	1	09OCT2020	2/4	1	Yes		NA/TC	R (12OCT2020)	N/N	
16-55/ C4591001 1123 11231359	MUSC	Neck pain/ Worsening of chronic neck pain	1	30OCT2020	19/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1123 11231360	SKIN	Pruritus/ Pruritus generalized	1	14OCT2020	3/7	1	Yes		NA/TC	R (20OCT2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1123 11231365		Injection site pruritus/ Injection site pruritus	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/Y
16-55/ C4591001 1123 11231366	GASTR	Nausea/ Nausea	1	13OCT2020	2/4	1	Yes		NA/TC	R (16OCT2020)	N/N
	GASTR	Vomiting/ Vomiting	1	15OCT2020	4/1	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1123 11231375	GENRL	Chills/ Chills	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/N
		Fatigue/ Fatigue	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/N
		Pyrexia/ Fever	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C4591001 1123 11231381	NERV	Headache/ Headache	2	06NOV2020	1/2	1	Yes		NA/TC	R (07NOV2020)	N/N
	BLOOD	Lymphadenopathy/ Left Axillary lymphadenopathy	2	07NOV2020	2/1	1	Yes		NA	R (07NOV2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	07NOV2020	2/1	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001	INV	Blood pressure diastolic increased/ Increased diastolic blood pressure	2	09NOV2020	1/C	1	Yes		NA	N	N/Y

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1123 11231392 16-55/ C4591001	MUSC	Arthralgia/ Arthralgia of hips	2	12NOV2020	1/4	1	Yes		NA	R (15NOV2020)	N/N	
1123 11231399	GENRL	Chills/ Chills	2	13NOV2020	2/3	1	Yes		NA	R (15NOV2020)	N/N	
		Pyrexia/ Fever	2	13NOV2020	2/1	1	Yes		NA/TC	R (13NOV2020)	N/N	
	NERV	Paraesthesia/ Paresthesia of lower extremities	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N	
16-55/ C4591001	GENRL	Chills/ Chills	2	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N	
1123 11231405		Pyrexia/ Fever	2	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N	
	MUSC	Arthralgia/ Arthralgia generalized	2	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N	
		Myalgia/ Myalgia	2	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N	
	NERV	Headache/ Headache	2	17NOV2020	2/3	1	Yes		NA	R (19NOV2020)	N/N	
16-55/ C4591001	GENRL	Injection site erythema/ Redness at injection site	2	18NOV2020	2/3	1	Yes		NA	R (20NOV2020)	N/N	
1123 11231408		Injection site induration/ Induration at injection site	2	18NOV2020	2/3	1	Yes		NA	R (20NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1124 11241003	MUSC	Injection site swelling/ Swelling at injection site	2	18NOV2020	2/3	1	Yes		NA/TC	R (20NOV2020)	N/N
		Osteitis/ Inflamed first metatarsal	1	02SEP2020	24/36	2	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1124 11241012	NERV	Headache/ worsening headache#	4	10MAR2021	1/2	1	Yes		NA	R (11MAR2021)	N/N
		Injection site rash/ injection site rash#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N
16-55/ C4591001 1124 11241026	GENRL	Fatigue/ Fatigue	1	28AUG2020	17/2	1	Yes		NA/TC	R (29AUG2020)	N/N
16-55/ C4591001 1124 11241036	GENRL	Pain/ Body aches#	4	04MAR2021	1/2	1	Yes		NA	R (05MAR2021)	N/N
16-55/ C4591001 1124 11241042	INJ&P	Foot fracture/ Right foot fracture	1	01SEP2020	16/8	1	No	O	NA/TC	R (08SEP2020)	N/N
		Limb injury/ Left thumb injury	1	02SEP2020	17/1	1	No	O	NA/TCN	R (02SEP2020)	N/N
16-55/ C4591001 1124 11241047	GENRL	Injection site pain/ Muscle Soreness at injection site	2	13SEP2020	4/4	2	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1124 11241049	GENRL	Chills/ Chills	1	18AUG2020	2/C	2	Yes		NA	N	N/N
		Pyrexia/ Fever (101 degrees F)	1	18AUG2020	2/C	2	Yes		NA	N	N/N
	MUSC	Myalgia/ Muscle Pain	1	18AUG2020	2/C	2	Yes		NA	N	N/N
	NERV	Headache/ Headache	1	18AUG2020	2/C	2	Yes		NA	N	N/N
16-55/ C4591001 1124 11241050	GENRL	Injection site pain/ injection site soreness#	4	05MAR2021	1/2	1	Yes		NA	R (06MAR2021)	N/N
16-55/ C4591001 1124 11241053	MUSC	Myalgia/ Myalgias	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
	NERV	Headache/ Headache	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1124 11241058	INFEC	Herpes zoster/ Shingles	2	04OCT2020	25/8	2	No	O	NA/TC	R (11OCT2020)	N/N
	MUSC	Rotator cuff syndrome/ Torn rotator cuff (right)	2	08OCT2020	29/25	2	No	O	NA/TC	R (01NOV2020)	N/N
16-55/ C4591001 1124 11241066	INJ&P	Foot fracture/ Left foot fracture	1	07SEP2020	20/44	1	No	O	NA/TCN	R (20OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1124 11241071	GENRL	Injection site pain/ Injection site soreness	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1124 11241075	GENRL	Chills/ Chills	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GASTR	Abdominal distension/ Bloating	2	28NOV2020	80/8	2	No	O	NA	R (05DEC2020)	N/N
		Abdominal pain/ Abdominal pain	2	28NOV2020	80/8	1	No	O	NA	R (05DEC2020)	N/N
	SKIN	Rash/ diffuse body rash	2	03DEC2020	85/3	1	No	O	NA	R (05DEC2020)	N/N
16-55/ C4591001 1124 11241081	GENRL	Pain/ Body Aches#	4	10MAR2021	2/2	1	Yes		NA	R (11MAR2021)	N/N
16-55/ C4591001 1124 11241083	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/4	2	Yes		NA	R (27AUG2020)	N/N
16-55/ C4591001 1124 11241084	METAB	Hypokalaemia/ Hypokalemia (2.8)	1	01SEP2020	9/1	1	No	O	NA/TC	R (01SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	25AUG2020	2/2	2	Yes		NA	R (26AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1124 11241086	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ Injection site pain	2	15SEP2020	2/2	2	Yes		NA/TC	R (16SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1124 11241094	MUSC	Myalgia/ Myalgia	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1124 11241095	GENRL	Pyrexia/ Fever	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1124 11241099	GENRL	Fatigue/ Fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1124 11241100	INJ&P	Head injury/ Mild trauma to central forehead	1	12SEP2020	18/7	2	No	O	NA/TC	R (18SEP2020)	N/N
	GENRL	Injection site erythema/ Injection site erythema	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001	REPRO	Dysmenorrhoea/ Menstrual cramps	1	11SEP2020	17/4	1	No	O	NA/TC	R (14SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1124 11241102	RESP	Nasal congestion/ Nasal Congestion	1	12SEP2020	18/6	1	No	O	NA/TC	R (17SEP2020)	N/N	
		Oropharyngeal pain/ Sore Throat	1	12SEP2020	18/2	1	No	O	NA/TC	R (13SEP2020)	N/N	
	NERV	Headache/ Headache	2	25SEP2020	12/4	2	No	O	NA/TC	R (28SEP2020)	N/N	
		Lethargy/ Lethargy	2	25SEP2020	12/4	2	No	O	NA	R (28SEP2020)	N/N	
	GASTR	Nausea/ NAUSEA#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N	
	NERV	Headache/ HEADACHE#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N	
16-55/ C4591001 1124 11241106	CARD	Acute myocardial infarction/ ST elevation myocardial infarction	2	27SEP2020	12/17	4	No	O	NA	R (13OCT2020)	Y/N	
	INJ&P	Fall/ Fall from Bicycle	2	27SEP2020	12/1	2	No	O	NA	R (27SEP2020)	N/N	
16-55/ C4591001 1124 11241108	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	1/5	2	Yes		NA	R (21SEP2020)	N/N	
16-55/ C4591001 1124 11241113	MUSC	Myalgia/ Myalgias	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N	
	NERV	Headache/ Worsening Headache	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1124 11241118	GENRL	Malaise/ Malaise	1	28AUG2020	2/3	2	Yes		NA	R (30AUG2020)	N/N	
16-55/ C4591001 1124 11241125	INJ&P	Ligament sprain/ Right Ankle Sprain	2	07OCT2020	16/8	1	No	O	NA	R (14OCT2020)	N/N	
16-55/ C4591001 1124 11241127	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N	
		Pyrexia/ Fever	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N	
16-55/ C4591001 1124 11241142	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	1/1	2	Yes		NA	R (02SEP2020)	N/N	
	GENRL	Chills/ Chills	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
	MUSC	Myalgia/ Myalgias	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 1124 11241149	GENRL	Pyrexia/ Fever	2	25SEP2020	2/4	1	Yes		NA	R (28SEP2020)	N/N	
	MUSC	Myalgia/ Myalgias	2	25SEP2020	2/4	2	Yes		NA	R (28SEP2020)	N/N	
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	23SEP2020	3/2	1	Yes		NA	R (24SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1124 11241152		Injection site pain/ Injection site pain	2	23SEP2020	3/2	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	3/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1124 11241167	INFEC	Urinary tract infection/ Suspected Urinary Tract Infection	1	20SEP2020	18/2	1	No	O	NA/TC	R (21SEP2020)	N/N
	NERV	Sciatic nerve neuropathy/ Left sided sciatic neuropathy	2	16OCT2020	25/78	2	No	O	NA	R (01JAN2021)	N/N
16-55/ C4591001 1124 11241168	GENRL	Pain/ body aches#	3	17DEC2020	2/2	1	Yes		NA	R (18DEC2020)	N/N
	NERV	Headache/ Headache#	3	17DEC2020	2/2	1	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1124 11241170	GENRL	Chills/ Chills	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		Injection site pain/ Injection site soreness	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		Malaise/ General Malaise	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1124 11241174	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1124 11241179	NERV	Headache/ Headache	2	02OCT2020	4/1	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1124 11241184	MUSC	Myalgia/ Myalgias	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1124 11241196	SKIN	Rash/ Diffuse body rash#	4	02MAR2021	2/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1124 11241198	GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1124 11241200	GENRL	Chills/ Chills	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		Fatigue/ Fatigue	2	02OCT2020	1/4	2	Yes		NA	R (05OCT2020)	N/N
		Pyrexia/ Fever	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/4	2	Yes		NA/TC	R (13SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1124 11241202	GENRL	Injection site pain/ Injection site soreness	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N	
16-55/ C4591001 1124 11241207	BLOOD	Lymphadenopathy/ Left axilla adenopathy	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N	
	GENRL	Pyrexia/ Fever	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N	
	MUSC	Myalgia/ Myalgias	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N	
16-55/ C4591001 1124 11241213	MUSC	Pain in extremity/ Bilateral hand soreness	1	13SEP2020	3/2	1	Yes		NA	R (14SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site soreness	2	02OCT2020	1/3	2	Yes		NA	R (04OCT2020)	N/N	
		Pyrexia/ Fever	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N	
	MUSC	Joint stiffness/ Joint stiffness	2	02OCT2020	1/3	2	Yes		NA	R (04OCT2020)	N/N	
16-55/ C4591001 1124 11241216	GENRL	Injection site pain/ Injection site pain	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N	
	MUSC	Myalgia/ Myalgias	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1124 11241218	NERV	Headache/ Headache	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001 1124 11241219	GENRL	Fatigue/ Fatigue	2	02OCT2020	3/8	1	Yes		NA	R (09OCT2020)	N/N	
16-55/ C4591001 1124 11241222	METAB	Decreased appetite/ Loss of appetite	2	02OCT2020	3/15	1	Yes		NA	R (16OCT2020)	N/N	
16-55/ C4591001 1124 11241222	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N	
16-55/ C4591001 1124 11241223	SKIN	Night sweats/ Increased diaphoresis during sleep	2	25OCT2020	19/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1124 11241225	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	2	NOV2020	26/C	2	No	O	NA	RG	N/N	
16-55/ C4591001 1124 11241225	GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/5	1	Yes		NA	R (09OCT2020)	N/N	
16-55/ C4591001 1124 11241226	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/5	1	Yes		NA/TC	R (20SEP2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection site soreness	1	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1124 11241234	GENRL	Fatigue/ Fatigue	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
		Pyrexia/ Fever	1	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N	
	NERV	Headache/ Headache	1	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N	
	GENRL	Pyrexia/ Fever	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N	
	NERV	Headache/ Headache	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N	
16-55/ C4591001 1124 11241235	GENRL	Fatigue/ Fatigue	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N	
16-55/ C4591001 1125 11251014	MUSC	Pain in extremity/ Pain in 3rd digit of Right hand	2	26NOV2020	86/1	1	No	O	NA/TC	R (26NOV2020)	N/N	
16-55/ C4591001 1125 11251020	INJ&P	Cervical vertebral fracture/ Cervical Spine fracture	2	23DEC2020	111/30	2	No	O	NA	R (21JAN2021)	N/N	
		Craniocerebral injury/ traumatic brain injury	2	23DEC2020	111/30	3	No	O	NA/TC	R (21JAN2021)	Y/N	
		Fall/ Fall from Stairs	2	23DEC2020	111/1	3	No	O	NA	R (23DEC2020)	N/N	
		Rib fracture/ Rib Fractures	2	23DEC2020	111/30	2	No	O	NA	R (21JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1125 11251021	GENRL	Skull fracture/ Skull Fracture	2	23DEC2020	111/30	2	No	O	NA	R (21JAN2021)	N/N	
16-55/ C4591001 1125 11251021	GENRL	Swelling/ under arm swelling left arm	1	18AUG2020	6/2	1	Yes		NA	R (19AUG2020)	N/N	
16-55/ C4591001 1125 11251028	INFEC	Sinusitis/ Sinus Infection	1	26AUG2020	14/5	1	No	O	NA/TC	R (30AUG2020)	N/N	
16-55/ C4591001 1125 11251029	INFEC	Sinusitis/ Sinus Infection	1	26AUG2020	14/5	1	No	O	NA/TC	R (30AUG2020)	N/N	
16-55/ C4591001 1125 11251044	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	23/4	1	Yes		NA	R (11SEP2020)	N/N	
16-55/ C4591001 1125 11251053	BLOOD	Iron deficiency anaemia/ Iron deficiency anemia	2	03DEC2020	86/75	1	No	O	NA/TC	R (15FEB2021)	N/N	
16-55/ C4591001 1125 11251062	VASC	Deep vein thrombosis/ Deep vein thrombosis of left leg	2	03DEC2020	86/1	1	No	O	NA/TC	R (03DEC2020)	N/N	
16-55/ C4591001 1125 11251062	GENRL	Injection site pain/ INJECTION SITE PAIN	1	21AUG2020	1/1	1	Yes		NA	R (21AUG2020)	N/N	
	MUSC	Arthralgia/ JOINT PAIN	1	26AUG2020	6/2	1	Yes		NA	R (27AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1125 11251067	GENRL	Injection site pain/ injection site pain	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	24AUG2020	4/1	1	Yes		NA	R (24AUG2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	25AUG2020	5/1	2	Yes		NA	R (25AUG2020)	N/N
	MUSC	Arthralgia/ JOINT PAIN	1	25AUG2020	5/1	2	Yes		NA	R (25AUG2020)	N/N
		Myalgia/ MUSCLE PAIN	1	25AUG2020	5/1	2	Yes		NA	R (25AUG2020)	N/N
	NERV	Headache/ headache	1	04SEP2020	15/2	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1125 11251075	INFEC	Sinusitis/ Sinus infection	2	05OCT2020	22/16	1	No	O	NA/TC	R (20OCT2020)	N/N
	MUSC	Osteoarthritis/ generalized Osteoarthritis	2	FEB2021	141/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1125 11251087	INFEC	Upper respiratory tract infection/ upper respiratory infection	2	13OCT2020	30/8	1	No	O	NA	R (20OCT2020)	N/N
16-55/ C4591001 1125 11251091	GENRL	Injection site pain/ injection site pain	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1125 11251097	NERV	Headache/ headache	1	27AUG2020	3/1	1	Yes		NA	R (27AUG2020)	N/N	
	GENRL	Fatigue/ fatigue	1	28AUG2020	4/1	2	Yes		NA	R (28AUG2020)	N/N	
16-55/ C4591001 1125 11251098	INJ&P	Fall/ fall	2	08FEB2021	146/1	1	No	O	NA	R (08FEB2021)	N/N	
		Ligament rupture/ Ligament tear in right wrist	2	08FEB2021	146/1	1	No	O	NA	R (08FEB2021)	N/N	
16-55/ C4591001 1125 11251106	RESP	Oropharyngeal pain/ Sore throat	2	28SEP2020	15/1	1	No	O	NA	R (28SEP2020)	N/N	
16-55/ C4591001 1125 11251109	IMMUN	Seasonal allergy/ Acute exacerbation of seasonal allergies	2	18SEP2020	4/62	1	No	O	NA/TC	R (18NOV2020)	N/N	
	METAB	Insulin resistance/ Insulin Resistance#	3	21DEC2020	4/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1125 11251126	GENRL	Pain/ Body Aches	1	08SEP2020	12/8	1	Yes		NA	R (15SEP2020)	N/N	
16-55/ C4591001 1125 11251127	INFEC	Vulvovaginal candidiasis/ Vaginal Candidiasis#	3	04MAR2021	13/8	1	No	O	NA/TC	R (11MAR2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1125 11251131	GASTR	Gastroesophageal reflux disease/ Acid Reflux#	3	28JAN2021	7/C	1	No	O	NA/TC	RG	N/N	
	PSYCH	Anxiety/ Anxiety#	3	28JAN2021	7/C	2	No	O	NA/TC	RG	N/N	
	VASC	Hypertension/ Hypertension#	3	05FEB2021	15/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1125 11251134	PSYCH	Attention deficit hyperactivity disorder/ Attention Deficit Hyperactivity disorder#	2	23FEB2021	156/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1125 11251144	INFEC	Urinary tract infection/ Urinary tract infection	1	23SEP2020	22/5	1	No	O	NA/TC	R (27SEP2020)	N/N	
16-55/ C4591001 1125 11251174	METAB	Hypocholesterolaemia/ Hypocholesterolemia	2	28SEP2020	6/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1125 11251180	GENRL	Fatigue/ fatigue	2	25SEP2020	1/5	1	Yes		NA	R (29SEP2020)	N/N	
		Pain/ bodyaches	2	25SEP2020	1/5	1	Yes		NA	R (29SEP2020)	N/N	
		Pyrexia/ Fever	2	25SEP2020	1/5	1	Yes		NA	R (29SEP2020)	N/N	
16-55/ C4591001	REPRO	Ovarian cyst/ Right Ovarian Cyst	2	22OCT2020	24/C	2	No	O	NA	RG	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1125 11251181	GASTR	Appendix disorder/ Appendicoliths	2	27OCT2020	29/93	2	No	O	NA	R (27JAN2021)	N/N	
16-55/ C4591001 1125 11251182	GENRL	Injection site pain/ Injection Site Pain	2	06OCT2020	8/2	1	Yes		NA	R (07OCT2020)	N/N	
16-55/ C4591001 1125 11251183	GENRL	Pain/ bodyaches	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N	
16-55/ C4591001 1125 11251193	GENRL	Injection site pain/ injection site pain	2	01OCT2020	4/1	1	Yes		NA	R (01OCT2020)	N/N	
16-55/ C4591001 1125 11251201	RESP	Nasal congestion/ Stuffy nose	2	15OCT2020	14/4	1	No	O	NA	R (18OCT2020)	N/N	
16-55/ C4591001 1125 11251202	GASTR	Oropharyngeal pain/ Sore throat	2	15OCT2020	14/3	1	No	O	NA	R (17OCT2020)	N/N	
16-55/ C4591001 1125 11251207	GASTR	Peptic ulcer/ Peptic Ulcer	1	20SEP2020	11/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1125 11251207	GENRL	Injection site pain/ Injection Site pain	1	14SEP2020	5/2	1	Yes		NA	R (15SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1125 11251212	NERV	Syncope/ syncopal episode during vasovagal response during venous puncture	2	03NOV2020	35/1	1	No	O	NA	R (03NOV2020)	N/N	
16-55/ C4591001 1125 11251219	PSYCH	Depression/ Worsening of Depression	2	26OCT2020	13/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1125 11251243	GENRL	Injection site pain/ Grade 3 Pain at Injection site	1	09DEC2020	2/1	3	Yes		P	R (09DEC2020)	N/N	
	NERV	Headache/ Grade 3 Headache	1	09DEC2020	2/1	3	Yes		P/TC	R (09DEC2020)	N/N	
16-55/ C4591001 1126 11261005	INFEC	Herpes zoster/ Shingles	2	11NOV2020	73/11	1	No	O	NA/TC	R (21NOV2020)	N/N	
	GENRL	Fatigue/ Fatigue#	3	04JAN2021	1/2	1	Yes		NA/TC	R (05JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	05JAN2021	2/5	1	Yes		NA	R (09JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	26JAN2021	2/7	2	Yes		NA/TC	R (01FEB2021)	N/N	
		Injection site pain/ Injection site pain#	4	26JAN2021	2/7	1	Yes		NA/TC	R (01FEB2021)	N/N	
	NERV	Disturbance in attention/ Mental concentration difficulty#	4	26JAN2021	2/7	1	Yes		NA/TC	R (01FEB2021)	N/N	
		Dizziness/ Dizziness#	4	26JAN2021	2/7	1	Yes		NA/TC	R (01FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261006	INFEC	Dizziness/ Light headed#	4	26JAN2021	2/7	1	Yes		NA/TC	R (01FEB2021)	N/N
		Otitis media/ Left otitis media	1	16AUG2020	6/12	1	No	O	NA/TC	R (27AUG2020)	N/N
	GENRL	Injection site pain/ Pain, injection site#	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	03FEB2021	1/4	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1126 11261012	GENRL	Malaise/ Malaise#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Pain, injection site#	3	11JAN2021	1/2	2	Yes		NA	R (12JAN2021)	N/N
	NERV	Dizziness/ Dizziness#	3	11JAN2021	1/1	1	Yes		NA	R (11JAN2021)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	4	02FEB2021	1/3	2	Yes		NA	R (04FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	NERV	Headache/ Headache#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	INFEC	Sinusitis/ Sinus Infection#	4	26FEB2021	25/5	2	No	O	NA/TC	R (02MAR2021)	N/N
16-55/ C4591001 1126 11261013	GENRL	Injection site pain/ Injection site pain#	3	29DEC2020	2/2	1	Yes		NA	R (30DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261014	GENRL	Fatigue/ Fatigue#	4	19JAN2021	1/2	2	Yes		NA	R (20JAN2021)	N/N
		Pyrexia/ Fever#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Pain/ Body aches#	4	20JAN2021	2/1	2	Yes		NA	R (20JAN2021)	N/N
	NERV	Paraesthesia/ Generalized Body Tingling	1	12AUG2020	1/1	1	No	O	NA	R (12AUG2020)	N/N
16-55/ C4591001 1126 11261017	SKIN	Urticaria/ Hives	1	12AUG2020	1/1	1	No	O	NA	R (12AUG2020)	N/N
	INFEC	Vulvovaginal candidiasis/ Candida of vagina	2	03SEP2020	2/4	1	No	O	NA/TC	R (06SEP2020)	N/N
	INFEC	Acute sinusitis/ Acute sinusitis	1	15AUG2020	3/6	1	No	O	NA/TC	R (20AUG2020)	N/N
	GASTR	Nausea/ Nausea#	3	07JAN2021	1/1	1	Yes		NA/TC/TCN	R (07JAN2021)	N/N
	GENRL	Swelling face/ Facial swelling#	3	07JAN2021	1/2	2	Yes		NA/TC/TCN	R (08JAN2021)	N/Y
	IMMUN	Allergy to vaccine/ VACCINE ALLERGIC REACTION#	3	07JAN2021	1/2	2	Yes		P/TC/TCN	R (08JAN2021)	N/Y
	SKIN	Urticaria/ Hives, abdomen#	3	07JAN2021	1/2	1	Yes		NA/TC/TCN	R (08JAN2021)	N/N
	VASC	Flushing/ Facial Flushing#	3	07JAN2021	1/2	2	Yes		NA/TC/TCN	R (08JAN2021)	N/Y
	MUSC	Myalgia/ Muscle aches#	3	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1126 11261018	INFEC	Diverticulitis/ Diverticulitis	1	28AUG2020	16/4	1	No	O	NA	R (31AUG2020)	N/N	
	GENRL	Injection site pain/ Left upper arm injection site pain#	3	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N	
16-55/ C4591001 1126 11261022	GENRL	Injection site pain/ Left upper arm injection site pain#	3	01FEB2021	1/3	2	Yes		NA	R (03FEB2021)	N/N	
16-55/ C4591001 1126 11261024	GENRL	Chills/ Chills#	3	30DEC2020	2/3	1	Yes		NA/TC	R (01JAN2021)	N/N	
		Injection site pain/ Injection site pain#	3	30DEC2020	2/3	2	Yes		NA/TC	R (01JAN2021)	N/N	
		Pyrexia/ Fever, 100.4F#	3	30DEC2020	2/3	1	Yes		NA/TC	R (01JAN2021)	N/N	
	GASTR	Dry mouth/ Dry mouth#	4	19JAN2021	1/1	1	Yes		NA	R (19JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	19JAN2021	1/3	2	Yes		NA	R (21JAN2021)	N/N	
		Injection site pain/ Pain, injection site#	4	19JAN2021	1/4	1	Yes		NA/TC	R (22JAN2021)	N/N	
	NERV	Headache/ Headache#	4	19JAN2021	1/2	1	Yes		NA/TC	R (20JAN2021)	N/N	
		Paraesthesia/ Facial tingling#	4	19JAN2021	1/1	1	Yes		NA	R (19JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Body Chills#	4	21JAN2021	3/1	2	Yes		NA	R (21JAN2021)	N/N
		Pyrexia/ Fever#	4	21JAN2021	3/1	1	Yes		NA/TC	R (21JAN2021)	N/N
16-55/ C4591001 1126 11261028	INV	Blood thyroid stimulating hormone increased/ Elevated Thyroid Stimulating Hormone, 5.0 UIU/ML	2	02OCT2020	29/155	1	No	O	NA	R (05MAR2021)	N/N
		SARS-CoV-2 antibody test positive/ SARS-COV2-IGG, QL, IA Positive	2	02OCT2020	29/1	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1126 11261029	GENRL	Injection site pain/ Pain, Injection site	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		Pain/ Bodyaches	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ Headache	1	09SEP2020	24/2	2	Yes		NA	R (10SEP2020)	N/N
	GENRL	Non-cardiac chest pain/ Chest Pain, non-cardiac	2	28SEP2020	20/6	2	No	O	NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1126 11261030	GENRL	Injection site pain/ Left Arm Injection Site Pain#	3	23DEC2020	2/3	1	Yes		NA	R (25DEC2020)	N/N
16-55/ C4591001 1126 11261033	GENRL	Injection site pain/ Pain, injection site#	3	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Malaise/ Malaise#	4	16FEB2021	1/1	2	Yes		NA	R (16FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1126 11261034	NERV	Headache/ Headache#	4	16FEB2021	1/1	1	Yes		NA	R (16FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N	
	MUSC	Myalgia/ Muscle Aches	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N	
		Pain in extremity/ Left upper arm pain	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N	
	GENRL	Chills/ Body Chills	2	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N	
		Fatigue/ Fatigue	2	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N	
	MUSC	Myalgia/ Muscle Pain	2	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N	
	16-55/ C4591001 1126 11261035	INJ&P	Ligament sprain/ Left ankle sprain	2	08NOV2020	61/13	1	No	O	NA	R (20NOV2020)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	3	29DEC2020	1/3	1	Yes		NA	R (31DEC2020)	N/Y	
	GENRL	Chills/ Chills#	4	19JAN2021	1/1	1	Yes		NA	R (19JAN2021)	N/N	
	Injection site pain/ Left upper arm injection site pain#	4	19JAN2021	1/4	2	Yes		NA	R (22JAN2021)	N/N		
	MUSC	Myalgia/ Muscle aches#	4	20JAN2021	2/1	2	Yes		NA	R (20JAN2021)	N/N	
16-55/ C4591001	GASTR	Nausea/ Nausea#	3	29DEC2020	1/4	1	Yes		NA	R (01JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1126 11261037	MUSC	Myalgia/ Generalized Muscle aches#	3	29DEC2020	1/4	2	Yes		NA/TC	R (01JAN2021)	N/N	
	NERV	Headache/ Headache#	3	29DEC2020	1/4	2	Yes		NA/TC	R (01JAN2021)	N/N	
	GENRL	Injection site pain/ Pain, injection site#	4	19JAN2021	1/3	2	Yes		NA/TC	R (21JAN2021)	N/N	
		Injection site swelling/ Swelling, injection site#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N	
		Pain/ Body Aches#	4	19JAN2021	1/3	2	Yes		NA/TC	R (21JAN2021)	N/N	
	METAB	Decreased appetite/ Decreased appetite#	4	19JAN2021	1/3	2	Yes		NA	R (21JAN2021)	N/N	
	NERV	Headache/ Headache#	4	19JAN2021	1/3	2	Yes		NA/TC	R (21JAN2021)	N/N	
	GENRL	Chills/ Body Chills#	4	20JAN2021	2/2	2	Yes		NA	R (21JAN2021)	N/N	
		Pyrexia/ Fever#	4	20JAN2021	2/1	1	Yes		NA/TC	R (20JAN2021)	N/N	
16-55/ C4591001 1126 11261040	GENRL	Pain/ Body aches#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N	
16-55/ C4591001 1126 11261041	INFEC	Cellulitis/ Cellulitis, Right Thumb	2	10SEP2020	2/11	2	No	O	NA/TC	R (20SEP2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	2/4	2	Yes		NA	R (13SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1126 11261043	HEPAT	Cholelithiasis/ Cholelithiasis	1	30AUG2020	12/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1126 11261044	MUSC	Arthralgia/ Shoulder pain, Right	1	30AUG2020	12/1	2	No	O	NA/TC	R (30AUG2020)	N/N
16-55/ C4591001 1126 11261046	GENRL	Injection site pain/ Injection site pain#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1126 11261047	GENRL	Injection site pain/ Pain, injection site#	4	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1126 11261048	GENRL	Injection site pain/ Pain, injection site#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1126 11261048	GENRL	Injection site pain/ Left arm injection site pain#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1126 11261048	INFEC	Vulvovaginal candidiasis/ Candida of vagina	1	08SEP2020	20/31	1	No	O	NA	R (08OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	10SEP2020	2/3	2	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001	GENRL	Pain/ Body aches	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001	EAR	Cerumen impaction/ Bilateral Cerumen Impaction	1	07SEP2020	19/2	1	No	O	NA	R (08SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1126 11261053 16-55/ C4591001 1126 11261055	INJ&P	Fall/ Mechanical Fall	2	29SEP2020	20/1	2	No	O	NA	R (29SEP2020)	N/N
	MUSC	Musculoskeletal chest pain/ Chest wall pain, left	2	29SEP2020	20/25	2	No	O	NA	R (23OCT2020)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	3	28DEC2020	1/2	1	Yes		NA	R (29DEC2020)	N/N
	GENRL	Injection site pain/ Pain, injection site#	4	18JAN2021	1/3	2	Yes		NA/TC	R (20JAN2021)	N/N
	NERV	Headache/ Headache#	4	18JAN2021	1/3	1	Yes		NA/TC	R (20JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	19JAN2021	2/2	2	Yes		NA	R (20JAN2021)	N/N
	GENRL	Chills/ Body chills#	4	19JAN2021	2/2	2	Yes		NA	R (20JAN2021)	N/N
	GENRL	Pain/ Body Aches#	4	19JAN2021	2/2	2	Yes		NA/TC	R (20JAN2021)	N/N
16-55/ C4591001 1126 11261056	GENRL	Injection site pain/ Pain, injection site	1	21AUG2020	1/2	2	Yes		NA	R (22AUG2020)	N/N
16-55/ C4591001 1126 11261060	GENRL	Injection site pain/ Injection site pain#	3	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	4	25JAN2021	1/3	2	Yes		NA	R (27JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261061	MUSC	Pain in extremity/ Left upper arm pain	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N
	MUSC	Pain in extremity/ Left upper arm pain	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11SEP2020	2/1	2	Yes		NA	R (11SEP2020)	N/N
		Malaise/ Malaise	2	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1126 11261062	REPRO	Pelvic pain/ Pelvic pain	1	25AUG2020	5/4	2	No	O	NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ Headache	2	11SEP2020	2/2	2	Yes		NA/TC	R (12SEP2020)	N/N
	ENDO	Hypothyroidism/ Hypothyroidism	2	12SEP2020	3/C	2	No	O	NA	N	N/N
	INV	C-reactive protein/ C-reactive protein, 1.6mg/dl	2	12SEP2020	3/C	2	No	O	NA	N	N/N
	RESP	Sleep apnoea syndrome/ Sleep Apnea	2	14OCT2020	35/C	2	No	O	NA/TCN	N	N/N
16-55/ C4591001 1126 11261063	GENRL	Injection site pain/ Left arm injection site pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1126 11261064	MUSC	Pain in extremity/ Left upper arm pain	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ Headache	2	14SEP2020	1/2	2	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1126 11261068	PSYCH	Stress/ Stress	2	17SEP2020	3/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ Left Upper Arm Injection Site Pain#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/3	2	Yes		NA	R (20FEB2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	18FEB2021	2/3	2	Yes		NA	R (20FEB2021)	N/N
	INFEC	Urinary tract infection/ Urinary Tract Infection#	4	07MAR2021	19/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1126 11261075	GENRL	Injection site pain/ Left upper arm injection site pain#	3	01FEB2021	1/3	2	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1126 11261076	GENRL	Chills/ Chills	2	17SEP2020	2/3	2	Yes		NA/TC	R (19SEP2020)	N/N
		Fatigue/ Fatigue	2	17SEP2020	2/3	2	Yes		NA/TC	R (19SEP2020)	N/N
		Injection site pain/ Left upper arm injection site pain	2	17SEP2020	2/3	2	Yes		NA/TC	R (19SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Muscle aches	2	17SEP2020	2/3	2	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1126 11261078	MUSC	Pain in extremity/ Left upper arm pain	2	14SEP2020	1/3	2	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1126 11261081	GENRL	Injection site pain/ Left Arm Injection Site Pain#	3	30DEC2020	1/4	1	Yes		NA/TC	R (02JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	31DEC2020	2/1	1	Yes		NA	R (31DEC2020)	N/N
		Injection site pain/ Injection site pain#	3	31DEC2020	2/4	2	Yes		NA	R (03JAN2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	3	31DEC2020	2/2	1	Yes		NA/TC	R (01JAN2021)	N/N
16-55/ C4591001 1126 11261082	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	SKIN	Urticaria/ Urticaria all over body#	2	28FEB2021	166/5	2	No	O	NA/TC	R (04MAR2021)	N/N
16-55/ C4591001 1126 11261083	GENRL	Pain/ Body aches	2	17SEP2020	1/3	2	Yes		NA/TC	R (19SEP2020)	N/N
		Pyrexia/ Fever, 101.2F	2	17SEP2020	1/2	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	27AUG2020	1/4	1	Yes		NA	R (30AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1126 11261085	MUSC	Pain in extremity/ Upper right arm pain	1	27AUG2020	1/4	1	Yes		NA/TC	R (30AUG2020)	N/N
	NERV	Headache/ Headache	1	27AUG2020	1/2	1	Yes		NA/TC	R (28AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	16SEP2020	2/4	2	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	16SEP2020	2/4	1	Yes		NA/TC	R (19SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	2/4	2	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1126 11261086	GENRL	Injection site pain/ Pain, Injection site#	4	18JAN2021	1/3	2	Yes		NA/TC	R (20JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1126 11261092	GENRL	Injection site pain/ Pain, injection site#	3	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
	NERV	Somnolence/ Drowsiness#	3	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1126 11261093	MUSC	Pain in extremity/ Left upper arm pain	1	28AUG2020	1/4	1	Yes		NA/TC	R (31AUG2020)	N/N
	MUSC	Myalgia/ Muscle aches	1	29AUG2020	2/3	1	Yes		NA/TC	R (31AUG2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261099	GENRL	Injection site pain/ Injection site pain	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
		Malaise/ Malaise	2	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
		Pain/ Body aches	2	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ Headache	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
	INJ&P	Muscle strain/ LUMBAR MUSCLE STRAIN	2	07DEC2020	81/9	1	No	O	NA/TC	R (15DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	23DEC2020	1/3	1	Yes		NA/TC	R (25DEC2020)	N/N
		Pyrexia/ Fever, 100.3F#	3	23DEC2020	1/3	1	Yes		NA/TC	R (25DEC2020)	N/N
	GENRL	Chills/ Chills#	4	11JAN2021	1/2	2	Yes		NA/TC	R (12JAN2021)	N/N
		Pyrexia/ Fever#	4	11JAN2021	1/3	2	Yes		NA/TC	R (13JAN2021)	N/N
	MUSC	Myalgia/ Muscle aches#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N
NERV	Headache/ Headache#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N	
GENRL	Fatigue/ Fatigue#	4	12JAN2021	2/1	2	Yes		NA	R (12JAN2021)	N/N	
GASTR	Diarrhoea/ Diarrhea#	4	13JAN2021	3/1	2	Yes		NA/TC	R (13JAN2021)	N/N	
16-55/ C4591001	GENRL	Pain/ Body Aches	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1126 11261101	GENRL	Injection site pain/ Pain, injection site	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
1126 11261103	GENRL	Chills/ Chills	2	22SEP2020	2/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		Pain/ Body Aches	2	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1126 11261104	GENRL	Injection site pain/ Injection site pain#	3	30DEC2020	2/2	1	Yes		NA	R (31DEC2020)	N/N
	NERV	Headache/ Headache#	4	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
	INFEC	Conjunctivitis/ Left conjunctivitis#	4	22JAN2021	4/2	1	No	O	NA	R (23JAN2021)	N/N
16-55/ C4591001 1126 11261105	GENRL	Chills/ Chills#	3	07JAN2021	1/2	2	Yes		NA	R (08JAN2021)	N/N
		Fatigue/ Fatigue#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	2/4	1	Yes		NA/TC	R (25SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1126 11261109		Pain/ Body Aches	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N	
16-55/ C4591001 1126 11261111	INFEC	Urinary tract infection/ Urinary tract infection	2	18OCT2020	28/7	2	No	O	NA/TC	R (24OCT2020)	N/N	
	EAR	Vertigo/ Vertigo	2	13NOV2020	54/3	1	No	O	NA/TCN	R (15NOV2020)	N/N	
	INFEC	Herpes simplex/ Worsening Herpes Simples	2	25NOV2020	66/8	2	No	O	NA/TC	R (02DEC2020)	N/N	
	MUSC	Pain in jaw/ Mandibular pain	2	25NOV2020	66/8	1	No	O	NA/TCN	R (02DEC2020)	N/N	
	INFEC	Urinary tract infection/ Urinary Tract Infection	2	26NOV2020	67/6	2	No	O	NA/TC	R (01DEC2020)	N/N	
	INFEC	Urinary tract infection/ Urinary tract infection#	3	03JAN2021	5/9	1	No	O	NA/TC	R (11JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N	
16-55/ C4591001 1126 11261113	GENRL	Injection site pain/ Left upper arm injection site pain#	3	29DEC2020	1/3	1	Yes		NA	R (31DEC2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N	
16-55/ C4591001 1126 11261114	GENRL	Chills/ Chills, generalized#	4	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261116	INJ&P	Pyrexia/ Fever, 100.4F#	4	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
		Ligament sprain/ Left wrist sprain#	4	03FEB2021	17/C	2	No	O	NA/TC/TCN	N	N/N
	NERV	Headache/ Headache	1	01SEP2020	1/1	1	Yes		NA	R (01SEP2020)	N/N
	MUSC	Arthralgia/ Right shoulder joint pain	2	07JAN2021	108/C	1	No	O	NA/TC	N	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	3	25JAN2021	1/3	2	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	4	16FEB2021	1/3	2	Yes		NA	R (18FEB2021)	N/N
	MUSC	Myalgia/ Muscle aches#	4	16FEB2021	1/2	2	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1126 11261121	NERV	Headache/ Headache#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
	GENRL	Injection site pain/ Pain injection site	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ Pain, Injection site	2	21SEP2020	1/3	2	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/1	2	Yes		NA	R (22SEP2020)	N/N
	NERV	Pain/ Generalized Body Aches	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
Headache/ Headache		2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261122	GENRL	Fatigue/ Fatigue	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	MUSC	Pain in extremity/ Left upper arm pain	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
	EAR	Vertigo/ Vertigo	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		Nausea/ Nausea	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	24SEP2020	2/1	2	Yes		NA/TC	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1126 11261124	GENRL	Fatigue/ Fatigue	1	03SEP2020	2/3	2	Yes		NA	R (05SEP2020)	N/N
	MUSC	Pain in extremity/ Left upper arm pain	1	03SEP2020	2/5	2	Yes		NA/TC	R (07SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	23SEP2020	2/3	1	Yes		NA/TC	R (25SEP2020)	N/N
		Malaise/ Malaise	2	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N
	INFEC	Urinary tract infection/ Urinary tract infection	2	20OCT2020	29/4	1	No	O	NA/TC	R (23OCT2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1126 11261126		Injection site pain/ Injection site pain	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
		Pain/ Body Aches	2	25SEP2020	2/3	2	Yes		NA	R (27SEP2020)	N/N
	NERV	Dizziness/ Dizziness	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1126 11261128	GENRL	Fatigue/ Fatigue*		03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
		Malaise/ Malaise*		03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
	MUSC	Pain in extremity/ Left upper arm pain*		03SEP2020	1/3	2	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	25SEP2020	2/3	2	Yes		NA/TC	R (27SEP2020)	N/N
	NERV	Headache/ Headache#	4	10FEB2021	2/1	1	Yes		NA/TC	R (10FEB2021)	N/N
16-55/ C4591001 1126 11261131	GENRL	Injection site pain/ Pain Injection Site#	3	25JAN2021	1/2	2	Yes		NA	R (26JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	26JAN2021	2/2	2	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Left Upper Arm Injection Site Pain#	4	17FEB2021	1/3	2	Yes		NA/TC	R (19FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/7	2	Yes		NA	R (24FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261134	MUSC	Myalgia/ Muscle Aches#	4	18FEB2021	2/4	2	Yes		NA/TC	R (21FEB2021)	N/N
	GENRL	Pain/ Body aches, generalized	1	04SEP2020	2/2	1	Yes		NA/TC	R (05SEP2020)	N/N
	GENRL	Pain/ Body aches (generalized)	2	24SEP2020	2/1	2	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1126 11261141	MUSC	Pain in extremity/ Right Foot Pain	1	14SEP2020	11/12	1	No	O	NA/TCN	R (25SEP2020)	N/N
	INJ&P	Limb injury/ Left shoulder injury	2	05NOV2020	42/27	1	No	O	NA	R (01DEC2020)	N/N
	GENRL	Injection site pain/ Injection site soreness#	3	29DEC2020	1/3	1	Yes		NA	R (31DEC2020)	N/N
		Injection site pain/ Left upper arm injection site pain#	3	29DEC2020	1/4	2	Yes		NA	R (01JAN2021)	N/N
	NERV	Headache/ Headache#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N
	NERV	Headache/ Headache#	4	18JAN2021	1/3	1	Yes		NA/TC	R (20JAN2021)	N/N
	GASTR	Abdominal pain/ Abdominal pain#	4	19JAN2021	2/4	2	Yes		NA/TC	R (22JAN2021)	N/N
		Nausea/ Nausea#	4	19JAN2021	2/4	3	Yes		NA/TC	R (22JAN2021)	N/N
		Vomiting/ Vomiting#	4	19JAN2021	2/4	3	Yes		NA/TC	R (22JAN2021)	N/N
	GENRL	Pain/ Body Aches#	4	19JAN2021	2/4	2	Yes		NA/TC	R (22JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261142	MUSC	Pyrexia/ Fever, 102F#	4	19JAN2021	2/1	2	Yes		NA/TC	R (19JAN2021)	N/N
		Muscle fatigue/ Muscle Fatigue#	4	19JAN2021	2/3	3	Yes		NA/TC	R (21JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1126 11261143	REPRO	Pyrexia/ Fever, 102.1F	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
		Pelvic pain/ Acute Female Pelvic Pain	2	17OCT2020	20/8	2	No	O	NA/TC	R (24OCT2020)	N/N
16-55/ C4591001 1126 11261144	GENRL	Injection site pain/ Injection site pain#	3	31DEC2020	2/3	1	Yes		NA	R (02JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	23JAN2021	2/3	1	Yes		NA	R (25JAN2021)	N/N
	MUSC	Arthralgia/ Joint Aches, Generalized#	4	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
	NERV	Disturbance in attention/ Mental concentration difficulty#	4	23JAN2021	2/3	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261148	GENRL	Injection site pain/ Left Arm Injection Site Pain#	3	22DEC2020	2/3	1	Yes		NA	R (24DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1126 11261149		Pain/ Body aches	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Pain, injection site#	3	30DEC2020	1/2	2	Yes		NA/TC	R (31DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1126 11261150	MUSC	Myalgia/ Muscle aches#	4	22JAN2021	2/3	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
		Injection site pain/ Injection site pain	1	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N
	EAR	Tinnitus/ Left Tinnitus	1	14SEP2020	6/6	1	No	O	NA	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ Injection site pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261151	NERV	Headache/ Headache	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	EYE	Conjunctivitis allergic/ Bilateral Allergic Conjunctivitis	1	11SEP2020	3/6	1	No	O	NA/TC	R (16SEP2020)	N/N
	MUSC	Pain in extremity/ Left upper arm pain	1	09SEP2020	1/3	2	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Chills/ Chills	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Malaise/ Malaise	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches	1	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	29SEP2020	2/3	2	Yes		NA/TC	R (01OCT2020)	N/N
		Injection site pain/ Injection site pain	2	29SEP2020	2/4	2	Yes		NA/TC	R (02OCT2020)	N/N
		Pain/ Body Aches	2	29SEP2020	2/3	2	Yes		NA/TC	R (01OCT2020)	N/N
		Pyrexia/ Fever	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1126 11261158	GENRL	Fatigue/ Fatigue	2	01OCT2020	1/1	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Chills/ Chills#	3	25JAN2021	1/2	2	Yes		NA	R (26JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Injection site pain/ Left upper arm injection site pain#	3	25JAN2021	1/2	2	Yes		NA/TC	R (26JAN2021)	N/N
		Malaise/ Malaise#	3	25JAN2021	1/3	2	Yes		NA	R (27JAN2021)	N/N
		Pyrexia/ Fever#	3	25JAN2021	1/2	1	Yes		NA/TC	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Left Upper Arm Injection Site Pain#	4	16FEB2021	1/3	2	Yes		NA	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
		Pyrexia/ Fever#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1126 11261161	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/3	2	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1126 11261166	GENRL	Injection site pain/ Pain, Injection Site	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Chills/ Chills	1	01OCT2020	21/2	2	Yes		NA/TC	R (02OCT2020)	N/N
		Fatigue/ Fatigue	1	01OCT2020	21/2	2	Yes		NA/TC	R (02OCT2020)	N/N
		Injection site pain/ Injection site pain	1	01OCT2020	21/4	1	Yes		NA/TC	R (04OCT2020)	N/N
		Injection site pain/ Pain, Injection site	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Pain/ Body aches	1	01OCT2020	21/2	2	Yes		NA/TC	R (02OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261170	GENRL	Injection site pain/ Left upper arm injection site pain#	3	30DEC2020	1/4	2	Yes		NA	R (02JAN2021)	N/N
	GENRL	Injection site pain/ Pain, injection site#	4	22JAN2021	1/3	1	Yes		NA/TC	R (24JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
		Pain/ Body Aches#	4	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
	INFEC	Urinary tract infection/ Urinary tract infection#	4	03FEB2021	13/4	1	No	O	NA/TC	R (06FEB2021)	N/N
	INJ&P	Fall/ Fall#	4	16FEB2021	26/1	1	No	O	NA	R (16FEB2021)	N/N
16-55/ C4591001 1126 11261171		Head injury/ Head Trauma#	4	16FEB2021	26/C	1	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ Pain, injection site	1	11SEP2020	1/2	3	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Headache/ Headache	1	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Chills/ Body Chills	1	12SEP2020	2/1	2	Yes		NA	R (12SEP2020)	N/N
		Pyrexia/ Fever	1	12SEP2020	2/1	2	Yes		NA	R (12SEP2020)	N/N
	MUSC	Neck pain/ Neck Pain	1	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N
GENRL	Pain/ Body aches	2	30SEP2020	1/3	2	Yes		NA/TC	R (02OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261172	NERV	Pyrexia/ Fever	2	30SEP2020	1/3	2	Yes		NA/TC	R (02OCT2020)	N/N
		Headache/ Headache	2	30SEP2020	1/3	2	Yes		NA/TC	R (02OCT2020)	N/N
	GENRL	Injection site pain/ Pain, injection site	1	11SEP2020	1/2	2	Yes		NA	R (12SEP2020)	N/N
	GENRL	Malaise/ Malaise	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1126 11261173	GENRL	Pyrexia/ Fever, 101.6F	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
		Injection site pain/ Injection site pain	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
MUSC	GENRL	Injection site pain/ Injection site pain	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
		Arthralgia/ Joint Pain, Generalized	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
	GENRL	Myalgia/ Muscle Pain, Generalized	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
NERV	Headache/ Headache	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N	
GENRL	Pyrexia/ Fever, 100F	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261177	GENRL	Fatigue/ Fatigue#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	30JAN2021	2/6	2	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ Fever#	4	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
	MUSC	Arthralgia/ left side upper extremity joint pain#	4	30JAN2021	2/6	2	Yes		NA	R (04FEB2021)	N/N
		Joint swelling/ Left upper extremity joint swelling#	4	30JAN2021	2/6	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	4	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
16-55/ C4591001 1126 11261178	MUSC	Pain in extremity/ Left upper arm pain	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1126 11261182	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	08OCT2020	2/3	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1126 11261183	NERV	Headache/ Headache	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261184	GENRL	Injection site pain/ Left upper arm injection site pain#	3	28DEC2020	1/4	2	Yes		NA	R (31DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	19JAN2021	1/2	2	Yes		NA	R (20JAN2021)	N/N
		Injection site pain/ Left Upper Arm Injection Site Pain#	4	19JAN2021	1/2	2	Yes		NA/TC	R (20JAN2021)	N/N
	GENRL	Chills/ Chills#	4	20JAN2021	2/1	2	Yes		NA	R (20JAN2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	20JAN2021	2/1	1	Yes		NA/TC	R (20JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	31DEC2020	2/2	1	Yes		NA	R (01JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	1	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
	NERV	Dizziness/ Dizzy Spell	1	21SEP2020	5/1	2	No	O	NA	R (21SEP2020)	N/N
16-55/ C4591001 1126 11261185	GENRL	Fatigue/ Fatigue	2	09OCT2020	2/4	1	Yes		NA	R (12OCT2020)	N/N
		Injection site pain/ Injection site pain	2	09OCT2020	2/5	1	Yes		NA/TC	R (13OCT2020)	N/N
		Pain/ Body aches	2	09OCT2020	2/4	1	Yes		NA	R (12OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Chills/ Chills#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N	
		Injection site pain/ Left upper arm injection site pain#	3	27JAN2021	2/2	2	Yes		NA/TC	R (28JAN2021)	N/N	
		Pyrexia/ Fever#	3	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N	
	GENRL	Injection site pain/ Left Upper Arm Injection Site Pain#	4	16FEB2021	1/4	2	Yes		NA	R (19FEB2021)	N/N	
	GENRL	Chills/ Chills#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N	
		Pyrexia/ Fever#	4	17FEB2021	2/1	2	Yes		NA	R (17FEB2021)	N/N	
	NERV	Headache/ Headache#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N	
16-55/ C4591001 1126 11261186	GENRL	Injection site pain/ Pain, injection site	1	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N	
16-55/ C4591001 1126 11261187	GENRL	Fatigue/ Fatigue	1	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N	
		Injection site pain/ Pain, Injection site	1	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N	
		Pain/ Body aches	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001 1126 11261189	INJ&P	Splinter/ Foreign body (splinter) in left hand#	2	24JAN2021	108/3	1	No	O	NA/TC/TCN	R (26JAN2021)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261190	GENRL	Fatigue/ Fatigue#	3	28JAN2021	1/4	2	Yes		NA	R (31JAN2021)	N/N
		Injection site pain/ Pain, Injection Site#	3	28JAN2021	1/4	2	Yes		NA	R (31JAN2021)	N/N
	INFEC	Vulvovaginal candidiasis/ Candida of Vagina#	3	06FEB2021	10/5	1	No	O	NA/TC	R (10FEB2021)	N/N
	INJ&P	Frostbite/ Frostbite, Toes#	3	06FEB2021	10/8	1	No	O	NA	R (13FEB2021)	N/N
	GENRL	Injection site pain/ Left Upper Arm Injection Site Pain#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	29JAN2021	1/1	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
		Injection site pain/ Pain, injection site#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	NERV	Headache/ Headache#	3	29JAN2021	1/1	1	Yes		NA/TC	R (29JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1126 11261192	MUSC	Myalgia/ Muscle Aches#	4	12JAN2021	1/2	2	Yes		NA/TC	R (13JAN2021)	N/N
	NERV	Headache/ Headache#	4	12JAN2021	1/1	2	Yes		NA/TC	R (12JAN2021)	N/N
	GENRL	Chills/ Chills#	4	13JAN2021	2/1	2	Yes		NA	R (13JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261193	GENRL	Injection site pain/ Pain, Injection site	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
	NERV	Headache/ Headache	2	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1126 11261194	NERV	Headache/ Headache	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Pain, Injection site	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
	EAR	Vertigo/ Vertigo	2	06NOV2020	29/15	1	No	O	NA	R (20NOV2020)	N/N
	NERV	Headache/ Headache#	3	29JAN2021	1/2	1	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Pain, injection site#	3	30JAN2021	2/2	2	Yes		NA/TC	R (31JAN2021)	N/N
	GENRL	Injection site pain/ Pain, injection site#	4	19FEB2021	1/3	2	Yes		NA/TC	R (21FEB2021)	N/N
	NERV	Headache/ Headache#	4	19FEB2021	1/3	2	Yes		NA/TC	R (21FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	20FEB2021	2/1	2	Yes		NA	R (20FEB2021)	N/N
	MUSC	Myalgia/ Generalized muscle aches#	4	20FEB2021	2/2	2	Yes		NA/TC	R (21FEB2021)	N/N
	PSYCH	Insomnia/ Insomnia#	4	05MAR2021	15/C	1	No	O	NA	N	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain, injection site#	3	28JAN2021	1/4	2	Yes		NA/TC	R (31JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1126 11261195	NERV	Headache/ Headache#	3	29JAN2021	2/1	1	Yes		NA/TC	R (29JAN2021)	N/N	
	SKIN	Skin ulcer/ Ulcer of left lower leg#	3	13FEB2021	17/C	1	No	O	NA/TC/TCN	RG	N/N	
	GASTR	Abdominal pain upper/ Stomach cramps#	4	19FEB2021	1/4	2	Yes		NA	R (22FEB2021)	N/N	
		Diarrhoea/ Diarrhea#	4	19FEB2021	1/4	1	Yes		NA	R (22FEB2021)	N/N	
		Nausea/ Nausea#	4	19FEB2021	1/4	1	Yes		NA	R (22FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	19FEB2021	1/4	2	Yes		NA	R (22FEB2021)	N/N	
		Injection site warmth/ Injection site warmth#	4	19FEB2021	1/4	1	Yes		NA	R (22FEB2021)	N/N	
16-55/ C4591001 1126 11261196	MUSC	Myalgia/ Muscle Aches	2	13OCT2020	2/2	2	Yes		NA	R (14OCT2020)	N/N	
16-55/ C4591001 1126 11261197	GENRL	Chills/ Chills	1	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N	
		Malaise/ Malaise	1	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N	
	MUSC	Myalgia/ Muscle aches	1	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N	
		Pain in extremity/ Left upper arm pain	1	21SEP2020	1/3	2	Yes		NA/TC	R (23SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	1	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		Injection site pain/ Left injection site arm pain	2	12OCT2020	1/3	1	Yes		NA/TC	R (14OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	12OCT2020	1/2	2	Yes		NA/TC	R (13OCT2020)	N/N
	NERV	Headache/ Headache	2	12OCT2020	1/2	2	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 1126 11261198	GENRL	Injection site pain/ Left upper arm injection site pain#	3	29DEC2020	1/3	2	Yes		NA/TC	R (31DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	19JAN2021	1/2	1	Yes		NA/TC	R (20JAN2021)	N/N
16-55/ C4591001 1126 11261199	GENRL	Fatigue/ Fatigue	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		Injection site pain/ Pain, Injection site	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		Pyrexia/ Fever	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N
	NERV	Headache/ Headache	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1126 11261200	GENRL	Injection site pain/ Injection Site Pain	1	30OCT2020	2/3	2	Yes		NA	R (01NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261201	GENRL	Injection site pain/ Injection Site Pain	1	30OCT2020	1/8	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	18NOV2020	1/2	2	Yes		NA	R (19NOV2020)	N/N
		Injection site pain/ PAIN, INJECTION SITE	2	18NOV2020	1/3	2	Yes		NA	R (20NOV2020)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1126 11261202	GENRL	Injection site pain/ Injection site pain	1	31OCT2020	2/2	2	Yes		NA	R (01NOV2020)	N/N
16-55/ C4591001 1126 11261203	GENRL	Injection site pain/ Left upper arm injection site pain#	3	05FEB2021	1/3	2	Yes		NA/TC	R (07FEB2021)	N/N
	GASTR	Nausea/ Nausea#	3	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Chills/ Chills#	3	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1126 11261204	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/4	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1126 11261205	METAB	Decreased appetite/ Decreased appetite	1	23NOV2020	13/C	1	No	O	NA	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	PSYCH	Depressed mood/ Depressed mood	1	23NOV2020	13/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1126 11261206	GENRL	Injection site pain/ Pain, injection site#	3	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N	
16-55/ C4591001 1126 11261207	GENRL	Injection site pain/ Pain Injection Site#	3	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N	
16-55/ C4591001 1126 11261210	GENRL	Injection site pain/ Left upper arm injection site pain#	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N	
16-55/ C4591001 1126 11261211	GENRL	Chills/ Chills#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	
		Injection site pain/ Injection site pain#	3	08FEB2021	1/2	2	Yes		NA	R (09FEB2021)	N/N	
	NERV	Headache/ Headache#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	
16-55/ C4591001 1126 11261214	GENRL	Chills/ Chills#	3	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N	
		Injection site pain/ Injection site pain#	3	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N	
		Malaise/ Malaise#	3	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261215	GENRL	Injection site pain/ Left arm injection site pain#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1126 11261220	GENRL	Injection site pain/ Left upper arm injection site pain#	3	17FEB2021	1/4	2	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	3	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	3	18FEB2021	2/1	2	Yes		NA	R (18FEB2021)	N/N
		Pyrexia/ Fever#	3	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1126 11261223	GENRL	Injection site pain/ Injection site pain#	3	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1126 11261224	GENRL	Malaise/ Malaise#	3	12FEB2021	2/2	2	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1126 11261228	GENRL	Injection site pain/ Injection Site Pain#	3	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
	NERV	Headache/ Headache#	3	12FEB2021	1/3	2	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	05FEB2021	1/4	2	Yes		NA	R (08FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1126 11261236		Injection site pain/ Pain, injection site#	3	05FEB2021	1/3	2	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1126 11261237	GENRL	Injection site pain/ Injection Site Pain#	3	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1126 11261238	GENRL	Injection site pain/ Injection site pain#	3	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1126 11261244	BLOOD	Lymphadenopathy/ Lymph node swelling left armpit#	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	3	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Chills/ Chills#	3	25FEB2021	2/1	2	Yes		NA	R (25FEB2021)	N/N
		Pyrexia/ Fever#	3	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1126 11261247	GENRL	Injection site pain/ Left upper arm injection site pain#	3	11FEB2021	1/3	2	Yes		NA/TC	R (13FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Left upper arm injection site pain#	3	11FEB2021	1/3	1	Yes		NA/TC	R (13FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1126 11261248	MUSC	Myalgia/ Muscle aches, generalized#	3	12FEB2021	2/2	2	Yes		NA/TC	R (13FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	3	13FEB2021	3/1	2	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001	GASTR	Irritable bowel syndrome/ Worsening irritable bowel syndrome#	2	14FEB2021	55/C	2	No	O	NA/TC/TCN	N	N/N
1126 11261259	GENRL	Chills/ Chills#	3	12FEB2021	2/1	2	Yes		NA	R (12FEB2021)	N/N
1126 11261260		Fatigue/ Fatigue#	3	12FEB2021	2/2	2	Yes		NA	R (13FEB2021)	N/N
	MUSC	Myalgia/ Muscle aches, generalized#	3	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N
	INFEC	Vulvitis/ Vulvitis#	3	16FEB2021	6/7	2	No	O	NA/TC	R (22FEB2021)	N/N
	RENAL	Dysuria/ Dysuria#	3	17FEB2021	7/6	2	No	O	NA	R (22FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Left upper arm injection site pain#	3	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N
1126 11261261	INFEC	Nasopharyngitis/ common cold	2	01OCT2020	45/4	1	No	O	NA	R (04OCT2020)	N/N
1127 11271015											

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1127 11271017	GENRL	Fatigue/ FATIGUE#	3	06FEB2021	1/C	1	Yes		NA	N	N/N
	MUSC	Arthralgia/ JOINT PAIN generalized#	3	06FEB2021	1/C	1	Yes		NA	N	N/N
16-55/ C4591001 1127 11271022	MUSC	Arthralgia/ joint pain	1	31JUL2020	2/C	2	Yes		NA/TC	N	N/N
	NERV	Headache/ headache	1	03AUG2020	5/14	3	Yes		NA/TC	R (16AUG2020)	N/N
	INFEC	Sinusitis/ Sinus infection	1	04AUG2020	6/C	2	No	O	NA/TC	N	N/N
	PSYCH	Insomnia/ Insomnia	1	22AUG2020	24/C	1	No	O	NA/TC	N	N/N
		Schizophrenia/ Schizophrenia	1	22AUG2020	24/C	1	No	O	NA/TC	N	N/N
	NERV	Headache/ Headache	1	15SEP2020	48/C	1	No	O	NA/TC	N	N/N
	GENRL	Influenza like illness/ Flu like symptoms	1	26SEP2020	59/C	1	No	O	NA	N	N/N
16-55/ C4591001 1127 11271026	SKIN	Dermatitis contact/ Contact dermatitis (poison ivy)	2	26AUG2020	8/9	1	No	O	NA/TC	R (03SEP2020)	N/N
16-55/ C4591001 1127 11271028	MUSC	Myalgia/ muscle pain#	4	02MAR2021	2/C	2	Yes		NA	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1127 11271072	GENRL	Pain/ BODY ACHES#	4	05FEB2021	1/3	2	Yes		NA	R (07FEB2021)	N/N
	RESP	Immune-mediated pneumonitis/ IMMUNE RESPONSE pneumonitis#	4	08FEB2021	4/5	2	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1127 11271073	PSYCH	Anxiety/ worsening of anxiety	2	02SEP2020	9/C	1	No	O	NA	N	N/N
		Depression/ worsening of depression	2	02SEP2020	9/C	1	No	O	NA	N	N/N
16-55/ C4591001 1127 11271086	GASTR	Dental caries/ Dental caries	2	04SEP2020	6/3	1	No	O	NA	R (06SEP2020)	N/N
		Toothache/ toothache	2	04SEP2020	6/3	1	No	O	NA/TC/TCN	R (06SEP2020)	N/N
16-55/ C4591001 1127 11271097	NERV	Sinus headache/ headache sinus	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1127 11271112	CARD	Cardio-respiratory arrest/ Cardiopulmonary arrest	2	04DEC2020	86/1	4	No	O	NA/W	F (04DEC2020)	Y/N
16-55/ C4591001 1128 11281005	SKIN	Rash/ Rash upper torso	2	12SEP2020	25/C	2	No	O	NA/TC	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1128 11281017	INJ&P	Fall/ Fall	1	08AUG2020	8/1	2	No	O	NA	R (08AUG2020)	N/N	
		Lumbar vertebral fracture/ L2/L3 Fracture	1	08AUG2020	8/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1128 11281018	GASTR	Abdominal pain upper/ STOMACH PAIN	2	03SEP2020	15/22	2	No	O	NA/TC	R (24SEP2020)	N/N	
	GENRL	Chest discomfort/ CENTRAL CHEST DISCOMFORT	2	10OCT2020	52/1	2	No	O	NA/TC	R (10OCT2020)	N/N	
16-55/ C4591001 1128 11281045	GENRL	Injection site pain/ Injection site soreness, left arm#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N	
16-55/ C4591001 1128 11281057	INFEC	Tonsillitis/ tonsillitis	2	19SEP2020	25/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1128 11281061	INJ&P	Muscle strain/ intercostal muscle strain	1	07AUG2020	1/C	1	No	O	NA	N	N/N	
	GENRL	Injection site pain/ Left Deltoid Soreness, at injection site#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
	GENRL	Chills/ Chills#	3	28JAN2021	22/4	1	Yes		NA	R (31JAN2021)	N/N	
		Fatigue/ Fatigue#	3	28JAN2021	22/4	1	Yes		NA	R (31JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1128 11281064	MUSC	Injection site pain/ Injection site soreness, Left arm#	3	28JAN2021	22/4	1	Yes		NA	R (31JAN2021)	N/N
		Myalgia/ Muscle aches#	3	28JAN2021	22/4	1	Yes		NA	R (31JAN2021)	N/N
	NERV	Headache/ Headache#	3	28JAN2021	22/4	1	Yes		NA	R (31JAN2021)	N/N
	EAR	Vertigo/ Vertigo	2	31AUG2020	5/4	1	No	O	NA/TCN	R (03SEP2020)	N/N
	METAB	Dehydration/ dehydration	2	08OCT2020	43/3	1	No	O	NA/TC	R (10OCT2020)	N/N
	GENRL	Chills/ Chills#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness, Left Arm#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness, right arm#	3	25FEB2021	1/5	1	Yes		NA	R (01MAR2021)	N/N
	GENRL	Chills/ Chills#	3	26FEB2021	2/3	1	Yes		NA	R (28FEB2021)	N/N
	MUSC	Fatigue/ Fatigue#	3	26FEB2021	2/3	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001	MUSC	Arthralgia/ Joint Aches#	3	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain, Left arm#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1128 11281077		Pain/ Body Aches#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
		Pyrexia/ Fever (102.0 F)#	4	23FEB2021	1/2	2	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1128 11281078	INFEC	Kidney infection/ Kidney Infection	1	15AUG2020	9/7	2	No	O	NA/TC	R (21AUG2020)	N/N
		Urinary tract infection/ URINARY TRACT INFECTION	1	15AUG2020	9/7	2	No	O	NA/TC	R (21AUG2020)	N/N
	RESP	Nasal congestion/ Nasal Congestion	2	02OCT2020	38/6	1	No	O	NA	R (07OCT2020)	N/N
16-55/ C4591001 1128 11281095	GENRL	Injection site pain/ INJECTION SITE PAIN#	3	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1128 11281098	SKIN	Macule/ Erythematous, Macule upper anterior thigh	2	13SEP2020	10/27	2	No	O	NA/TC	R (09OCT2020)	N/N
	MUSC	Musculoskeletal chest pain/ chest wall pain	2	08OCT2020	35/5	1	No	O	NA	R (12OCT2020)	N/N
	GENRL	Chills/ Chills#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
		Injection site pain/ Injection Site Soreness, Left Arm#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001	MUSC	Tendonitis/ Bilateral Knee Pain (Patellar Tendonitis)	1	15AUG2020	4/C	1	No	O	NA/TC/TCN	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1128 11281101	INFEC	Escherichia urinary tract infection/ Escherichia coli urinary tract infection	2	03OCT2020	33/20	2	No	O	NA/TC	R (22OCT2020)	Y/N
1128 11281103	METAB	Hypokalaemia/ Severe Hypokalemia	2	03OCT2020	33/20	2	No	O	NA/TC	R (22OCT2020)	Y/N
	RENAL	Nephrolithiasis/ Kidney Stones	2	03OCT2020	33/20	2	No	O	NA/TC	R (22OCT2020)	Y/N
16-55/ C4591001	NERV	Presyncope/ presyncope (following blood draw)*		12AUG2020	1/1	2	Yes		NA	R (12AUG2020)	N/N
1128 11281107	GENRL	Fatigue/ Fatigue#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Pain in extremity/ Left Arm Soreness#	3	28JAN2021	2/2	1	Yes		NA/TC	R (29JAN2021)	N/N
	GENRL	Injection site erythema/ INJECTION SITE REDNESS#	4	26FEB2021	1/C	1	Yes		NA	RG	N/N
16-55/ C4591001	REPRO	Ovarian cyst/ RIGHT OVARIAN CYST	2	JAN2021	121/C	2	No	O	NA/TC	RG	N/N
1128 11281115	GASTR	Nausea/ nausea	1	27AUG2020	14/1	2	No	O	NA	R (27AUG2020)	N/N
1128 11281119		Vomiting/ vomiting	1	27AUG2020	14/4	2	No	O	NA	R (30AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	REPRO	Menorrhagia/ Menorrhagia#	2	28JAN2021	148/C	1	Yes		NA/TC	RG	N/N
16-55/ C4591001 1128 11281123	INFEC	Appendicitis/ APPENDICITIS#	2	15JAN2021	129/2	3	No	O	NA/TC/TCN	R (16JAN2021)	Y/N
16-55/ C4591001 1128 11281124	GENRL	Injection site pain/ Injection Site soreness, left arm#	3	13JAN2021	2/3	1	Yes		NA/TC	R (15JAN2021)	N/N
16-55/ C4591001 1128 11281125	GENRL	Injection site pain/ INJECTION SITE SORENESS#	3	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1128 11281128	INFEC	Urinary tract infection/ Urinary Tract Infection	1	06SEP2020	21/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1128 11281129	GENRL	Chills/ Chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Pyrexia/ Fever	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1128 11281132	MUSC	Myalgia/ MUSCLE ACHES	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Soreness, right arm#	4	24FEB2021	1/2				NA	RS (25FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1128 11281134 16-55/ C4591001 1128 11281143	INJ&P  MUSC	Muscle strain/ Bilateral LEG muscle strain  Spondylitis/ unknown LUMBAR INFLAMATION	2	18SEP2020	9/32	2	No	O	NA/TC	R (19OCT2020)	N/N
16-55/ C4591001 1128 11281147	GENRL	Pain/ Body aches	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1128 11281152	GENRL	Pyrexia/ Fever	2	08SEP2020	1/3	1	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1128 11281152	GENRL	Injection site pain/ Injection Site Soreness, left arm#	4	02FEB2021	1/3	1	Yes		NA/TC	R (04FEB2021)	N/N
16-55/ C4591001 1128 11281153	GENRL	Fatigue/ Fatigue#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1128 11281153	HEPAT	Hepatocellular injury/ Hepatocellular injury	2	04NOV2020	57/10	3	No	O	NA/TC	R (13NOV2020)	Y/N
	INFEC	Sepsis/ Sepsis	2	04NOV2020	57/10	3	No	O	NA/TC	R (13NOV2020)	Y/N
		Viral infection/ VIRAL SYNDROME	2	04NOV2020	57/10	3	No	O	NA/TC	R (13NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness, left arm#	4	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1128 11281157	GENRL	Pain/ Body aches	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N	
		Pyrexia/ Fever	1	21AUG2020	2/2	2	Yes		NA/TC	R (22AUG2020)	N/N	
	NERV	Headache/ Headache	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N	
	GENRL	Pain/ Body aches	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N	
		Pyrexia/ Fever	2	11SEP2020	2/2	2	Yes		NA/TC	R (12SEP2020)	N/N	
	NERV	Headache/ Headache	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N	
16-55/ C4591001 1128 11281170	GENRL	Pain/ Body Aches	1	25AUG2020	2/3	1	Yes		NA/TC	R (27AUG2020)	N/N	
	RESP	Paranasal sinus discomfort/ Nasal Sinus Discomfort	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N	
	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	2	12OCT2020	28/7	1	No	O	NA	R (18OCT2020)	N/N	
16-55/ C4591001 1128 11281171	MUSC	Myalgia/ left deltoid soreness#	4	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N	
16-55/ C4591001 1128 11281173	MUSC	Arthritis/ RIGHT SHOULDER INFLAMATION	1	17SEP2020	25/1	1	No	O	NA/TC	R (17SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1128 11281175	GENRL	Chills/ Chills	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		Pain/ Body Aches	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		Pyrexia/ Subjective Fever	2	15SEP2020	2/1	1	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1128 11281176	NERV	Syncope/ vasovagal syncope*		24AUG2020	1/1	3	No	O	NA	R (24AUG2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		Pain/ Body Aches	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1128 11281178	GENRL	Pyrexia/ Subject Fever	2	15SEP2020	2/1	1	Yes		NA/TC	R (15SEP2020)	N/N
		Injection site pain/ Injection Site Pain, left arm	1	25AUG2020	2/2	2	Yes		NA	R (26AUG2020)	N/N
		Injection site pain/ Injection Site Pain, left arm	1	26AUG2020	3/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Pyrexia/ Fever	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Periarthritis/ ADGESIVE CAPSULITITS (LEFT SHOULDER)	2	NOV2020	48/C	2	No	O	NA/TC/TCN	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1128 11281188	GENRL	Injection site pain/ Injection Site Soreness, Left arm#	4	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1128 11281190	GENRL	Pain/ Body Aches	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ Subjective Fever	2	16SEP2020	2/1	2	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ Headaches	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1128 11281195	GASTR	Toothache/ Toothache, upper right side	1	27AUG2020	3/1	1	No	O	NA	R (27AUG2020)	N/N
	GENRL	Chills/ Chills	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		Pain/ generalized body aches	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		Pyrexia/ Fever	2	14SEP2020	1/2	2	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1128 11281198	BLOOD	Lymphadenopathy/ Axillary Adenopathy, left side	1	26AUG2020	1/4	1	Yes		NA/TCN	R (29AUG2020)	N/N
16-55/ C4591001 1128 11281199	RENAL	Haematuria/ hematuria	2	15OCT2020	29/1	1	No	O	NA	R (15OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1128 11281204	GENRL	Fatigue/ FATIGUE#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	04FEB2021	2/3	1	Yes		NA/TC	R (06FEB2021)	N/N
		Pain/ body ache#	3	04FEB2021	2/3	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1128 11281209		Pyrexia/ fever#	3	04FEB2021	2/3	1	Yes		NA/TC	R (06FEB2021)	N/N
	MUSC	Myalgia/ left deltoid pain#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1128 11281220	GENRL	Fatigue/ fatigue#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ fever#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	GASTR	Nausea/ NAUSEA	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1128 11281225	GENRL	Pyrexia/ FEVER (101)	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site, left arm	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1128 11281228	GENRL	Pain/ Body Aches	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
		Chills/ CHILLS	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Myalgia/ MUSCLE PAIN, RIGHT ARM	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1128 11281230	NERV	Headache/ HEADACHE	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness, left arm#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1128 11281231	GENRL	Injection site pain/ Soreness left arm, at injection site.*		31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Soreness left arm, at injection site.	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001		Pyrexia/ Subjective fever	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1128 11281232		Injection site pain/ INJECTION SITE SORENESS, LEFT ARM	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N	
	GENRL	Fatigue/ FATIGUE	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 1128 11281235	INFEC	Bacterial vulvovaginitis/ Bacterial Vaginitis	2	15OCT2020	25/5	1	No	O	NA/TC	R (19OCT2020)	N/N	
16-55/ C4591001 1128 11281241	NEOPL	Breast cancer/ Breast Cancer	2	NOV2020	42/C	3	No	O	NA/TC/W	RG	N/N	
16-55/ C4591001 1128 11281245	GENRL	Injection site pain/ INJECTION SITE SORENESS#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N	
16-55/ C4591001 1128 11281247	NERV	Dizziness/ Dizziness*		01SEP2020	1/1	1	Yes		NA	R (01SEP2020)	N/N	
	GENRL	Pyrexia/ SUBJECTIVE FEVER	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N	
	NERV	Headache/ HEADACHE	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N	
	GASTR	Nausea/ NAUSEA	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N	
	GENRL	Fatigue/ FATIGUE	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1128 11281255	RESP	Cough/ COUGH	2	24SEP2020	2/2	1	No	O	NA	R (25SEP2020)	N/N	
		Nasal congestion/ NASAL CONGESTION	2	24SEP2020	2/2	1	No	O	NA	R (25SEP2020)	N/N	
	INFEC	Vulvovaginal mycotic infection/ Vaginal Yeast Infection#	2	08JAN2021	110/5	2	No	O	NA/TC	R (12JAN2021)	N/N	
16-55/ C4591001 1128 11281257	GENRL	Injection site pain/ Left arm soreness, at injection site#	3	16JAN2021	5/11	2	Yes		NA	R (26JAN2021)	N/N	
	GASTR	Abdominal pain upper/ Stomach pain#	3	18JAN2021	7/9	1	No	O	NA/TC	R (26JAN2021)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN, LEFT ARM	1	01SEP2020	1/5	1	Yes		NA	R (05SEP2020)	N/N	
	GENRL	Fatigue/ FATIGUE	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N	
	GENRL	Chills/ CHILLS	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
		Fatigue/ FATIGUE	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
		Injection site pain/ INJECTION SITE SORENESS, LEFT ARM	2	22SEP2020	2/2	1	Yes		NA/TCN	R (23SEP2020)	N/N	
16-55/ C4591001 1128 11281267	MUSC	Myalgia/ SORE NECK MUSCLES	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
	MUSC	Arthralgia/ Joint Pain	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Body Ache (muscle pain)	1	04SEP2020	3/1	2	Yes		NA	R (04SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	1	05SEP2020	4/2	2	Yes		NA	R (06SEP2020)	N/N
		Myalgia/ Body Aches (Muscle pain)	1	05SEP2020	4/2	3	Yes		NA	R (06SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	07SEP2020	6/2	2	Yes		NA	R (08SEP2020)	N/N
	REPRO	Vaginal prolapse/ Vaginal Prolapse	2	01DEC2020	70/18	3	No	O	NA/TCN	R (18DEC2020)	Y/N
	REPRO	Rectocele/ Rectocele	2	17DEC2020	86/2	3	No	O	NA/TCN	R (18DEC2020)	Y/N
16-55/ C4591001 1128 11281268	GENRL	Injection site pain/ SORENESS AT INJECTION SITE, LEFT ARM	1	02SEP2020	1/2	1	Yes		NA/TC	R (03SEP2020)	N/N
	GENRL	Injection site pain/ SORENESS AT INJECTION SITE, LEFT ARM	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1128 11281269	MUSC	Myalgia/ MUSCLE PAIN	1	04SEP2020	3/2	1	Yes		NA	R (05SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	05SEP2020	4/1	1	Yes		NA/TC	R (05SEP2020)	N/N
	GENRL	Injection site pain/ SORENESS AT INJECTION SITE, LEFT	1	07SEP2020	6/2	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1128 11281272	MUSC	Myalgia/ right deltoid soreness	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ right deltoid pain	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1128 11281274	GENRL	Chills/ Chills	1	06SEP2020	4/3	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C4591001 1128 11281283	NERV	Headache/ Headache	1	08SEP2020	6/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1128 11281286	INFEC	Vulvovaginal mycotic infection/ Vaginal Yeast Infection	1	04SEP2020	1/6	2	No	O	NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1128 11281287	MUSC	Myalgia/ left deltoid Soreness#	3	08JAN2021	1/3	2	Yes		NA/TC	R (10JAN2021)	N/N
	NERV	Headache/ Headache#	3	08JAN2021	1/3	2	Yes		NA/TC	R (10JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	4	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1128 11281288		Pyrexia/ Fever#	4	29JAN2021	1/3	1	Yes		NA/TC	R (31JAN2021)	N/N	
	MUSC	Pain in extremity/ Arm Soreness#	4	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N	
	INFEC	Ear infection/ Ear Infection	2	30SEP2020	6/10	2	No	O	NA	R (09OCT2020)	N/N	
	RESP	Respiratory tract congestion/ Chest Congestion	2	30SEP2020	6/10	1	No	O	NA/TC	R (09OCT2020)	N/N	
	GENRL	Injection site pain/ Injection Site Soreness, Left arm#	2	10JAN2021	108/6	1	Yes		NA	R (15JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N	
		Pyrexia/ Fever 102.5F#	4	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site soreness, left arm#	4	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N	
16-55/ C4591001 1128 11281289	NERV	Headache/ Headache#	4	02FEB2021	2/2	1	Yes		NA/TC	R (03FEB2021)	N/N	
	GENRL	Chills/ Chills	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N	
		Injection site pain/ left arm injection site pain/soreness	1	04SEP2020	1/5	1	Yes		NA	R (08SEP2020)	N/N	
		Pyrexia/ Subjective Fever	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N	
	GENRL	Chills/ CHILLS	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1128 11281294	GENRL	Injection site pain/ INJECTION SITE SORENESS, LEFT ARM	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N	
		Pain/ BODY ACHES	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
		Pyrexia/ SUBJECTIVE FEVER	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
		Chills/ Chills	2	04OCT2020	2/2	1	Yes		NA/TC	R (05OCT2020)	N/N	
16-55/ C4591001 1128 11281299	GENRL	Pain/ body aches	2	04OCT2020	2/2	1	Yes		NA/TC	R (05OCT2020)	N/N	
		Pyrexia/ Subjective fever (99.7)	2	04OCT2020	2/2	1	Yes		NA/TC	R (05OCT2020)	N/N	
		Injection site pain/ Injection Site Soreness, left arm#	3	10MAR2021	2/C	1	Yes		NA	N	N/N	
16-55/ C4591001 1128 11281300	MUSC	Pain in extremity/ Left arm soreness#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N	
	GENRL	Pyrexia/ Fever#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N	
16-55/ C4591001 1128 11281301	GENRL	Chills/ Chills	2	29SEP2020	2/4	1	Yes		NA	R (02OCT2020)	N/N	
		Fatigue/ Fatigue	2	29SEP2020	2/4	2	Yes		NA	R (02OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1128 11281305	SKIN	Pyrexia/ Subjective Fever	2	29SEP2020	2/1	1	Yes		NA/TC	R (29SEP2020)	N/N	
		Night sweats/ Night Sweats	2	29SEP2020	2/4	1	Yes		NA	R (02OCT2020)	N/N	
16-55/ C4591001 1128 11281306	GENRL	Injection site pain/ Injection Site Soreness, Left arm#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N	
		Chills/ CHILLS	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N	
16-55/ C4591001 1128 11281309	INFEC	Fatigue/ FATIGUE	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N	
		Pain/ BODY ACHE	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N	
		Urinary tract infection/ URINARY TRACT INFECTION	2	01OCT2020	3/29	2	No	O	NA/TC	R (29OCT2020)	N/N	
16-55/ C4591001 1128 11281311	GENRL	Injection site pain/ INJECTION SITE SORNESS (RIGHT ARM)#	3	04FEB2021	1/3	1	Yes		NA/TC	R (06FEB2021)	N/N	
		Pyrexia/ Subjective Fever	2	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N	
16-55/ C4591001 1128 11281332	GENRL	Chills/ chills	2	04OCT2020	2/1	1	Yes		NA	R (04OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1128 11281334	GENRL	Injection site pain/ INJECTION SITE SORENESS, LEFT ARM#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Injection site pain/ INJECTION SITE SORENESS, LEFT ARM#	4	28JAN2021	1/C	1	Yes		NA	N	N/N
		Pain/ BODY ACHES#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	INV	Body temperature increased/ ELEVATED BODY TEMPERATURE (99.9)#	4	28JAN2021	1/1	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Chills/ Chills	1	03OCT2020	23/1	1	Yes		NA	R (03OCT2020)	N/N
		Pain/ Body Aches	1	03OCT2020	23/1	1	Yes		NA	R (03OCT2020)	N/N
		Pyrexia/ Fever	1	03OCT2020	23/1	1	Yes		NA	R (03OCT2020)	N/N
	GASTR	Vomiting/ VOMITTING#	3	01MAR2021	1/2	1	Yes		NA	R (02MAR2021)	N/N
	GENRL	Chills/ CHILLS#	3	01MAR2021	1/2	1	Yes		NA	R (02MAR2021)	N/N
		Pain/ BODY ACHES#	3	01MAR2021	1/3	1	Yes		NA	R (03MAR2021)	N/N
	Pyrexia/ FEVER (101.3F)#	3	01MAR2021	1/2	1	Yes		NA	R (02MAR2021)	N/N	
NERV	Headache/ HEADACHE#	3	02MAR2021	2/2	1	Yes		NA/TC	R (03MAR2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1128 11281345	GENRL	Pain/ Aches/Pain	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
		Pyrexia/ Subjective Fever	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1128 11281357	GENRL	Injection site pain/ Injection Site Soreness, Left arm#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1128 11281358	GENRL	Injection site pain/ INJECTION SITE SORENESS#	4	19JAN2021	1/1	1	Yes		NA	R (19JAN2021)	N/N
16-55/ C4591001 1128 11281359	BLOOD	Lymphadenopathy/ Left Supraclavicular Adenopathy	2	07OCT2020	2/2	2	Yes		NA/TC	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Left Arm injection site Pain	2	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1128 11281384	GENRL	Chills/ CHILLS	1	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Chills/ Body Chills	2	17OCT2020	2/2	2	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C4591001 1128 11281385	GENRL	Injection site pain/ Soreness left arm, at injection site.	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1129 11291001	GENRL	Fatigue/ Fatigue	1	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Pyrexia/ subjective fever	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	3	23DEC2020	1/3	1	Yes		NA	R (25DEC2020)	N/N
16-55/ C4591001 1129 11291005		Injection site pain/ left deltoid injection site tenderness#	3	23DEC2020	1/3	1	Yes		NA	R (25DEC2020)	N/N
	GENRL	Chills/ chills#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	GENRL	Pyrexia/ fever#	4	11JAN2021	1/2	2	Yes		NA/TC	R (12JAN2021)	N/N
16-55/ C4591001 1129 11291017	GASTR	Internal hernia/ Internal Hernia	2	21JAN2021	157/2	3	No	O	NA/TCN	RS (22JAN2021)	N/N
	MUSC	Intestinal obstruction/ bowel obstruction	2	21JAN2021	157/2	4	No	O	NA/TC/TCN	RS (22JAN2021)	Y/N
16-55/ C4591001 1129 11291017	MUSC	Musculoskeletal stiffness/ left deltoid muscle stiffness#	3	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N
	NERV	Radiculopathy/ left arm radiculopathy#	3	22FEB2021	8/C	2	Yes		NA/TC	N	N/N
	GENRL	Pyrexia/ Fever#	4	09MAR2021	2/2	2	Yes		NA/TC	R (10MAR2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1129 11291019	SKIN	Pruritus/ Generalized Purities#	4	10MAR2021	3/C	2	Yes		NA/TC	N	N/N	
	NERV	Headache/ headache#	4	30JAN2021	6/8	2	No	O	NA	R (06FEB2021)	N/N	
	VASC	Hypertension/ worsened hypertension#	4	30JAN2021	6/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1129 11291029	INFEC	Vulval abscess/ worsening furuncle vulva	2	30SEP2020	38/31	2	No	O	NA/TC	R (30OCT2020)	N/N	
16-55/ C4591001 1129 11291042	MUSC	Intervertebral disc protrusion/ herniated disk c-6	2	26NOV2020	95/C	2	No	O	NA/TC/TCN	N	N/N	
	GASTR	Toothache/ right upper molar tooth pain	2	03JAN2021	133/C	1	Yes		NA/TC	RG	N/N	
	GASTR	Dyspepsia/ Dyspepsia	1	08AUG2020	5/4	2	No	O	NA/TC	R (11AUG2020)	N/N	
16-55/ C4591001 1129 11291045	INJ&P	Fall/ fall	2	31JAN2021	160/1	2	No	O	NA	RS (31JAN2021)	N/N	
16-55/ C4591001 1129 11291047		Wrist fracture/ compound fracture left wrist	2	31JAN2021	160/C	2	No	O	NA/TCN	N	Y/N	
	INFEC	Sinusitis/ sinusitis#	4	22FEB2021	1/C	1	No	O	NA/TC	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1129 11291061	INJ&P	Foot fracture/ fracture right great toe	2	10OCT2020	47/C	2	No	O	NA/TCN	RG	N/N	
		Foot fracture/ fracture right second toe	2	10OCT2020	47/C	2	No	O	NA/TC/TCN	RG	N/N	
16-55/ C4591001 1129 11291063	MUSC	Tendonitis/ sesamoiditis left big toe	2	15NOV2020	80/38	2	No	O	NA/TCN	R (22DEC2020)	N/N	
16-55/ C4591001 1129 11291072	MUSC	Back pain/ low back pain	2	31AUG2020	1/26	1	No	O	NA/TC	R (25SEP2020)	N/N	
16-55/ C4591001 1129 11291092	NEOPL	Benign breast neoplasm/ benign breast nodules bilateral	1	17AUG2020	7/10	2	No	O	NA/TC/TCN	R (26AUG2020)	N/N	
16-55/ C4591001 1129 11291096	IMMUN	Hypersensitivity/ allergic reaction bilateral hands, back, neck, left shoulder, right foot	2	12JAN2021	134/15	2	No	O	NA/TC	R (26JAN2021)	N/N	
	INJ&P	Joint injury/ SI joint back injury#	2	23JAN2021	145/C	2	No	O	NA/TC	N	N/N	
		Joint injury/ Sacroiliac Joint back injury#	2	23JAN2021	145/8	1	No	O	NA	R (30JAN2021)	N/N	
	GENRL	Pain/ Body aches#	3	23FEB2021	1/1	1	Yes		NA	R (23FEB2021)	N/N	
	NERV	Headache/ Headache#	3	23FEB2021	1/1	1	Yes		NA/TC	R (23FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1129 11291097	INFEC	Urinary tract infection/ urinary tract infection	2	19DEC2020	110/3	2	No	O	NA/TC	R (21DEC2020)	N/N	
16-55/ C4591001 1129 11291120	GENRL	Fatigue/ fatigue#	4	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/N	
		Injection site pain/ left deltoid injection site pain#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N	
16-55/ C4591001 1129 11291129	GENRL	Injection site pain/ left deltoid injection site tenderness#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N	
	GENRL	Fatigue/ fatigue#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N	
		Pain/ body aches#	4	11JAN2021	1/3	2	Yes		NA/TC	R (13JAN2021)	N/N	
16-55/ C4591001 1129 11291142	NERV	Headache/ Headache	2	09OCT2020	26/3	1	No	O	NA/TC	R (11OCT2020)	N/N	
	RESP	Sinus congestion/ sinus congestion	2	09OCT2020	26/3	1	No	O	NA/TC	R (11OCT2020)	N/N	
16-55/ C4591001 1129 11291145	NERV	Lethargy/ Lethargy#	4	14JAN2021	1/1	1	Yes		NA	R (14JAN2021)	N/N	
16-55/ C4591001	INJ&P	Muscle strain/ neck muscle strain	1	11SEP2020	18/4	1	No	O	NA/TC	R (14SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1129 11291148 16-55/ C4591001	MUSC	Myalgia/ myalgias	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
1129 11291153 16-55/ C4591001	MUSC	Myalgia/ Left deltoid tenderness	1	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
1129 11291157	INFEC	Vulvovaginal mycotic infection/ vaginal yeast infection	2	02JAN2021	104/5	2	No	O	NA/TC	R (06JAN2021)	N/N
16-55/ C4591001	GENRL	Pyrexia/ fever#	4	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
1129 11291163	MUSC	Myalgia/ generalized muscle aches#	4	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001	GENRL	Chest pain/ Acute chest pain	1	13SEP2020	6/19	2	No	O	NA/TC	R (01OCT2020)	N/N
1129 11291165	GENRL	Pyrexia/ fever	2	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001	MUSC	Myalgia/ muscle aches	2	07OCT2020	2/2	2	Yes		NA/TC	R (08OCT2020)	N/N
1129 11291187	NERV	Headache/ headache	2	07OCT2020	2/2	2	Yes		NA/TC	R (08OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1129 11291189	MUSC	Arthralgia/ knee pain-right#	4	08FEB2021	28/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1129 11291196	INFEC	Ear infection/ ear infection-left	2	21NOV2020	41/12	2	No	O	NA/TC	R (02DEC2020)	N/N
	PSYCH	Attention deficit hyperactivity disorder/ Attention Deficit Hyperactive Disorder	2	23JAN2021	104/C	2	No	O	NA/TC	N	N/N
	GENRL	Injection site pain/ left arm injection site soreness#	3	02FEB2021	1/3	1	Yes		NA/TC	R (04FEB2021)	N/N
	MUSC	Back pain/ worsening low back pain#	3	03FEB2021	2/8	2	No	O	NA/TC	R (10FEB2021)	N/N
16-55/ C4591001 1129 11291197	GASTR	Nausea/ Nausea	1	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ Left arm injection site soreness	1	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	GASTR	Lip swelling/ Upper lip swelling	1	06OCT2020	15/2	1	Yes		NA/TC	R (07OCT2020)	N/N
	GASTR	Lip swelling/ lower lip swelling	1	11OCT2020	20/2	1	Yes		NA/TC	R (12OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
	GASTR	Lip swelling/ upper lip swelling	2	15OCT2020	3/C	1	Yes		NA/TC	RG	N/N
	IMMUN	Drug hypersensitivity/ allergic reaction to study investigational product	2	15OCT2020	3/C	1	Yes		NA/TC	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	SKIN	Urticaria/ Urticaria upper back	2	15OCT2020	3/C	1	Yes		NA/TC	RG	N/N
	GASTR	Lip swelling/ lower lip swelling	2	17OCT2020	5/C	1	Yes		NA/TC	RG	N/N
	EYE	Swelling of eyelid/ left lower eyelid swelling	2	18OCT2020	6/C	1	Yes		NA/TC	RG	N/N
	GENRL	Swelling face/ facial swelling	2	18OCT2020	6/C	1	Yes		NA/TC	RG	N/N
16-55/ C4591001 1129 11291201	MUSC	Myalgia/ Left Deltoid tenderness	1	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Myalgia/ left deltoid tenderness	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1129 11291202	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	1	26SEP2020	5/5	1	No	O	NA	R (30SEP2020)	N/N
16-55/ C4591001 1129 11291209	GENRL	Injection site pain/ left deltoid muscle injection site tenderness#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Pyrexia/ fever#	4	19FEB2021	1/2	2	Yes		NA/TC	R (20FEB2021)	N/N
	MUSC	Myalgia/ generalized muscle aches#	4	19FEB2021	1/3	2	Yes		NA/TC	R (21FEB2021)	N/N
	NERV	Headache/ headache#	4	19FEB2021	1/3	2	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue	1	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1129 11291210	MUSC	Myalgia/ left deltoid tenderness	1	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N	
16-55/ C4591001 1129 11291212	MUSC	Myalgia/ right deltoid muscle tenderness	1	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N	
	GENRL	Chills/ chills	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N	
		Malaise/ malaise	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N	
		Pain/ body aches	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N	
16-55/ C4591001 1129 11291213	GENRL	Injection site pain/ left deltoid injection site tenderness#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N	
16-55/ C4591001 1129 11291220	MUSC	Joint stiffness/ Joint Stiffness	1	09OCT2020	3/3	1	Yes		NA	R (11OCT2020)	N/N	
	MUSC	Joint stiffness/ Joint Stiffness	2	29OCT2020	2/3	1	Yes		NA	R (31OCT2020)	N/N	
16-55/ C4591001 1129 11291224	GENRL	Malaise/ malaise#	4	20JAN2021	2/2	2	Yes		NA/TC	R (21JAN2021)	N/N	
16-55/ C4591001	GENRL	Fatigue/ fatigue	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1129 11291228		Injection site pain/ injection site pain	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N	
		Pyrexia/ Fever	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N	
	MUSC	Myalgia/ Increased Muscle Pain	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N	
	VASC	Hypertension/ worsening hypertension	2	14NOV2020	12/C	2	No	O	NA/TC	N	N/N	
	MUSC	Trigger finger/ worsening right 4th trigger finger	2	08DEC2020	36/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1129 11291238	GENRL	Chills/ chills	2	07NOV2020	2/2	1	Yes		NA	R (08NOV2020)	N/N	
16-55/ C4591001 1129 11291244	GENRL	Injection site pain/ injection site tenderness-left deltoid	1	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N	
16-55/ C4591001 1129 11291245	MUSC	Pain in extremity/ left arm soreness#	3	29DEC2020	2/2	1	Yes		NA	R (30DEC2020)	N/N	
	NERV	Headache/ headache#	3	29DEC2020	2/2	1	Yes		NA	R (30DEC2020)	N/N	
	GENRL	Chills/ chills#	4	19JAN2021	2/1	1	Yes		NA	R (19JAN2021)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1129 11291256		Injection site pain/ left deltoid muscle injection site soreness#	4	19JAN2021	2/1	2	Yes		NA/TC	R (19JAN2021)	N/N
	NERV	Headache/ headache#	4	19JAN2021	2/1	2	Yes		NA/TC	R (19JAN2021)	N/N
	EYE	Eye pain/ eye pain#	3	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
	GENRL	Chills/ chills#	3	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ headache#	3	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
	MUSC	Back pain/ back pain muscular#	3	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
	GENRL	Chills/ Chills#	4	10MAR2021	2/2	1	Yes		NA	R (11MAR2021)	N/N
	IMMUN	Anaphylactoid reaction/ Anaphylactoid Reaction#	3	27JAN2021	3/1	4	Yes		P/TC	R (27JAN2021)	Y/N
	16-55/ C4591001 1129 11291262	GASTR	Lip swelling/ lip swelling	1	23NOV2020	1/12	1	No	O	NA/TC	R (04DEC2020)
	GASTR	Aphthous ulcer/ worsening canker sore episode of lips	1	27NOV2020	5/8	2	Yes		NA/TC	R (04DEC2020)	N/N
16-55/ C4591001 1129 11291263	GENRL	Injection site pain/ left deltoid injection site soreness#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1130 11301001	GENRL	Chills/ chills	2	14SEP2020	1/1	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
	MUSC	Myalgia/ muscle aches in bilateral legs	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1130 11301002	REPRO	Breast pain/ bilateral breast pain	1	25AUG2020	2/28	1	No	O	NA	R (21SEP2020)	N/N
16-55/ C4591001 1130 11301014	GENRL	Chills/ Chills#	4	16FEB2021	1/C	1	Yes		NA/TC	RG	N/N
	MUSC	Myalgia/ Muscle aches#	4	16FEB2021	1/C	1	Yes		NA/TC	RG	N/N
	NERV	Headache/ Headache#	4	16FEB2021	1/C	1	Yes		NA/TC	RG	N/N
16-55/ C4591001 1130 11301021	GENRL	Chills/ Chills#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ muscle pain whole body#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	29JAN2021	2/1	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Chills/ chills#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1130 11301032	INFEC	Genital herpes simplex/ Genital HSV1 outbreak#	4	18FEB2021	2/8	2	No	O	NA/TC	R (25FEB2021)	N/N
	MUSC	Myalgia/ generalized muscle pain#	4	18FEB2021	2/C	1	Yes		NA	RG	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/C	1	Yes		NA	RG	N/N
	GASTR	Vomiting/ emesis	1	02SEP2020	1/1	1	No	O	NA	R (02SEP2020)	N/N
	NERV	Presyncope/ near syncope*		02SEP2020	1/1	1	No	O	NA	R (02SEP2020)	N/N
	RESP	Cough/ Cough	1	19SEP2020	18/4	1	No	O	NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	30JAN2021	2/1	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N
	NERV	Lethargy/ Mild lethargy#	4	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1130 11301045	INJ&P	Skin laceration/ Laceration to the Left 2nd finger#	4	06MAR2021	17/C	1	No	O	NA	N	N/N
	CARD	Palpitations/ Heart palpitations	2	21NOV2020	59/1	1	No	O	NA/TC	RS (21NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1130 11301046	GENRL	Chills/ chills#	4	03FEB2021	2/2	2	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ Fever#	4	03FEB2021	2/2	2	Yes		NA	R (04FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	4	03FEB2021	2/2	2	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1130 11301051	NERV	Headache/ Headache#	4	18FEB2021	1/3	1	Yes		NA/TC	RS (20FEB2021)	N/N
	BLOOD	Lymph node pain/ Tender lymph nodes in armpits and neck#	4	19FEB2021	2/6	1	Yes		NA/TC	R (24FEB2021)	N/N
	GENRL	Chills/ Chills#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
		Fatigue/ Significant fatigue#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
		Pain/ Body Aches#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
		Pyrexia/ Fever 100.6-101F#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
	REPRO	Breast discharge/ Right Nipple Discharge#	4	24FEB2021	7/9	1	No	O	NA	R (04MAR2021)	N/N
NERV	Headache/ Headache	2	28SEP2020	1/8	1	Yes		NA	R (05OCT2020)	N/N	
16-55/ C4591001	EAR	Vertigo positional/ Benign paroxysmal positional vertigo	1	19SEP2020	10/6	1	No	O	NA/TC/TCN	R (24SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine Subject	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1130 11301064 16-55/ C4591001 1130 11301068	GENRL	Chills/ chills#	4	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
	MUSC	Pyrexia/ fever#	4	27FEB2021	2/1	1	Yes		NA	R (27FEB2021)	N/N
	MUSC	Arthralgia/ joint pain/ache - generalized#	4	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
	MUSC	Back pain/ Low back pain#	4	27FEB2021	2/1	1	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1130 11301075	GENRL	Chills/ Chills#	3	07JAN2021	4/2	1	Yes		NA/TC	R (08JAN2021)	N/N
	GENRL	Pain/ generalized aching#	3	07JAN2021	4/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Chills/ Chills#	4	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Fatigue/ Fatigue#	4	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	NERV	Headache/ Headache#	4	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1130 11301078	GENRL	Injection site pain/ Injection Site Soreness#	4	02FEB2021	1/2	1	Yes		NA/TC	R (03FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Chills/ Chills#	4	03FEB2021	2/1	1	Yes		NA/TC	R (03FEB2021)	N/N	
16-55/ C4591001 1130 11301081	BLOOD	Lymphadenopathy/ swollen lymph node - right side of neck#	3	11FEB2021	15/2	1	No	O	NA	R (12FEB2021)	N/N	
16-55/ C4591001 1130 11301082	GASTR	Diarrhoea/ Diarrhea#	4	02FEB2021	1/2	2	Yes		NA	R (03FEB2021)	N/N	
	GENRL	Chills/ Chills#	4	02FEB2021	1/3	2	Yes		NA/TC	R (04FEB2021)	N/N	
		Injection site pain/ Injection Site Pain#	4	02FEB2021	1/3	2	Yes		NA/TC	R (04FEB2021)	N/N	
		Pain/ Body Aches#	4	02FEB2021	1/3	2	Yes		NA/TC	R (04FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	03FEB2021	2/2	2	Yes		NA	R (04FEB2021)	N/N	
		Pyrexia/ Fever of 100.5F#	4	03FEB2021	2/2	2	Yes		NA/TC	R (04FEB2021)	N/N	
	NERV	Headache/ Massive headache#	4	03FEB2021	2/2	2	Yes		NA/TC	R (04FEB2021)	N/N	
16-55/ C4591001 1130 11301087	INJ&P	Skin laceration/ Right foot laceration	2	06DEC2020	26/1	2	No	O	NA/TC/TCN	R (06DEC2020)	N/N	
16-55/ C4591001 1130 11301088	GENRL	Chest discomfort/ chest tightness#	3	03JAN2021	13/2	1	No	O	NA	R (04JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1130 11301090	MUSC	Back pain/ Back pain#	3	03JAN2021	13/5	1	No	O	NA/TC	R (07JAN2021)	N/N	
	GENRL	Chills/ chills#	4	13JAN2021	1/2	1	Yes		NA/TC	R (14JAN2021)	N/N	
		Pyrexia/ fever#	4	13JAN2021	1/2	1	Yes		NA/TC	R (14JAN2021)	N/N	
16-55/ C4591001 1130 11301091	MUSC	Myalgia/ Myalgia#	4	13JAN2021	1/2	1	Yes		NA/TC	R (14JAN2021)	N/N	
	INFEC	Hordeolum/ LEFT LOWER HORDEOLUM INTERNUM	2	25NOV2020	9/10	1	No	O	NA/TC/TCN	R (04DEC2020)	N/N	
16-55/ C4591001 1130 11301094	NERV	Radiculopathy/ worsening radiculopathy	2	24DEC2020	22/43	2	No	O	NA	R (04FEB2021)	N/N	
16-55/ C4591001 1131 11311015	INJ&P	Eye contusion/ contusion of right eye	2	25SEP2020	18/5	1	No	O	NA	R (29SEP2020)	N/N	
16-55/ C4591001 1131 11311020	MUSC	Coccydynia/ coccygeal pain	2	21OCT2020	50/C	2	No	O	NA/TCN	N	N/N	
16-55/ C4591001 1131 11311024	IMMUN	Drug hypersensitivity/ allergic reaction, potentially related to study drug	1	17AUG2020	1/1	2	Yes		NA/TC	R (17AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	SKIN	Urticaria/ allergic reaction, one hive appearing on right armpit	1	17AUG2020	1/1	2	Yes		NA/TC	R (17AUG2020)	N/N
	NERV	Headache/ headache	1	18AUG2020	2/4	2	Yes		NA/TC	R (21AUG2020)	N/N
16-55/ C4591001 1131 11311026	GASTR	Abdominal pain lower/ lower abdominal pain(near inguinal hernia removal site-2005)#	3	FEB2021	1/C	2	No	O	NA	N	N/N
16-55/ C4591001 1131 11311031	GENRL	Injection site pain/ injection site pain	2	08SEP2020	1/4	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Chills/ chills	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ headache	2	09SEP2020	2/3	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1131 11311032	GENRL	Injection site pain/ pain at injection site#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1131 11311035	GENRL	Fatigue/ fatigue	2	08SEP2020	1/3	2	Yes		NA/TC	R (10SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	09SEP2020	2/2	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1131 11311038	GENRL	Fatigue/ fatigue#	3	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1131 11311042	SKIN	Pain/ body aches#	3	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N	
		Night sweats/ night sweats#	3	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N	
16-55/ C4591001 1131 11311046	INJ&P	Ligament sprain/ sprained left ankle	2	03OCT2020	26/39	2	No	O	NA/TC	R (10NOV2020)	N/N	
16-55/ C4591001 1131 11311046	GENRL	Fatigue/ fatigue	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N	
16-55/ C4591001 1131 11311048	EAR	Pyrexia/ fever	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N	
		Vertigo/ vertigo	2	20OCT2020	43/C	3	No	O	NA	RG	N/N	
16-55/ C4591001 1131 11311049	GENRL	Fatigue/ fatigue#	3	05FEB2021	1/2	2	Yes		NA	R (06FEB2021)	N/N	
16-55/ C4591001 1131 11311051	GENRL	Injection site pain/ injection site pain#	3	05FEB2021	1/4	2	Yes		NA/TC	R (08FEB2021)	N/N	
		Injection site pain/ injection site soreness#	3	22FEB2021	1/4	2	Yes		NA	R (25FEB2021)	N/N	
16-55/ C4591001	GENRL	Chills/ chills	2	11SEP2020	1/3	2	Yes		NA/TC	R (13SEP2020)	N/Y	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1131 11311053		Pain/ body aches	2	11SEP2020	1/3	2	Yes		NA/TC	R (13SEP2020)	N/Y
	INV	Body temperature increased/ elevated temperature	2	11SEP2020	1/3	1	Yes		NA/TC	R (13SEP2020)	N/Y
16-55/ C4591001 1131 11311062	NERV	Headache/ headache#	3	18FEB2021	1/4	1	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1131 11311069	NERV	Dizziness/ light headedness	2	11SEP2020	2/5	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1131 11311071	INJ&P	Procedural pain/ left arm pain post injection	1	22AUG2020	2/2	2	Yes		NA	R (23AUG2020)	N/N
	GENRL	Injection site pain/ left arm injection site pain	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	SKIN	Rash/ rash across chest	2	09SEP2020	1/6	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001 1131 11311073	MUSC	Back pain/ left side low back pain	2	27SEP2020	14/10	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1131 11311076	MUSC	Arthralgia/ generalized joint pain	1	26AUG2020	3/16	1	No	O	NA	R (10SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1131 11311080	GENRL	Chills/ chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Fatigue/ fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1131 11311081	NERV	Presyncope/ Near syncope*		25AUG2020	1/1	1	No	O	NA	R (25AUG2020)	N/N
	INFEC	Ear infection/ bilateral ear infection	2	14JAN2021	122/C	1	No	O	NA	RG	N/N
	EAR	Tinnitus/ tinnitus after exposure to loud sounds	2	10FEB2021	149/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1131 11311090	GENRL	Injection site haematoma/ injection site hematoma	2	18SEP2020	1/6	1	No	O	NA	R (23SEP2020)	N/N
16-55/ C4591001 1131 11311094	PSYCH	Anxiety/ Increased Anxiety#	3	02MAR2021	21/C	3	No	O	NA/TC	N	Y/N
	PSYCH	Major depression/ Major Depressive Disorder, single episode#	3	03MAR2021	22/C	3	No	O	NA/TC	N	Y/N
		Suicide attempt/ Suicidal Attempt#	3	03MAR2021	22/3	3	No	O	NA	R (05MAR2021)	Y/N
16-55/ C4591001 1131 11311097	SKIN	Pruritus/ generalized pruritus	1	28AUG2020	2/1	1	Yes		NA/TC	R (28AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1131 11311104	GENRL	Chills/ chills	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Fatigue/ fatigue	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1131 11311107	GENRL	Injection site pain/ injection site tenderness	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C4591001 1131 11311111	GENRL	Injection site pain/ pain at injection site#	3	03MAR2021	1/1	1	Yes		NA	R (03MAR2021)	N/N
16-55/ C4591001 1131 11311117	NERV	Dizziness/ Worsening of dizziness	2	08NOV2020	48/2	3	No	O	NA/TC	R (09NOV2020)	N/N
16-55/ C4591001 1131 11311124	GENRL	Injection site pain/ Injection site arm pain	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C4591001 1131 11311129	GENRL	Injection site pain/ Injection site pain in arm	2	24SEP2020	1/4	2	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1131 11311132	INJ&P	Contusion/ right sided facial bruising	2	11OCT2020	20/8	1	No	O	NA	R (18OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1131 11311134	MUSC	Contusion/ right-sided shoulder bruising	2	11OCT2020	20/8	2	No	O	NA	R (18OCT2020)	N/N	
		Fall/ mechanical fall	2	11OCT2020	20/1	2	No	O	NA	R (11OCT2020)	N/N	
		Arthralgia/ shoulder pain, right	2	11OCT2020	20/C	2	No	O	NA/TC	N	N/N	
		Contusion/ contusion on right thigh	1	17SEP2020	15/15	2	No	O	NA	R (01OCT2020)	N/N	
16-55/ C4591001 1131 11311136	GENRL	Road traffic accident/ bicycle accident	1	17SEP2020	15/1	2	No	O	NA	R (17SEP2020)	N/N	
		Skin abrasion/ abrasion right forearm	1	17SEP2020	15/15	2	No	O	NA/TCN	R (01OCT2020)	N/N	
		Injection site pain/ injection site arm pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 1131 11311147	METAB	Decreased appetite/ decreased appetite	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
	SKIN	Night sweats/ night sweats	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N	
	GENRL	Injection site pain/ injection site pain in left arm	2	29SEP2020	2/3	2	Yes		NA	R (01OCT2020)	N/N	
16-55/ C4591001 1131 11311148	GASTR	Nausea/ nausea	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1131 11311152	GENRL	Chills/ chills	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		Injection site pain/ arm pain at injection site	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		Pyrexia/ fever	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1131 11311157	INJ&P	Fall/ Fall	1	25SEP2020	17/1	1	No	O	NA	RS (25SEP2020)	N/N
		Skin abrasion/ bilateral knee abrasion	1	25SEP2020	17/21	1	No	O	NA/TC/TCN	RS (15OCT2020)	N/N
	INFEC	Carbuncle/ both axillary carbuncles	2	24OCT2020	25/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1131 11311157	GENRL	Pyrexia/ low grade temperature#	3	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
	METAB	Decreased appetite/ decreased appetite#	3	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	GASTR	Vomiting/ vomiting#	4	28JAN2021	1/2	1	Yes		NA/TC	R (29JAN2021)	N/N
	GENRL	Chills/ chills#	4	28JAN2021	1/2	1	Yes		NA/TC	R (29JAN2021)	N/N
16-55/ C4591001 1131 11311160	GENRL	Chills/ chills#	3	29DEC2020	1/2	2	Yes		NA	R (30DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1131 11311161	MUSC	Fatigue/ fatigue#	3	29DEC2020	1/2	2	Yes		NA	R (30DEC2020)	N/N
		Pyrexia/ low grade temperature elevation#	3	29DEC2020	1/2	1	Yes		NA/TC	R (30DEC2020)	N/N
		Myalgia/ myalgia#	3	29DEC2020	1/2	2	Yes		NA/TC	R (30DEC2020)	N/N
	SURG	Chondroplasty/ arthroscopic labrum repair left shoulder#	4	03FEB2021	17/1	2	No	O	NA/TC/TCN	R (03FEB2021)	N/N
	GENRL	Fatigue/ fatigue	1	10SEP2020	2/3	2	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	05JAN2021	1/4	2	Yes		NA/TC	R (08JAN2021)	N/N
	GENRL	Pain/ body aches#	4	25JAN2021	1/3	2	Yes		NA/TC	R (27JAN2021)	N/N
	INV	Body temperature increased/ low grade temperature elevation (99.9)#	4	25JAN2021	1/3	1	Yes		NA/TC/TCN	R (27JAN2021)	N/N
	NERV	Headache/ headache#	4	25JAN2021	1/3	2	Yes		NA	R (27JAN2021)	N/N
	BLOOD	Lymphadenopathy/ lymph node swelling right axillary and supra-clavicular#	4	28JAN2021	4/5	2	Yes		NA	R (01FEB2021)	N/N
16-55/ C4591001 1131 11311162	MUSC	Myalgia/ muscle pain in back	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1131 11311172	MUSC	Joint swelling/ right knee swelling	2	02NOV2020	32/C	2	No	O	NA/TC	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ injection site pain#	3	11FEB2021	1/4	2	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1131 11311173	GENRL	Injection site pain/ injection site pain	2	02OCT2020	2/7	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1131 11311178	GENRL	Pyrexia/ fever, 100.7 degrees Fahrenheit	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
	MUSC	Myalgia/ muscle aches	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1131 11311181	GENRL	Chills/ Chills	2	06OCT2020	1/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1131 11311183	NERV	Syncope/ vasovagal episode with syncope*		16SEP2020	1/1	1	No	O	NA	R (16SEP2020)	N/N
16-55/ C4591001 1131 11311190	RESP	Sinus congestion/ Sinus congestion	1	06OCT2020	19/6	1	No	O	NA/TC	R (11OCT2020)	N/N
16-55/ C4591001 1131 11311193	GENRL	Pain/ generalized body pain	1	04OCT2020	17/C	2	No	O	NA/TC	RG	N/N
	INJ&P	Rib fracture/ fracture of left rib	1	04OCT2020	17/C	2	No	O	NA/TC	RG	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1131 11311201	GENRL	Road traffic accident/ bicycle collision with motor vehicle	1	04OCT2020	17/1	2	No	O	NA/TC	RS (04OCT2020)	N/N
		Skin laceration/ laceration of left elbow	1	04OCT2020	17/C	1	No	O	NA/TC/TCN	RG	N/N
		Fatigue/ fatigue	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		Chills/ chills	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
		Fatigue/ fatigue	2	12OCT2020	1/4	1	Yes		NA	R (15OCT2020)	N/N
		Body temperature increased/ elevated temperature, low grade	2	12OCT2020	1/4	1	Yes		NA	R (15OCT2020)	N/N
		Myalgia/ generalized myalgia	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1131 11311209	EYE	Angle closure glaucoma/ narrow angle glaucoma bilateral	2	22FEB2021	134/C	1	No	O	NA/TCN	N	N/N
		Arthralgia/ right knee pain	2	19OCT2020	4/28	1	No	O	NA/TC	R (15NOV2020)	N/N
16-55/ C4591001 1131 11311221	GENRL	Injection site reaction/ injection site reaction#	3	13FEB2021	2/8	2	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1131 11311228	VASC	Hypertension/ worsening hypertension	1	01OCT2020	2/3	1	No	O	NA/TC	R (03OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1131 11311230	MUSC	Myalgia/ muscle pain in left arm#	3	15JAN2021	1/3	1	Yes		NA	R (17JAN2021)	N/N
16-55/ C4591001 1131 11311232	GENRL	Injection site pain/ injection site pain	1	09OCT2020	2/3	1	Yes		NA	R (11OCT2020)	N/N
	NERV	Migraine/ worsening of migraine headache, severe	2	30OCT2020	2/1	3	Yes		NA/TC	R (30OCT2020)	N/N
16-55/ C4591001 1131 11311241	INFEC	Bacterial rhinitis/ bacterial infection in right nostril#	2	17FEB2021	108/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1131 11311243	INJ&P	Fall/ Fall	1	24OCT2020	12/1	2	No	O	NA	R (24OCT2020)	N/N
	MUSC	Musculoskeletal chest pain/ left rib pain	1	24OCT2020	12/C	2	No	O	NA/TC	RG	N/N
	CARD	Atrial fibrillation/ atrial fibrillation	2	01DEC2020	28/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1131 11311253	NERV	Somnolence/ somnolence	1	23OCT2020	1/2	2	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1131 11311254	GENRL	Chills/ chills	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Pain/ body aches	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
		Pyrexia/ fever	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1131 11311257	RESP	Epistaxis/ epistaxis in right nostril, post nasal swab collection	1	29OCT2020	1/5	2	No	CND	NA	R (02NOV2020)	N/N
16-55/ C4591001 1131 11311279	GENRL	Fatigue/ fatigue	2	12JAN2021	2/4	1	Yes		NA	R (15JAN2021)	N/N
		Injection site pain/ injection site pain	2	12JAN2021	2/3	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1133 11331059	GASTR	Vomiting/ vomiting	2	10OCT2020	25/2	2	No	O	NA/TC	R (11OCT2020)	N/N
16-55/ C4591001 1133 11331113	NERV	Headache/ headache	2	27OCT2020	60/5	2	No	O	NA/TC	R (31OCT2020)	N/N
16-55/ C4591001 1133 11331115	GASTR	Vomiting/ vomiting	2	19SEP2020	22/2	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C4591001 1133 11331117	INJ&P	Thermal burn/ right calf skin burn due to contact with very hot motorcycle pipe exhaust.	1	15AUG2020	8/45	2	No	O	NA/TC	R (28SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1133 11331119	NERV	Headache/ headache	1	04SEP2020	24/1	1	No	O	NA	R (04SEP2020)	N/N	
	RESP	Nasal congestion/ NASAL CONGESTION	1	04SEP2020	24/6	1	No	O	NA	R (09SEP2020)	N/N	
16-55/ C4591001 1133 11331120	INFEC	Upper respiratory tract infection/ Upper Respiratory INFECTION	2	01NOV2020	33/	2	No	O	NA	N	N/N	
16-55/ C4591001 1133 11331139	MUSC	Arthralgia/ Worsening left Hip Pain	2	06SEP2020	3/C	1	No	O	NA	RG	N/N	
		Arthralgia/ Worsening left elbow pain	2	06SEP2020	3/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1133 11331152	SKIN	Rash/ Intermittent Rash (arms, legs, and abdomen)	1	31AUG2020	18/9	2	Yes		NA/TC	R (08SEP2020)	N/N	
16-55/ C4591001 1133 11331170	VASC	Hypertension/ Worsening of Hypertension	1	04SEP2020	22/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1133 11331188	GENRL	Pain/ Body Ache	1	31AUG2020	13/4	2	Yes		NA/TC	R (03SEP2020)	N/N	
	NERV	Headache/ Headache	1	31AUG2020	13/4	2	Yes		NA/TC	R (03SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1133 11331195	MUSC	Arthralgia/ JOINT PAIN BOTH ARMS	2	12SEP2020	4/C	1	Yes		NA	N	N/N
16-55/ C4591001 1133 11331198	GENRL	Chills/ CHILLS	2	16SEP2020	8/2	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ FEVER	2	16SEP2020	8/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1133 11331207	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	1	20AUG2020	2/38		No	O	NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1133 11331230	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ injection site pain	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1133 11331263	GENRL	Malaise/ malaise	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
	RESP	Cough/ cough	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ tiredness	2	16SEP2020	1/5	1	Yes		NA	R (20SEP2020)	N/N
		Injection site pain/ injection site pain	2	16SEP2020	1/5	1	Yes		NA	R (20SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1133 11331265	MUSC	Musculoskeletal discomfort/ back discomfort	2	16SEP2020	1/5	1	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ headaches	2	16SEP2020	1/5	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	20SEP2020	5/1	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN	2	20SEP2020	5/1	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Back pain/ back pain	2	19SEP2020	2/3	2	No	CND	NA/TC	R (21SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	04SEP2020	9/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ injection site soreness	1	27AUG2020	1/5	1	Yes		NA	R (31AUG2020)	N/N
	GENRL	Pyrexia/ fever	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
	NERV	Headache/ headaches	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	1	17SEP2020	22/1	1	No	O	NA	R (17SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1133 11331313	GENRL	Chills/ CHILLS	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N	
		Pyrexia/ FEVER	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N	
	NERV	Headache/ HEADACHE	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N	
16-55/ C4591001 1133 11331317	NEOPL	Brain cancer metastatic/ Metastatic Brain Tumor#	2	08FEB2021	139/17	3	No	O	NA/TC	R (24FEB2021)	Y/N	
16-55/ C4591001 1133 11331328	GENRL	Injection site pain/ Soreness injection site	1	30AUG2020	2/2	1	Yes		NA	R (31AUG2020)	N/N	
	EAR	Tinnitus/ Tinnitus - intermittent	1	14SEP2020	17/C	2	No	O	NA	N	N/N	
	NERV	Headache/ Headache	1	14SEP2020	17/60	1	Yes		NA/TCN	R (12NOV2020)	N/N	
16-55/ C4591001 1133 11331335	GENRL	Asthenia/ WEAKNESS#	3	17FEB2021	1/1	1	Yes		NA/TC	R (17FEB2021)	N/N	
16-55/ C4591001 1133 11331346	INFEC	Upper respiratory tract infection/ UPPER Respiratory Infection	1	20SEP2020	23/4	2	No	O	NA/TC	R (23SEP2020)	N/N	
16-55/ C4591001	GENRL	Chills/ CHILLS	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1133 11331360	MUSC	Myalgia/ MUSCLE ACHES	2	23SEP2020	1/3	2	Yes	NA/TC	R (25SEP2020)	N/N		
16-55/ C4591001 1133 11331365	GASTR	Diarrhoea/ DIARRHEA	2	23SEP2020	1/4	1	Yes	NA	R (26SEP2020)	N/N		
	GENRL	Chills/ CHILLS	2	23SEP2020	1/4	2	Yes	NA/TC/TCN	R (26SEP2020)	N/N		
		Pyrexia/ FEVER	2	23SEP2020	1/4	2	Yes	NA/TC/TCN	R (26SEP2020)	N/N		
	NERV	Headache/ HEADACHE	2	23SEP2020	1/4	2	Yes	NA/TC	R (26SEP2020)	N/N		
16-55/ C4591001 1133 11331367	GENRL	Chills/ CHILLS	2	23SEP2020	1/2	1	Yes	NA	R (24SEP2020)	N/N		
		Pyrexia/ FEVER	2	23SEP2020	1/2	2	Yes	NA/TC/TCN	R (24SEP2020)	N/N		
	GASTR	Vomiting/ VOMITING (ONE EPISODE)	2	24SEP2020	2/1	1	Yes	NA	R (24SEP2020)	N/N		
16-55/ C4591001 1133 11331370	GENRL	Pyrexia/ FEVER	2	01OCT2020	2/2	1	Yes	NA	R (02OCT2020)	N/N		
16-55/ C4591001 1133 11331376	GENRL	Pyrexia/ FEVER	2	26SEP2020	2/3	1	Yes	NA	R (28SEP2020)	N/N		



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1133 11331385	INV	Blood glucose abnormal/ UNCONTROLLED BLOOD SUGAR LEVEL	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
	MUSC	Arthralgia/ JOINT PAIN	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
	GENRL	Pyrexia/ FEVER	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	EAR	Vertigo/ Vertigo	2	30SEP2020	8/11	2	No	O	NA/TC	R (10OCT2020)	N/N
	GASTR	Abdominal discomfort/ Stomach upset	2	30SEP2020	8/11	2	No	O	NA/TC	R (10OCT2020)	N/N
	GENRL	Injection site pain/ PAIN IN INJECTION SITE	2	26SEP2020	2/5	1	Yes		NA/TC	R (30SEP2020)	N/N
	MUSC	Pain/ BODY ACHES	2	26SEP2020	2/15	1	Yes		NA/TC	R (10OCT2020)	N/N
	MUSC	Musculoskeletal discomfort/ NECK DISCOMFORT	2	26SEP2020	2/5	1	Yes		NA/TC	R (30SEP2020)	N/N
	NERV	Tension headache/ tension HEADACHE	2	26SEP2020	2/3	1	Yes		NA/TC	R (28SEP2020)	N/N
	GENRL	Pyrexia/ FEVER	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1133 11331398	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	18DEC2020	1/1	1	Yes		NA	R (18DEC2020)	N/Y

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1133 11331408	GENRL	Chills/ CHILLS#	3	19DEC2020	2/1	1	Yes		NA	R (19DEC2020)	N/N	
16-55/ C4591001 1133 11331413	NERV	Headache/ intermittent headache	1	16SEP2020	8/8	1	Yes		NA/TC	R (23SEP2020)	N/N	
	NERV	Headache/ intermittent headaches	2	07OCT2020	8/17	2	Yes		NA/TC	R (23OCT2020)	N/N	
	NERV	Sciatica/ LEFT LEG SCIATICA	2	01NOV2020	33/100	2	No	O	NA/TC/TCN	R (08FEB2021)	N/N	
16-55/ C4591001 1133 11331419	INJ&P	Thermal burn/ left wrist burn	1	17SEP2020	9/5	1	No	O	NA	R (21SEP2020)	N/N	
16-55/ C4591001 1133 11331441	INFEC	Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION (URI)	2	02OCT2020	3/21	1	No	O	NA	R (22OCT2020)	N/N	
16-55/ C4591001 1133 11331450	GASTR	Diarrhoea/ Diarrhea	2	09OCT2020	1/5	1	Yes		NA	R (13OCT2020)	N/N	
	GENRL	Injection site pain/ Pain Injection site	2	09OCT2020	1/4	1	Yes		NA	R (12OCT2020)	N/N	
	NERV	Tension headache/ Tension Headache	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N	
	METAB	Diabetes mellitus/ WORSENING OF DIABETES	2	11OCT2020	3/1	2	No	O	NA/TC	R (11OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1133 11331460	GENRL	Chills/ chills	1	19SEP2020	2/2	2	Yes		NA/TC/TCN	R (20SEP2020)	N/N
		Injection site pain/ injection site pain	1	19SEP2020	2/2	2	Yes		NA/TC/TCN	R (20SEP2020)	N/N
	MUSC	Arthralgia/ joint pain	1	19SEP2020	2/2	2	Yes		NA/TC/TCN	R (20SEP2020)	N/N
16-55/ C4591001 1133 11331463	GENRL	Pain/ body aches	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ fever	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1133 11331465	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	2	15OCT2020	7/6	1	No	O	NA/TCN	R (20OCT2020)	N/N
16-55/ C4591001 1133 11331474	RESP	Rhinorrhoea/ RUNNY NOSE	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA (1 EPISODE)	1	21SEP2020	4/1	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1133 11331478	NERV	Headache/ headache#	3	14FEB2021	13/1	2	No	O	NA/TC	R (14FEB2021)	N/N
16-55/ C4591001	INJ&P	Wound/ LEFT EAR WOUND	2	16NOV2020	28/C	2	No	O	NA/TC/TCN	RG	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1133 11331480 16-55/ C4591001	GASTR	Vomiting/ EMESIS	1	03OCT2020	11/2	2	No	O	NA/TC	R (04OCT2020)	N/N
1133 11331495	GENRL	Pyrexia/ FEVER	2	15OCT2020	2/6	2	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C4591001 1133 11331496†	INJ&P	Foot fracture/ BROKEN PINKY ON LEFT FOOT	1	29SEP2020	7/35	2	No	O	NA/TCN	R (02NOV2020)	N/N
16-55/ C4591001 1133 11331505	GENRL	Influenza like illness/ FLU-LIKE SYMPTOMS	2	14OCT2020	1/13	2	Yes		NA/TC/TCN	R (26OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	14OCT2020	1/7	2	Yes		NA/TC/TCN	R (20OCT2020)	N/N
16-55/ C4591001 1133 11331506	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	14OCT2020	1/5	2	Yes		NA/TC/TCN	R (18OCT2020)	N/N
	GENRL	Influenza like illness/ FLU-LIKE SYMPTOMS	2	15OCT2020	2/2	2	Yes		NA/TC/TCN	R (16OCT2020)	N/N
16-55/ C4591001 1133 11331524	GENRL	Injection site pain/ soreness at injection site	1	25OCT2020	3/4	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001	EAR	Ear pain/ left ear pain	1	11NOV2020	20/15	1	No	O	NA/TCN	R (25NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1133 11331526 16-55/ C4591001	GENRL	Pain/ BODY ACHES	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N	
1133 11331528 16-55/ C4591001	GENRL	Fatigue/ FATIGUE	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N	
1133 11331532		Injection site pain/ SORENESS AT INJECTION SITE	1	23OCT2020	1/8	1	Yes		NA	R (30OCT2020)	N/N	
	NERV	Headache/ HEADACHE	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N	
16-55/ C4591001	MUSC	Intervertebral disc disorder/ Lumbar disc disease	1	08NOV2020	17/C	2	No	O	NA/TC	RG	N/N	
1133 11331537	BLOOD	Lymphadenopathy/ BILATERAL CERVICAL SWOLLEN LYMPH NODES	2	13NOV2020	3/3	1	No	O	NA	R (15NOV2020)	N/N	
	RESP	Oropharyngeal pain/ SORE THROAT	2	13NOV2020	3/3	1	Yes		NA	R (15NOV2020)	N/N	
	PSYCH	Depression/ DEPRESSION#	4	19FEB2021	3/C	1	No	O	NA	N	N/N	
16-55/ C4591001	MUSC	Pain in extremity/ LEFT ARM PAIN	1	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N	
1133 11331546 16-55/ C4591001	NERV	Paraesthesia/ Paresthesia right lower leg	2	18NOV2020	3/C	1	No	O	NA	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1133 11331548 16-55/ C4591001	GENRL	Pyrexia/ FEVER#	3	05FEB2021	1/2	2	Yes		NA/TC	R (06FEB2021)	N/N	
1133 11331552 16-55/ C4591001	NERV	Paraesthesia/ LEFT ARM TINGLING	1	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N	
1133 11331558 16-55/ C4591001	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	26OCT2020	1/2	1	Yes		NA/TC	R (27OCT2020)	N/N	
1133 11331564 16-55/ C4591001	GENRL	Fatigue/ FATIGUE	1	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N	
1133 11331565		Injection site pain/ SORENESS AT INJECTION SITE	1	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N	
		Pain/ BODY ACHES	1	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N	
16-55/ C4591001 1133 11331585	GENRL	Injection site pain/ PAIN AT INJECTION SITE*		29OCT2020	1/3	1	Yes		NA	R (31OCT2020)	N/N	
	GENRL	Chills/ CHILLS	2	19NOV2020	1/2	2	Yes		NA/TC	R (20NOV2020)	N/N	
		Fatigue/ FATIGUE	2	19NOV2020	1/2	2	Yes		NA/TC	R (20NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1133 11331587	GENRL	Pain/ BODY ACHES	2	19NOV2020	1/2	2	Yes		NA/TC	R (20NOV2020)	N/N	
		Pyrexia/ FEVER	2	19NOV2020	1/2	2	Yes		NA/TC	R (20NOV2020)	N/N	
		RESP							NA/TC	R (20NOV2020)	N/N	
		Oropharyngeal pain/ SORE THROAT	2	19NOV2020	1/2	2	Yes		NA/TC	R (20NOV2020)	N/N	
16-55/ C4591001 1133 11331589	GENRL	Pain/ BODY ACHE	2	19NOV2020	1/2	2	Yes		NA/TC/TCN	R (20NOV2020)	N/N	
		RESP							NA	R (20NOV2020)	N/N	
16-55/ C4591001 1133 11331591	NERV	Rhinorrhoea/ RUNNING NOSE	2	19NOV2020	1/2	1	Yes		NA	R (20NOV2020)	N/N	
		Pyrexia/ FEVER	2	20NOV2020	2/1	1	Yes		NA	R (20NOV2020)	N/N	
16-55/ C4591001 1133 11331592	GENRL	Headache/ HEADACHE	2	19NOV2020	1/1	1	Yes		NA	R (19NOV2020)	N/Y	
		Pain/ BODY ACHE	1	30OCT2020	2/1	2	Yes		NA/TC	R (30OCT2020)	N/N	
16-55/ C4591001 1133 11331595	NERV	Pyrexia/ FEVER	1	30OCT2020	2/1	2	Yes		NA/TC/TCN	R (30OCT2020)	N/N	
		INTERMITENT BILATERAL HAND TINGLING	1	09NOV2020	12/C	1	No	O	NA	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1133 11331596	GENRL	Injection site pain/ Soreness at injection site	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N	
16-55/ C4591001 1133 11331600	INFEC	Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION (COUGH, NASAL CONGESTION AND HEADACHE)	1	07NOV2020	10/7	1	No	O	NA	R (13NOV2020)	N/N	
16-55/ C4591001 1133 11331602	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	29OCT2020	1/4	1	Yes		NA	R (01NOV2020)	N/N	
	MUSC	Myalgia/ GENERAL MUSCLE ACHE	2	20NOV2020	2/3	1	Yes		NA	R (22NOV2020)	N/N	
	NERV	Headache/ HEADACHE	2	20NOV2020	2/3	1	Yes		NA	R (22NOV2020)	N/N	
16-55/ C4591001 1133 11331609	GENRL	Pain/ BODY ACHES	1	29OCT2020	1/3	1	Yes		NA	R (31OCT2020)	N/N	
	GASTR	Abdominal discomfort/ UPSET STOMACH	1	31OCT2020	3/4	1	Yes		NA	R (03NOV2020)	N/N	
16-55/ C4591001 1133 11331610	INFEC	Upper respiratory tract infection/ upper respiratory infection	2	15DEC2020	29/6	1	No	O	NA	RS (20DEC2020)	N/N	
16-55/ C4591001 1133 11331612	METAB	Hyperlipidaemia/ HYPERLIPIDEMIA	2	03DEC2020	15/C	2	No	O	NA/TC	N	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	VASC	Hypertension/ HYPERTENSION	2	03DEC2020	15/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1133 11331621	GENRL	Fatigue/ fatigue	2	20NOV2020	2/2	1	Yes		NA	R (21NOV2020)	N/N	
		Pyrexia/ FEVER	2	20NOV2020	2/2	1	Yes		NA	R (21NOV2020)	N/N	
16-55/ C4591001 1133 11331622	NERV	Headache/ HEADACHE	1	29OCT2020	1/2	1	Yes		NA/TC	R (30OCT2020)	N/N	
	NERV	Dysgeusia/ DYSGEUSIA	2	19NOV2020	1/4	1	Yes		NA	R (22NOV2020)	N/N	
16-55/ C4591001 1133 11331625	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	30OCT2020	2/3	1	Yes		NA/TC	R (01NOV2020)	N/N	
16-55/ C4591001 1133 11331627	NERV	Headache/ headache#	3	05FEB2021	1/3	2	Yes		NA/TC	R (07FEB2021)	N/N	
16-55/ C4591001 1133 11331629	GENRL	Pyrexia/ FEVER	2	20NOV2020	2/2	1	Yes		NA/TC/TCN	R (21NOV2020)	N/N	
16-55/ C4591001 1133 11331631	GENRL	Pyrexia/ FEVER	2	20NOV2020	2/4	2	Yes		NA/TC	R (23NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1133 11331637 16-55/ C4591001 1133 11331638 16-55/ C4591001 1133 11331640 16-55/ C4591001 1134 11341005 16-55/ C4591001 1134 11341007 16-55/ C4591001 1134 11341070	NERV	Headache/ HEADACHE	2	20NOV2020	2/4	2	Yes		NA/TC	R (23NOV2020)	N/N	
	RESP	Nasal congestion/ NASAL CONGESTION	2	20NOV2020	2/4	2	Yes		NA/TC	R (23NOV2020)	N/N	
	MUSC	Muscle spasms/ LEFT ARM CRAMP	1	02NOV2020	4/18	1	No	O	NA	R (19NOV2020)	N/N	
	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	31OCT2020	2/3	1	Yes		NA	R (02NOV2020)	N/N	
	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	31OCT2020	2/5	2	Yes		NA/TC/TCN	R (04NOV2020)	N/N	
	BLOOD	Lymphadenopathy/ BILATERAL SWOLLEN CERVICAL LYMPH NODES	2	20NOV2020	2/2	2	Yes		NA/TC/TCN	R (21NOV2020)	N/N	
	MUSC	Joint effusion/ Left Knee Pain secondary to joint effusion	1	14AUG2020	9/15	2	No	O	NA/TC	R (28AUG2020)	N/N	
	RESP	Asthma/ ASTHMA	2	15JAN2021	142/C	2	No	O	NA/TC	N	N/N	
	GASTR	Diarrhoea/ Diarrhea	1	18AUG2020	6/2	1	Yes		NA	R (19AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1134 11341093	INV	Blood pressure increased/ ELEVATED BLOOD PRESSURE#	2	26JAN2021	148/C	2	No	O	NA/TC	N	N/N	
	INFEC	Urinary tract infection/ URINARY TRACT INFECTION#	4	07FEB2021	17/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1134 11341107	GASTR	Diarrhoea/ LOOSE STOOL	2	13DEC2020	96/1	1	No	O	NA	R (13DEC2020)	N/N	
16-55/ C4591001 1134 11341112	GENRL	Pyrexia/ FEVER#	3	17DEC2020	1/2	2	Yes		NA/TC	R (18DEC2020)	N/N	
16-55/ C4591001 1134 11341151	NERV	Headache/ HEADACHE#	3	17DEC2020	1/2	2	Yes		NA/TC	R (18DEC2020)	N/N	
	NERV	Headache/ headache	1	25AUG2020	2/3	3	Yes		NA/TC/TCN	R (27AUG2020)	N/N	
16-55/ C4591001 1134 11341153	GENRL	Pyrexia/ fever	1	26AUG2020	3/1	1	Yes		NA	R (26AUG2020)	N/N	
	GENRL	Fatigue/ fatigue	2	14SEP2020	1/3	3	Yes		NA	R (16SEP2020)	N/N	
	SKIN	Psoriasis/ psoriasis	2	16SEP2020	3/C	2	Yes		NA/TC	N	N/N	
16-55/ C4591001 1134 11341153	EYE	Eye pain/ right eye pain	1	25AUG2020	2/28	2	Yes		P	R (21SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1134 11341154	GASTR	Abdominal discomfort/ upset stomach	1	25AUG2020	2/28	2	Yes		NA/TC	R (21SEP2020)	N/N	
		Diarrhoea/ diarrhea	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N	
		Diarrhoea/ loose stools	1	25AUG2020	2/28	2	Yes		NA	R (21SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	1	25AUG2020	2/28	2	Yes		NA	R (21SEP2020)	N/N	
	MUSC	Muscular weakness/ muscle weakness	1	25AUG2020	2/28	2	Yes		NA	R (21SEP2020)	N/N	
	NERV	Headache/ headache	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N	
			1	25AUG2020	2/1	2	Yes		NA/TC	R (25AUG2020)	N/N	
	GENRL	Chills/ chills#	4	09MAR2021	2/C	1	Yes		NA	N	N/N	
			MUSC	Myalgia/ muscle aches#	4	09MAR2021	2/C	1	Yes		NA	N
	16-55/ C4591001 1134 11341173	GENRL	Chills/ chills#	4	01MAR2021	1/C	1	Yes		NA	N	N/N
4				01MAR2021	1/C	1	Yes		NA	N	N/N	
MUSC		Injection site pain/ injection site pain#	4	01MAR2021	1/C	1	Yes		NA	N	N/N	
			4	01MAR2021	1/C	1	Yes		NA	N	N/N	
MUSC	Myalgia/ muscle pain#	4	01MAR2021	1/C	1	Yes		NA	N	N/N		

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1134 11341174	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	26AUG2020	1/5	3	Yes		NA	R (30AUG2020)	N/N	
	NERV	Headache/ WORSENING HEADACHE	1	27AUG2020	2/8	2	Yes		P/TC	R (03SEP2020)	N/N	
	MUSC	Pain in extremity/ ARM PAIN (LEFT)	1	28AUG2020	3/6	3	Yes		NA/TC	R (02SEP2020)	N/N	
	GENRL	Chest discomfort/ CHEST TIGHTNESS	1	30AUG2020	5/8	2	Yes		NA/TC	R (06SEP2020)	N/N	
	METAB	Hypokalaemia/ HYPOKALEMIA	1	30AUG2020	5/3	1	No	O	NA/TC	R (01SEP2020)	N/N	
16-55/ C4591001 1134 11341188	GENRL	Chills/ chills	2	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001 1134 11341195	INFEC	Bacterial vaginosis/ Bacterial Vaginosis	2	11OCT2020	27/24	1	No	O	NA/TC	R (03NOV2020)	N/N	
	PSYCH	Anxiety/ Anxiety	2	20OCT2020	36/C	2	No	O	NA/TC	RG	N/N	
	GENRL	Pyrexia/ LOW GRADE FEVER#	4	09MAR2021	2/1	2	Yes		NA/TC	R (09MAR2021)	N/N	
16-55/ C4591001 1134 11341225	GENRL	Injection site pain/ Left Arm Soreness at the injection site	1	31AUG2020	1/4	2	Yes		NA	R (03SEP2020)	N/N	
16-55/ C4591001	MUSC	Intervertebral disc protrusion/ Worsening Herniated Lumbar Disc	1	12SEP2020	12/7	2	No	O	NA/TC	R (18SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1134 11341228 16-55/ C4591001 1134 11341236	MUSC	Fibromyalgia/ worsening of fibromyalgia	2	16OCT2020	25/C	2	No	O	NA/TC	RG	N/N	
1134 11341236	CARD	Postural orthostatic tachycardia syndrome/ Postural tachycardia syndrome (POTS)	2	DEC2020	71/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1134 11341248	GENRL	Chills/ chills	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1134 11341254	GENRL	Pain/ body aches Injection site warmth/ warmth at injection site	2 1	23SEP2020 03SEP2020	2/3 1/2	1 1	Yes Yes		NA NA	R (25SEP2020) R (04SEP2020)	N/N N/Y	
16-55/ C4591001 1134 11341259	INFEC	Pneumonia/ right lung pneumonia	2	22OCT2020	29/21	2	No	O	NA/TC	R (11NOV2020)	N/N	
16-55/ C4591001 1134 11341259	GENRL	Fatigue/ FATIGUE	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1134 11341290	GASTR	Injection site pain/ PAIN AT INJECTION SITE Nausea/ nausea	2 2	24SEP2020 30SEP2020	1/2 2/1	2 1	Yes Yes		NA NA	R (25SEP2020) R (30SEP2020)	N/N N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1134 11341295	GENRL	Chills/ chills	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
		Fatigue/ fatigue	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	NERV	Headache/ worsening headache	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
	NERV	Headache/ headache#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1134 11341301	GENRL	Chills/ chills#	4	13JAN2021	2/1	2	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ muscle soreness	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1134 11341308	GENRL	Pyrexia/ Fever	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site erythema/ redness at injection site	2	03OCT2020	3/3	2	Yes		NA	R (05OCT2020)	N/N
		Injection site pruritus/ itching at injection site	2	03OCT2020	3/4	1	Yes		NA	R (06OCT2020)	N/N
	NERV	Head discomfort/ head pressure	2	03OCT2020	3/2	2	Yes		NA	R (04OCT2020)	N/N
	GASTR	Nausea/ NAUSEA	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1134 11341315	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	09SEP2020	1/3	2	Yes		NA/TC	R (11SEP2020)	N/N	
		Injection site swelling/ SWELLING AT INJECTION SITE	1	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N	
16-55/ C4591001 1134 11341321	GENRL	Injection site pain/ left arm muscle pain at injection site	2	01OCT2020	1/3	2	Yes		NA/TC	R (03OCT2020)	N/Y	
		Injection site pain/ Pain at injection site*		10SEP2020	1/4	1	Yes		NA	R (13SEP2020)	N/N	
16-55/ C4591001 1134 11341325	GENRL	Injection site pain/ Shoulder Pain on Injection arm	2	02OCT2020	1/4	2	Yes		NA	R (05OCT2020)	N/N	
		SKIN	Hyperhidrosis/ Sweating	2	02OCT2020	1/1	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1134 11341327	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N	
		IN FEC	Pneumonia/ DOUBLE PNEUMONIA#	2	10MAR2021	160/C	3	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1134 11341344	GENRL	Fatigue/ fatigue	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N	
			Pain/ body aches	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1134 11341351	INV	Blood cholesterol increased/ high cholesterol	1	28SEP2020	14/C	1	No	O	NA/TC	N	N/N	
	METAB	Folate deficiency/ folate deficiency	1	28SEP2020	14/C	1	No	O	NA/TC	N	N/N	
		Vitamin B12 deficiency/ vitamin b12 deficiency	1	28SEP2020	14/C	1	No	O	NA/TC	N	N/N	
		Vitamin D deficiency/ vitamin d deficiency	1	28SEP2020	14/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1134 11341364	GENRL	Injection site mass/ hard knot at injection site#	3	17FEB2021	1/12	1	Yes		NA	R (28FEB2021)	N/N	
		Injection site pain/ soreness at injection site#	3	17FEB2021	1/12	1	Yes		NA	R (28FEB2021)	N/N	
16-55/ C4591001 1134 11341378	GASTR	Nausea/ NAUSEA	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N	
	GENRL	Chills/ CHILLS	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N	
		Pain/ BODY ACHES	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N	
	NERV	Headache/ HEADACHE	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N	
	NERV	Facial paralysis/ Bell's Palsy	2	04NOV2020	9/68	2	Yes		NA/TC	R (10JAN2021)	N/N	
16-55/ C4591001	GENRL	Chills/ chills	2	28OCT2020	1/3	2	Yes		NA/TC	R (30OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1134 11341379		Pyrexia/ low grade fever	2	28OCT2020	1/3	2	Yes		NA/TC	R (30OCT2020)	N/N	
	GENRL	Pain/ body aches	2	29OCT2020	2/2	2	Yes		NA/TC	R (30OCT2020)	N/N	
16-55/ C4591001 1134 11341381	GENRL	Injection site erythema/ Injection Site Redness	2	26OCT2020	1/6	2	Yes		NA	R (31OCT2020)	N/N	
		Injection site swelling/ Injection Site Swelling	2	26OCT2020	1/6	2	Yes		NA	R (31OCT2020)	N/N	
16-55/ C4591001 1134 11341392	GENRL	Injection site erythema/ redness at injection site	2	30OCT2020	1/3	2	Yes		NA	R (01NOV2020)	N/N	
		Injection site pain/ pain at injection site	2	30OCT2020	1/3	2	Yes		NA	R (01NOV2020)	N/N	
	GENRL	Fatigue/ fatigue	2	31OCT2020	2/2	2	Yes		NA	R (01NOV2020)	N/N	
		Pyrexia/ fever	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N	
16-55/ C4591001 1134 11341393	NERV	Presyncope/ vasovagal reaction*		09OCT2020	1/1	2	No	O	NA	R (09OCT2020)	N/N	
16-55/ C4591001 1134 11341404	GENRL	Fatigue/ fatigue	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1134 11341416	MUSC	Arthralgia/ joint pain	1	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N	
	NERV	Headache/ HEADACHE	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N	
	GENRL	Swelling face/ FACIAL SWELLING	1	18OCT2020	4/2	2	Yes		NA/TC	R (19OCT2020)	N/N	
	SKIN	Pruritus/ ITCHING	1	18OCT2020	4/2	2	Yes		NA/TC	R (19OCT2020)	N/N	
	VASC	Hot flush/ HOT FLASHES	1	18OCT2020	4/2	2	Yes		NA	R (19OCT2020)	N/N	
	INJ&P	Ligament sprain/ SPRAINED LEFT ANKLE	1	05NOV2020	22/22	2	No	O	NA	R (26NOV2020)	N/N	
	VASC	Hypertension/ HYPERTENSION	2	NOV2020	1/C	1	No	O	NA/TC	N	N/N	
	INJ&P	Ligament sprain/ Left lower back sprain	2	14NOV2020	4/48	2	No	O	NA	R (31DEC2020)	N/N	
	VASC	Hypertension/ worsening of hypertension	2	01DEC2020	99/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1135 11351016	GENRL	Pyrexia/ fever	2	27AUG2020	2/1	1	Yes		NA/TC	R (27AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1135 11351025	NERV	Headache/ headache	2	27AUG2020	2/1	1	Yes		NA/TC	R (27AUG2020)	N/N	
16-55/ C4591001 1135 11351037	INFEC	Urinary tract infection/ urinary tract infection	1	07AUG2020	3/11	1	No	O	NA/TC	R (17AUG2020)	N/N	
16-55/ C4591001 1135 11351038	GENRL	Pain/ bodyaches#	3	29DEC2020	1/2	1	Yes		NA/TC	R (30DEC2020)	N/N	
	NERV	Lethargy/ lethargy#	3	29DEC2020	1/2	1	Yes		NA/TC	R (30DEC2020)	N/N	
16-55/ C4591001 1135 11351041	GASTR	Dyspepsia/ exacerbation of heartburn	2	04SEP2020	8/5	1	No	O	NA/TC	R (08SEP2020)	N/N	
16-55/ C4591001 1135 11351052	SKIN	Skin ulcer/ right foot ulcer	2	28AUG2020	2/7	1	No	O	NA	R (03SEP2020)	N/N	
16-55/ C4591001 1135 11351057	INFEC	Hordeolum/ left eye stye	1	15AUG2020	9/46	1	No	O	NA/TC	R (29SEP2020)	N/N	
	GENRL	Pain/ bodyaches#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N	
		Pyrexia/ fever#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351059	NERV	Headache/ headache#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	11MAR2021	1/3	1	Yes		NA/TC	R (13MAR2021)	N/N
		Pain/ body aches#	4	11MAR2021	1/C	1	Yes		NA	N	N/N
16-55/ C4591001 1135 11351061		Pyrexia/ fever#	4	11MAR2021	1/3	1	Yes		NA	R (13MAR2021)	N/N
	SKIN	Dermatitis contact/ allergic reaction to poison oak (left arm)	1	18AUG2020	12/16	2	No	O	NA/TC	R (02SEP2020)	N/N
16-55/ C4591001 1135 11351068	GENRL	Injection site pain/ pain at injection site#	3	19FEB2021	1/2	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1135 11351105	NERV	Headache/ headache#	3	19FEB2021	1/2	1	Yes		NA/TC	R (20FEB2021)	N/N
	INFEC	Urinary tract infection/ Urinary tract infection	1	13AUG2020	2/13	1	No	O	NA/TC	R (25AUG2020)	N/N
	MUSC	Back pain/ lower back pain	1	13AUG2020	2/83	1	No	O	NA/TCN	R (03NOV2020)	N/N
	REPRO	Prostatomegaly/ enlarged prostate	2	01NOV2020	63/C	1	No	O	NA/TC	RG	N/N
	INJ&P	Limb injury/ right shoulder injury#	2	15FEB2021	169/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351111	GENRL	Fatigue/ Fatigue#	3	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
		Pain/ body aches#	3	13FEB2021	2/2	1	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1135 11351121	INFEC	Herpes zoster/ shingles	1	17AUG2020	5/8	1	No	O	NA/TC	R (24AUG2020)	N/N
	PSYCH	Depression/ worsening of depression	2	15DEC2020	104/8	1	No	O	NA/TC	R (22DEC2020)	N/N
	GENRL	Chills/ chills#	4	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N
		Fatigue/ fatigue#	4	10FEB2021	1/4	2	Yes		NA	R (13FEB2021)	N/N
	MUSC	Myalgia/ muscle aches (generalized)#	4	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1135 11351142	GASTR	Nausea/ Nausea	1	17AUG2020	1/3	1	No	O	NA	R (19AUG2020)	N/N
	GASTR	Dental caries/ dental caries	1	04SEP2020	19/1	1	No	O	NA/TC	R (04SEP2020)	N/N
16-55/ C4591001 1135 11351144	MUSC	Back pain/ lower back pain	1	10SEP2020	25/11	1	No	O	NA/TC	R (20SEP2020)	N/N
16-55/ C4591001	MUSC	Pain in extremity/ Left arm pain	1	22AUG2020	5/2	1	No	O	NA	R (23AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1135 11351151	MUSC	Pain in extremity/ soreness on both arms and legs	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
1135 11351158	GENRL	Fatigue/ fatigue	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
1135 11351163	NERV	Headache/ headache	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Chills/ chills#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
		Pain/ bodyaches#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1135 11351166	GENRL	Chills/ chills	2	10SEP2020	1/2	2	Yes		NA/TC	R (11SEP2020)	N/N
		Pain/ bodyaches	2	10SEP2020	1/2	2	Yes		NA/TC	R (11SEP2020)	N/N
	NERV	Headache/ headache	1	10SEP2020	22/2	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1135 11351168	GENRL	Fatigue/ Fatigue	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	PSYCH	Attention deficit hyperactivity disorder/ Attention deficit disorder worsening	2	DEC2020	82/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1135 11351172	GASTR	Diarrhoea/ loose stool	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Pain/ bodyaches	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GASTR	Diarrhoea/ loose stool	2	12OCT2020	33/1	1	No	O	NA	R (12OCT2020)	N/N
16-55/ C4591001 1135 11351178	INFEC	Cellulitis/ left toe cellulitis	2	25SEP2020	16/4	1	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C4591001 1135 11351179	NERV	Syncope/ syncope episode*		21AUG2020	1/1	1	No	O	NA	R (21AUG2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
		Pain/ bodyaches#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
	GENRL	Chills/ chills#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
		Pain/ bodyaches#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
		Pyrexia/ fever#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351184	MUSC	Musculoskeletal chest pain/ muscle pain (chest)#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Pain/ Generalized pains	2	10DEC2020	88/2	1	No	O	NA/TC	R (11DEC2020)	N/N
	GENRL	Pain/ bodyaches#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N
16-55/ C4591001 1135 11351190		Pyrexia/ fever#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1135 11351198		Pyrexia/ Fever	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ headache	1	24AUG2020	1/33	1	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1135 11351201	GENRL	Pain/ body aches	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	18SEP2020	2/3	1	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1135 11351205	GASTR	Diarrhoea/ loose bowel movement	1	07SEP2020	14/1	1	No	O	NA/TC	R (07SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351222	GENRL	Injection site pain/ soreness left upper arm injection site	1	31AUG2020	1/2	1	Yes		NA/TC	R (01SEP2020)	N/N
16-55/ C4591001 1135 11351225	GENRL	Chills/ chills#	3	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ pain at injection site#	3	22FEB2021	1/3	1	Yes		NA/TC	R (24FEB2021)	N/N
		Pyrexia/ fever#	3	22FEB2021	1/3	1	Yes		NA/TC	R (24FEB2021)	N/N
	NERV	Headache/ headache#	3	22FEB2021	1/3	1	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1135 11351227	GENRL	Injection site pain/ Pain at Injection Site	1	01SEP2020	2/4	1	Yes		NA	R (04SEP2020)	N/N
		Pain/ Body Aches	1	01SEP2020	2/4	1	Yes		NA	R (04SEP2020)	N/N
	RESP	Nasal congestion/ Nasal Congestion	1	01SEP2020	2/4	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Chills/ chills	2	22SEP2020	2/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		Injection site pain/ pain at injection site	2	22SEP2020	2/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		Pain/ body aches	2	22SEP2020	2/3	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1135 11351228	MUSC	Myalgia/ muscle pain	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001 1135 11351229	GENRL	Injection site pain/ Pain on Injection Site	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection site soreness	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		Pain/ Body Aches	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
		Pyrexia/ Fever	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
	SKIN	Rash/ localized rash (scalp, neck, face)	2	16JAN2021	118/1	1	No	O	NA/TC	R (16JAN2021)	N/N
16-55/ C4591001 1135 11351231	GENRL	Pain/ bodyaches#	4	09JAN2021	2/2	2	Yes		NA	R (10JAN2021)	N/N
		Pyrexia/ fever#	4	09JAN2021	2/2	2	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ headache#	4	09JAN2021	2/2	2	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1135 11351235	NERV	Syncope/ vasovagal syncope*		31AUG2020	1/1	1	No	O	NA	R (31AUG2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1135 11351243		Pain/ Body Aches	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 1135 11351251	GENRL	Pain/ body aches	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N	
	GENRL	Pain/ Body Aches	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
		Pyrexia/ fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 1135 11351256	MUSC	Myalgia/ Muscle Aches	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1135 11351265	MUSC	Arthralgia/ pain on right knee	2	30OCT2020	36/60	1	No	O	NA/TC	R (28DEC2020)	N/N	
	VASC	Accelerated hypertension/ accelerated hypertension	2	23JAN2021	121/5	3	No	O	NA/TC	R (27JAN2021)	Y/N	
	VASC	Hypertension/ Hypertension	2	26JAN2021	124/2	2	No	O	NA/TC	R (27JAN2021)	N/N	
16-55/ C4591001 1135 11351269	GENRL	Pain/ body aches	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
		Pyrexia/ low grade temperature	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351276	NERV	Lethargy/ lethargy	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GASTR	Constipation/ worsening of constipation	2	21JAN2021	119/10	1	No	O	NA/TC/TCN	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		Pain/ Body Aches	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1135 11351281	GENRL	Pyrexia/ Fever	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		Chills/ chills#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1135 11351282	GENRL	Pain/ bodyaches#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
		Fatigue/ fatigue	2	24SEP2020	1/4	2	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1135 11351285	GENRL	Injection site pain/ pain at injection site	2	24SEP2020	1/4	1	Yes		NA/TC	R (27SEP2020)	N/N
		Pyrexia/ low grade temperature (99.1)	2	02MAR2021	159/2	1	No	O	NA	R (03MAR2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site soreness	1	03SEP2020	1/4	1	Yes		NA	R (06SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1135 11351290	GENRL	Pyrexia/ fever	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1135 11351292	GENRL	Chills/ chills	1	04SEP2020	2/32	1	Yes		NA	R (05OCT2020)	N/N
		Pain/ body aches	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
		Pyrexia/ fever	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1135 11351293	GENRL	Pain/ body aches#	3	19DEC2020	2/3	1	Yes		NA/TC	R (21DEC2020)	N/N
	GENRL	Chills/ chills#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Pain/ bodyaches#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/N
16-55/ C4591001 1135 11351297	GENRL	Pain/ body aches	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351313	GENRL	Pyrexia/ low grade temperature	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
		Pyrexia/ Fever (101.3)#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/N
16-55/ C4591001 1135 11351323	GASTR	Diarrhoea/ loose bowel movement	1	13SEP2020	6/1	1	No	O	NA	R (13SEP2020)	N/N
16-55/ C4591001 1135 11351326	GENRL	Injection site pain/ Pain at injection site	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
	GASTR	Diarrhoea/ loose stool	2	02OCT2020	4/45	1	No	O	NA/TCN	R (15NOV2020)	N/N
	GENRL	Gastrointestinal sounds abnormal/ borborygmus	2	02OCT2020	4/45	1	No	O	NA/TCN	R (15NOV2020)	N/N
16-55/ C4591001 1135 11351330	GENRL	Injection site pain/ pain at injection site	2	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1135 11351332	INFEC	Urinary tract infection/ urinary tract infection	1	14SEP2020	6/8	1	No	O	NA/TC	R (21SEP2020)	N/N
16-55/ C4591001 1135 11351349	GENRL	Chills/ Chills	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Headache/ headache	2	02OCT2020	1/3	2	Yes		NA/TC	R (04OCT2020)	N/N
16-55/ C4591001 1135 11351359	INFEC	Vulvovaginal mycotic infection/ vaginal yeast infection	1	01OCT2020	15/6	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1135 11351361	GENRL	Chills/ chills#	3	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
		Fatigue/ fatigue#	3	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ pain at injection site#	3	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
	GENRL	Chills/ chills#	4	13MAR2021	3/1	1	Yes		NA	R (13MAR2021)	N/N
16-55/ C4591001 1135 11351362	GENRL	Fatigue/ fatigue#	4	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
		Pyrexia/ low grade temperature#	4	05FEB2021	2/2	2	Yes		NA/TC	R (06FEB2021)	N/N
	MUSC	Myalgia/ generalized muscle pain#	4	05FEB2021	2/2	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1135 11351368	NERV	Guillain-Barre syndrome/ Guillain barre syndrome	2	29DEC2020	84/C	3	No	O	NA/TC/TCN	RG	Y/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1135 11351373	GASTR	Diarrhoea/ diarrhea	1	24SEP2020	7/2	1	No	O	NA/TC/TCN	R (25SEP2020)	N/N	
16-55/ C4591001 1135 11351374	GENRL	Fatigue/ Fatigue#	4	08JAN2021	2/2	1	Yes		NA/TC/TCN	R (09JAN2021)	N/N	
	NERV	Headache/ Headache#	4	08JAN2021	2/2	1	Yes		NA/TC/TCN	R (09JAN2021)	N/N	
16-55/ C4591001 1135 11351375	GENRL	Injection site pain/ pain at injection site#	3	06FEB2021	3/4	2	Yes		NA	R (09FEB2021)	N/N	
	GENRL	Injection site pain/ pain at injection site#	4	25FEB2021	2/15	2	Yes		NA/TC	R (11MAR2021)	N/N	
16-55/ C4591001 1135 11351376	PSYCH	Anxiety/ worsening of anxiety	2	01NOV2020	23/15	1	No	O	NA/TC	R (15NOV2020)	N/N	
16-55/ C4591001 1135 11351377	GENRL	Chills/ Chills	1	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N	
		Fatigue/ fatigue	1	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N	
		Pain/ Body Aches	1	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N	
	NERV	Headache/ Headache	1	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351381	GENRL	Injection site pain/ Pain at injection site	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1135 11351383	NERV	Headache/ Headache	1	16OCT2020	28/1	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1135 11351387	GENRL	Pain/ bodyaches#	3	17FEB2021	2/1	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1135 11351391	GENRL	Pyrexia/ fever (subjective) - low grade	2	01NOV2020	24/2	1	No	O	NA/TC	R (02NOV2020)	N/N
	GASTR	Toothache/ pain - right molar bottom tooth	2	03NOV2020	26/1	1	No	O	NA/TC	R (03NOV2020)	N/N
16-55/ C4591001 1135 11351392	GENRL	Injection site pain/ soreness at injection site - left arm	1	19SEP2020	1/2	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1135 11351403	MUSC	Back pain/ Exacerbation of lower back pain	1	22SEP2020	2/1	1	No	O	NA/TC	R (22SEP2020)	N/N
	GASTR	Diarrhoea/ loose bowel movements	1	24SEP2020	4/2	1	No	O	NA	R (25SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue	1	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1135 11351404		Pain/ Body Aches	1	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
	GASTR	Nausea/ nausea	1	14OCT2020	24/1	1	No	O	NA	R (14OCT2020)	N/N
	NERV	Dizziness/ dizziness	1	14OCT2020	24/1	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C4591001 1135 11351405	GENRL	Chills/ chills	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
		Pain/ body aches	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
		Pyrexia/ fever	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1135 11351416	GENRL	Injection site pain/ Pain at injection site	1	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Chills/ Chills	1	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
		Pyrexia/ Fever	1	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Chills/ chills	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
		Fatigue/ fatigue	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
		Pyrexia/ fever	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1135 11351417	MUSC	Myalgia/ muscle aches	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N	
	NERV	Headache/ headache	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N	
	GENRL	Injection site pain/ soreness on injection site (left arm)	1	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N	
	RESP	Nasal congestion/ nasal congestion	1	11OCT2020	19/2	1	No	O	NA/TC	R (12OCT2020)	N/N	
	GASTR	Nausea/ nausea	1	15OCT2020	23/3	1	No	O	NA	R (17OCT2020)	N/N	
	NERV	Headache/ headache	1	15OCT2020	23/1	1	No	O	NA	R (15OCT2020)	N/N	
	SKIN	Hyperhidrosis/ sweating	1	15OCT2020	23/1	1	No	O	NA	R (15OCT2020)	N/N	
	GENRL	Pain/ bodyaches#	3	30DEC2020	2/33	1	Yes		NA	R (31JAN2021)	N/N	
	NERV	Headache/ headache#	3	30DEC2020	2/2	1	Yes		NA	R (31DEC2020)	N/N	
	GENRL	Chills/ chills#	4	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N	
NERV	Dizziness/ dizziness#	4	19JAN2021	2/3	1	Yes		NA	R (21JAN2021)	N/N		

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1135 11351434	BLOOD	Headache/ headache#	4	19JAN2021	2/1	1	Yes		NA/TC	R (19JAN2021)	N/N	
		Lymphadenopathy/ cervical lymphadenopathy (bilateral)	1	10OCT2020	17/11	1	No	O	NA	R (20OCT2020)	N/N	
16-55/ C4591001 1135 11351435	GENRL	Pyrexia/ fever	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001 1135 11351439	NERV	Headache/ Headache	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N	
	RESP	Rhinitis allergic/ Exacerbating allergic rhinitis	1	28SEP2020	4/15	1	No	O	NA/TC	R (12OCT2020)	N/N	
16-55/ C4591001 1135 11351440	GENRL	Injection site erythema/ redness on the injection site	1	21OCT2020	1/4	1	Yes		NA	R (24OCT2020)	N/N	
		Injection site pain/ soreness at the injection site	1	21OCT2020	1/4	1	Yes		NA	R (24OCT2020)	N/N	
		Injection site swelling/ swelling at injection site	1	21OCT2020	1/15	1	Yes		NA/TCN	R (04NOV2020)	N/N	
16-55/ C4591001 1135 11351441	INFEC	Urinary tract infection/ urinary tract infection	2	27NOV2020	17/13	1	No	O	NA/TC	R (09DEC2020)	N/N	
	GENRL	Fatigue/ Tiredness	1	21OCT2020	1/1	1	Yes		NA	R (21OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351443	GENRL	Injection site pain/ pain at injection site#	3	18DEC2020	1/2	1	Yes		NA/TC	R (19DEC2020)	N/N
	MUSC	Myalgia/ muscle pain	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1135 11351448	GENRL	Chills/ chills	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
	METAB	Hypokalaemia/ hypokalemia	1	03NOV2020	14/1	1	No	O	NA/TC	R (03NOV2020)	N/N
16-55/ C4591001 1135 11351450	MUSC	Neck pain/ neck pain	1	03NOV2020	14/2	3	No	O	NA/TC/TCN	R (04NOV2020)	N/N
	NERV	Headache/ headache	1	03NOV2020	14/2	3	No	O	NA/TC/TCN	R (04NOV2020)	N/N
	MUSC	Arthritis/ Right shoulder arthritis	2	07DEC2020	27/C	2	No	O	NA/TC	RG	N/N
	GASTR	Diarrhoea/ loose stool	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
	MUSC	Pain in extremity/ left hand pain	2	10NOV2020	2/53	1	No	O	NA/TC	R (01JAN2021)	N/N
	GENRL	Fatigue/ fatigue	2	12NOV2020	4/2	1	Yes		NA	R (13NOV2020)	N/N
	GASTR	Diarrhoea/ diarrhea	2	13NOV2020	5/3	1	Yes		NA	R (15NOV2020)	N/N
	INFEC	Helicobacter infection/ H. pylori infection	2	29DEC2020	51/16	1	No	O	NA/TC	R (13JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1135 11351452	GENRL	Chills/ chills	2	10NOV2020	2/3	1	Yes		NA/TC	R (12NOV2020)	N/N	
		Pain/ bodyaches	2	10NOV2020	2/3	1	Yes		NA/TC	R (12NOV2020)	N/N	
16-55/ C4591001 1135 11351453	GENRL	Fatigue/ fatigue	1	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N	
	INV	Body temperature increased/ elevated temperature	1	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N	
16-55/ C4591001 1135 11351457	NEOPL	Uterine leiomyoma/ uterine fibroids	1	11NOV2020	22/C	1	No	O	NA	RG	N/N	
	GENRL	Chills/ chills	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N	
	INV	Body temperature increased/ elevated temperature	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N	
	NERV	Headache/ headache	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N	
16-55/ C4591001 1135 11351460	NERV	Headache/ headache	1	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N	
16-55/ C4591001 1135 11351462	NERV	Headache/ Headache	2	12NOV2020	2/3	1	No	O	NA/TC	R (14NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351465	METAB	Iron deficiency/ Iron deficiency	2	05FEB2021	87/C	1	No	O	NA/TC	N	N/N
	GENRL	Chills/ chills	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
		Pain/ body aches	2	12NOV2020	2/1	1	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1135 11351469	NERV	Headache/ headache	2	12NOV2020	2/1	1	Yes		NA/TC	R (12NOV2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N
	MUSC	Myalgia/ muscle aches (generalized)#	3	18FEB2021	1/3	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1135 11351472	NERV	Headache/ headache#	3	18FEB2021	1/4	1	Yes		NA/TC	R (21FEB2021)	N/N
	GENRL	Injection site pain/ soreness on injection site (left arm)	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Chills/ chills	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001		Pain/ body aches	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		Pyrexia/ fever	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
	EAR	Vertigo/ vertigo*		22OCT2020	1/2	1	Yes		NA/TC	R (23OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1135 11351475	GENRL	Pain/ body aches	2	13NOV2020	2/1	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1135 11351476	GENRL	Injection site pain/ pain at injection site	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
		Pyrexia/ low grade temperature	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
	NERV	Headache/ headache	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1135 11351482	GENRL	Chills/ chills	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Chills/ chills	2	11NOV2020	1/2	1	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1135 11351487	GENRL	Chills/ chills#	3	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ pain at injection site#	3	23FEB2021	1/2	1	Yes		NA/TC	R (24FEB2021)	N/N
		Pain/ bodyaches#	3	23FEB2021	1/2	1	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1135 11351490	GENRL	Injection site pain/ pain at injection site	1	23OCT2020	1/4	1	Yes		NA/TC	R (26OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351491	GENRL	Pain/ body aches	1	23OCT2020	1/4	1	Yes		NA/TC	R (26OCT2020)	N/N
		Fatigue/ fatigue	2	14NOV2020	2/3	1	Yes		NA/TC	R (16NOV2020)	N/N
	Pain/ bodyaches	2	14NOV2020	2/3	1	Yes		NA/TC	R (16NOV2020)	N/N	
	Chills/ chills	1	23OCT2020	1/3	1	Yes		NA/TC	R (25OCT2020)	N/N	
16-55/ C4591001 1135 11351492	GENRL	Pain/ body aches	1	23OCT2020	1/3	1	Yes		NA/TC	R (25OCT2020)	N/N
	GENRL	Fatigue/ fatigue	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001 1135 11351492	GENRL	Pain/ bodyaches#	3	28FEB2021	3/1	1	Yes		NA/TC	R (28FEB2021)	N/N
16-55/ C4591001 1135 11351495	GENRL	Injection site pain/ pain at injection site	2	13NOV2020	1/4	1	Yes		NA	R (16NOV2020)	N/N
16-55/ C4591001	GENRL	Pain/ body aches	2	13NOV2020	1/4	1	Yes		NA/TC	R (16NOV2020)	N/N
		Chills/ chills	2	14NOV2020	2/1	2	Yes		NA/TC	R (14NOV2020)	N/N
	Pyrexia/ low grade temperature	2	14NOV2020	2/3	1	Yes		NA/TC	R (16NOV2020)	N/N	
16-55/ C4591001	GENRL	Fatigue/ fatigue	1	23OCT2020	1/1	1	Yes		NA	R (23OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1135 11351496		Injection site pain/ pain on injection site left arm	1	23OCT2020	1/1	1	Yes		NA	R (23OCT2020)	N/N	
	INJ&P	Foot fracture/ broken right middle toe	2	01DEC2020	20/14	1	No	O	NA	R (14DEC2020)	N/N	
	GENRL	Injection site pain/ pain at injection site#	3	03FEB2021	1/2	1	Yes		NA/TC	R (04FEB2021)	N/N	
	NERV	Headache/ headache#	3	03FEB2021	1/2	1	Yes		NA/TC	R (04FEB2021)	N/N	
	GASTR	Vomiting/ vomiting#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	2	13NOV2020	1/1	1	Yes		NA	R (13NOV2020)	N/N	
1135 11351497												
16-55/ C4591001	GENRL	Pain/ body aches	1	24OCT2020	2/2	1	Yes		NA/TC	R (25OCT2020)	N/N	
1135 11351498												
	GENRL	Injection site pain/ Pain at injection site	2	13NOV2020	1/1	1	Yes		NA	R (13NOV2020)	N/N	
	GENRL	Chills/ chills	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N	
		Pyrexia/ fever	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N	
	MUSC	Myalgia/ muscle aches	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N	
16-55/ C4591001	PSYCH	Depression/ worsening of depression	2	JAN2021	50/C	2	No	O	NA/TC	RG	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1135 11351499 16-55/ C4591001 1135 11351501	GENRL	Chills/ chills	1	25OCT2020	3/2	1	Yes		NA/TC	R (26OCT2020)	N/N
		Pain/ body aches	1	25OCT2020	3/3	1	Yes		NA/TC	R (27OCT2020)	N/N
	INV	Body temperature increased/ elevated temperature	1	25OCT2020	3/2	1	Yes		NA/TC	R (26OCT2020)	N/N
	NERV	Headache/ headache	1	25OCT2020	3/3	1	Yes		NA/TC	R (27OCT2020)	N/N
	GENRL	Chills/ chills	2	13NOV2020	2/2	1	Yes		NA/TC	R (14NOV2020)	N/N
		Pain/ body aches	2	13NOV2020	2/2	1	Yes		NA/TC	R (14NOV2020)	N/N
	INV	Body temperature increased/ elevated temperature	2	13NOV2020	2/2	1	Yes		NA/TC	R (14NOV2020)	N/N
	NERV	Headache/ headache	2	13NOV2020	2/2	1	Yes		NA/TC	R (14NOV2020)	N/N
	GENRL	Fatigue/ fatigue#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
		Injection site pain/ pain at injection site#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1135 11351505	GENRL	Fatigue/ fatigue	2	14NOV2020	2/2	1	No	O	NA	R (15NOV2020)	N/N
		Pain/ body aches	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351508	NERV	Pyrexia/ low grade temp	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N
		Headache/ worsening headache	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N
	GENRL	Injection site pain/ pain at injection site	1	24OCT2020	2/2	1	Yes		NA/TC	R (25OCT2020)	N/N
		Pain/ body aches	1	24OCT2020	2/2	1	Yes		NA/TC	R (25OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N
		Injection site pain/ pain at injection site	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N
16-55/ C4591001 1135 11351509	MUSC	Pyrexia/ fever	2	14NOV2020	2/2	2	Yes		NA/TC	R (15NOV2020)	N/N
		Arthralgia/ joint aches (hands)	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N
	GENRL	Injection site pain/ pain at injection site	1	23OCT2020	1/4	1	Yes		NA/TC	R (26OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	13NOV2020	1/3	1	Yes		NA/TC	R (15NOV2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N
	NERV	Headache/ headache	2	14NOV2020	2/2	2	Yes		NA/TC	R (15NOV2020)	N/N
	GENRL	Injection site pain/ right arm injection site pain	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1135 11351513	NERV	Headache/ headache	2	13NOV2020	2/1	1	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1135 11351514	GENRL	Pain/ body aches	1	24OCT2020	1/2	1	Yes		NA	R (25OCT2020)	N/N
	NERV	Headache/ Headache (worsening)	1	24OCT2020	1/3	1	No	O	NA/TC	R (26OCT2020)	N/N
	RESP	Nasal congestion/ nasal congestion	1	24OCT2020	1/3	1	Yes		NA	R (26OCT2020)	N/N
	INFEC	Fungal infection/ yeast infection	2	15JAN2021	65/16	1	No	O	NA/TC	R (30JAN2021)	N/N
	INFEC	Ureaplasma infection/ urea plasma infection	2	28JAN2021	78/6	1	No	O	NA/TC	R (02FEB2021)	N/N
16-55/ C4591001 1135 11351516	GENRL	Chills/ chills#	4	11MAR2021	1/2	1	Yes		NA	R (12MAR2021)	N/N
		Fatigue/ fatigue#	4	11MAR2021	1/C	1	Yes		NA	N	N/N
	NERV	Headache/ headache#	4	11MAR2021	1/C	1	Yes		NA	N	N/N
16-55/ C4591001 1135 11351517	GENRL	Pain/ body aches	1	24OCT2020	1/1	1	Yes		NA	R (24OCT2020)	N/N
	NERV	Dizziness/ dizziness	1	24OCT2020	1/1	1	No	O	NA	R (24OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	NERV	Headache/ headache	1	25OCT2020	2/1	1	Yes		NA/TC	R (25OCT2020)	N/N	
	GENRL	Fatigue/ fatigue	2	16NOV2020	1/3	2	Yes		NA	R (18NOV2020)	N/N	
		Pain/ bodyaches	2	16NOV2020	1/1	1	Yes		NA	R (16NOV2020)	N/N	
	NERV	Headache/ headache	2	16NOV2020	1/2	2	Yes		NA/TC	R (17NOV2020)	N/N	
	GENRL	Chills/ chills#	4	12MAR2021	1/C	1	Yes		NA	N	N/N	
		Pain/ bodyaches#	4	12MAR2021	1/C	1	Yes		NA	N	N/N	
		Pyrexia/ fever#	4	12MAR2021	1/C	1	Yes		NA	N	N/N	
	NERV	Migraine/ migraine (worsening)#	4	12MAR2021	1/C	1	Yes		NA/TC	N	N/N	
16-55/ C4591001 1135 11351518	GENRL	Injection site pain/ pain at injection site	1	24OCT2020	1/2	1	Yes		NA/TC	R (25OCT2020)	N/N	
	GENRL	Chills/ chills	2	12NOV2020	1/2	1	Yes		NA/TC	R (13NOV2020)	N/N	
		Fatigue/ fatigue	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N	
		Injection site pain/ pain at injection site	2	12NOV2020	1/2	1	Yes		NA/TC	R (13NOV2020)	N/N	
		Pain/ body aches	2	12NOV2020	1/2	1	Yes		NA/TC	R (13NOV2020)	N/N	
16-55/ C4591001	GENRL	Chills/ chills#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1135 11351519		Pyrexia/ fever#	4	22FEB2021	1/3	1	Yes		NA/TC	R (24FEB2021)	N/N
	NERV	Headache/ headache#	4	22FEB2021	1/3	1	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1135 11351520	MUSC	Myalgia/ muscle pain	1	25OCT2020	2/1	1	Yes		NA/TC	R (25OCT2020)	N/N
	GENRL	Chills/ chills	2	13NOV2020	1/3	2	Yes		NA	R (15NOV2020)	N/N
		Injection site pain/ pain at injection site	2	13NOV2020	1/3	2	Yes		NA	R (15NOV2020)	N/N
	GENRL	Pain/ bodyaches	2	14NOV2020	2/2	2	Yes		NA/TC	R (15NOV2020)	N/N
16-55/ C4591001 1135 11351521	GENRL	Pyrexia/ low grade temperature	1	25OCT2020	2/2	1	Yes		NA	R (26OCT2020)	N/N
	NERV	Lethargy/ lethargy	1	25OCT2020	2/2	1	Yes		NA	R (26OCT2020)	N/N
	NERV	Headache/ headache	2	14NOV2020	2/1	1	Yes		NA/TC	R (14NOV2020)	N/N
		Lethargy/ lethargy	2	14NOV2020	2/1	1	Yes		NA/TC	R (14NOV2020)	N/N
16-55/ C4591001 1135 11351524	RESP	Asthma exercise induced/ exercise induced asthma	2	30NOV2020	18/C	1	No	O	NA/TC	RG	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache#	3	03FEB2021	1/2	1	Yes		NA/TC	R (04FEB2021)	N/N
	GASTR	Vomiting/ vomiting#	3	04FEB2021	2/1	1	Yes		NA/TC	R (04FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
	MUSC	Arthralgia/ generalized joint pain#	4	23FEB2021	1/2	1	Yes		NA/TC	R (24FEB2021)	N/N
	NERV	Headache/ headache#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1135 11351525	GENRL	Chills/ Chills	1	25OCT2020	2/1	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001 1135 11351528	GASTR	Diarrhoea/ loose stool	1	26OCT2020	3/1	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C4591001 1135 11351530	GENRL	Injection site pain/ pain at injection site	1	25OCT2020	2/2	1	Yes		NA/TC	R (26OCT2020)	N/N
	NERV	Headache/ headache	1	25OCT2020	2/2	1	Yes		NA/TC	R (26OCT2020)	N/N
16-55/ C4591001 1135 11351531	GENRL	Fatigue/ fatigue	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Pain/ body aches	2	14NOV2020	2/1	1	Yes		NA	R (14NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351532	NERV	Migraine/ migraine (headache)	2	15NOV2020	3/2	2	No	O	NA/TC	R (16NOV2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1135 11351533	NERV	Paraesthesia/ tingling sensation entire body	2	14NOV2020	3/4	1	Yes		NA	R (17NOV2020)	N/N
16-55/ C4591001 1135 11351534	GENRL	Pain/ bodyaches	2	15NOV2020	4/3	1	Yes		NA	R (17NOV2020)	N/N
	MUSC	Arthralgia/ joint pain (generalized)	2	15NOV2020	4/3	1	Yes		NA	R (17NOV2020)	N/N
16-55/ C4591001 1135 11351535	GENRL	Chills/ chills#	3	19FEB2021	1/4	1	Yes		NA	R (22FEB2021)	N/N
	MUSC	Myalgia/ muscle soreness (generalized)#	3	19FEB2021	1/4	1	Yes		NA	R (22FEB2021)	N/N
16-55/ C4591001 1135 11351535	GENRL	Injection site pain/ soreness on injection site (left arm)	1	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1135 11351535	GENRL	Pain/ bodyaches#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	MUSC	Myalgia/ muscle aches (generalized)#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351537	GENRL	Chills/ chills	2	16NOV2020	1/3	1	Yes		NA/TC	R (18NOV2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	17NOV2020	2/2	1	Yes		NA/TC	R (18NOV2020)	N/N
16-55/ C4591001 1135 11351538	GENRL	Injection site pain/ pain at injection site#	3	01FEB2021	1/3	1	Yes		NA/TC	R (03FEB2021)	N/N
	MUSC	Myalgia/ generalized muscle pain#	3	01FEB2021	1/3	1	Yes		NA/TC	R (03FEB2021)	N/N
16-55/ C4591001 1135 11351539	GENRL	Fatigue/ fatigue	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
		Injection site pain/ soreness on the injection site (left arm)	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
		Malaise/ malaise	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1135 11351540	GENRL	Fatigue/ fatigue	1	26OCT2020	1/2	1	Yes		NA/TC	R (27OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	16NOV2020	1/3	1	Yes		NA/TC	R (18NOV2020)	N/N
	MUSC	Arthralgia/ Joint pain (hands)	2	17NOV2020	2/2	1	Yes		NA/TC	R (18NOV2020)	N/N
16-55/ C4591001	MUSC	Myalgia/ muscle pain	2	17NOV2020	1/2	1	Yes		NA/TC	R (18NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1135 11351541	GASTR	Diarrhoea/ diarrhea	1	26OCT2020	1/1	1	Yes		NA	R (26OCT2020)	N/N
1135 11351542	GENRL	Fatigue/ fatigue	1	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
	INFEC	Tonsillitis/ tonsillitis	1	03NOV2020	9/1	2	No	O	NA/TC	R (03NOV2020)	N/N
	GASTR	Diarrhoea/ diarrhea	2	17NOV2020	1/23	1	Yes		NA	R (09DEC2020)	N/N
	METAB	Dehydration/ dehydration	2	28NOV2020	12/1	1	No	O	NA/TC/TCN	R (28NOV2020)	N/N
16-55/ C4591001	GENRL	Chills/ chills	1	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
1135 11351546	GENRL	Chills/ chills	2	17NOV2020	2/3	1	Yes		NA/TC	R (19NOV2020)	N/N
		Pain/ body aches	2	17NOV2020	2/3	1	Yes		NA/TC	R (19NOV2020)	N/N
		Pyrexia/ fever	2	17NOV2020	2/3	1	Yes		NA/TC	R (19NOV2020)	N/N
	MUSC	Exostosis/ right knee bone spur	2	29NOV2020	14/C	1	No	O	NA/TC	RG	N/N
	MUSC	Arthralgia/ worsening of right knee pain	2	30NOV2020	15/4	1	No	O	NA/TC	R (03DEC2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue	2	16NOV2020	1/2	1	Yes		NA/TC	R (17NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1135 11351548	GENRL	Pyrexia/ low grade temperature	2	17NOV2020	2/1	1	Yes	NA/TC	NA/TC	R (17NOV2020)	N/N
	NERV	Headache/ headache	2	17NOV2020	2/1	1	Yes	NA/TC	NA/TC	R (17NOV2020)	N/N
16-55/ C4591001	MUSC	Myalgia/ generalized muscle pain#	4	11MAR2021	1/2	1	Yes	NA/TC	NA/TC	R (12MAR2021)	N/N
1135 11351549	GASTR	Diarrhoea/ diarrhea	2	18NOV2020	2/2	1	Yes	NA	NA	R (19NOV2020)	N/N
1135 11351550		Nausea/ nausea	2	18NOV2020	2/2	1	Yes	NA	NA	R (19NOV2020)	N/N
	GENRL	Pain/ bodyaches	2	18NOV2020	2/2	1	Yes	NA	NA	R (19NOV2020)	N/N
	NERV	Dizziness/ dizziness	2	18NOV2020	2/2	1	Yes	NA	NA	R (19NOV2020)	N/N
		Headache/ headache	2	18NOV2020	2/2	1	Yes	NA	NA	R (19NOV2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue	2	18NOV2020	1/2	1	Yes	NA	NA	R (19NOV2020)	N/N
1135 11351553											
16-55/ C4591001	GENRL	Injection site pain/ soreness on injection site (left arm)	1	27OCT2020	1/2	1	Yes	NA	NA	R (28OCT2020)	N/N
1135 11351556											

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1135 11351559	GASTR	Diarrhoea/ loose stool	2	22NOV2020	6/1	1	Yes		NA	R (22NOV2020)	N/N	
16-55/ C4591001 1135 11351560	METAB	Vitamin D deficiency/ hypovitaminosis, Vitamin D	2	23NOV2020	7/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1135 11351563	GASTR	Pancreatitis acute/ acute pancreatitis	2	21NOV2020	2/4	2	No	O	NA/TC	R (24NOV2020)	Y/N	
16-55/ C4591001 1135 11351565	GENRL	Injection site pain/ pain at injection site	1	27OCT2020	1/2	1	Yes		NA/TC	R (28OCT2020)	N/N	
16-55/ C4591001 1135 11351566	GASTR	Diarrhoea/ diarrhea	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N	
	GENRL	Fatigue/ fatigue#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N	
	MUSC	Myalgia/ muscle aches#	3	18JAN2021	1/2	1	Yes		NA/TC	R (19JAN2021)	N/N	
	NERV	Headache/ headache#	3	18JAN2021	1/2	1	Yes		NA/TC	R (19JAN2021)	N/N	
16-55/ C4591001 1135 11351567	INFEC	Fungal skin infection/ right thumb fungus skin lesion	2	11DEC2020	25/16	1	No	O	NA/TC	R (26DEC2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1135 11351568	MUSC	Bursitis/ left elbow bursitis	2	17NOV2020	1/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1135 11351569	GENRL	Injection site pain/ pain at injection site	1	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N	
		Pyrexia/ low grade temp	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N	
	MUSC	Back pain/ right side back pain	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N	
	GENRL	Injection site reaction/ muscle twitching at injection site	1	30OCT2020	4/1	1	Yes		NA	R (30OCT2020)	N/N	
16-55/ C4591001 1135 11351571	GENRL	Chills/ chills	1	27OCT2020	1/1	1	Yes		NA	R (27OCT2020)	N/N	
		Injection site pain/ pain on the injection site (left arm)	1	27OCT2020	1/3	1	Yes		NA	R (29OCT2020)	N/N	
16-55/ C4591001 1135 11351572	GENRL	Injection site pain/ pain at injection site	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N	
	GENRL	Injection site pain/ pain at injection site	2	17NOV2020	1/2	1	Yes		NA	R (18NOV2020)	N/N	
16-55/ C4591001 1135 11351573	INJ&P	Arthropod bite/ spider bite on right side of neck#	3	15FEB2021	6/3	2	No	O	NA/TC	R (17FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ pain at injection site#	4	01MAR2021	1/3	1	Yes		NA	R (03MAR2021)	N/N
	GENRL	Fatigue/ fatigue#	4	02MAR2021	2/2	1	Yes		NA	R (03MAR2021)	N/N
	NERV	Headache/ headache#	4	02MAR2021	2/2	1	Yes		NA	R (03MAR2021)	N/N
16-55/ C4591001 1136 11361001	GENRL	Injection site pain/ injection site pain#	2	21JAN2021	135/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1136 11361004	EYE	Eye pain/ right orbital pain#	3	23DEC2020	2/8	1	No	O	NA	R (30DEC2020)	N/N
16-55/ C4591001 1136 11361007	NERV	Migraine/ MIGRAINE HEADACHES*		18AUG2020	1/2	2	Yes		NA	R (19AUG2020)	N/N
16-55/ C4591001 1136 11361012	INJ&P	Contusion/ BRUISED LEFT ARM	2	24SEP2020	17/53	2	No	O	NA/TC	R (15NOV2020)	N/N
		Contusion/ BRUISED LEFT HIP	2	24SEP2020	17/53	2	No	O	NA/TC	R (15NOV2020)	N/N
		Contusion/ BRUISED LEFT SHOULDER	2	24SEP2020	17/53	2	No	O	NA/TC	R (15NOV2020)	N/N
	GENRL	Pain/ body aches#	2	21JAN2021	136/2	1	Yes		NA	R (22JAN2021)	N/N
		Pyrexia/ fever#	2	21JAN2021	136/2	1	Yes		NA	R (22JAN2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1136 11361020	MUSC	Pain in extremity/ left arm soreness#	2	11FEB2021	156/3	2	Yes		NA	R (13FEB2021)	N/N	
	GENRL	Pyrexia/ mild fever#	3	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N	
16-55/ C4591001 1136 11361029	NERV	Seizure/ worsening of intermittent seizures	2	01DEC2020	82/56	1	No	O	NA/TC	R (25JAN2021)	N/N	
16-55/ C4591001 1136 11361030	MUSC	Pain in extremity/ left foot pain	1	01SEP2020	13/C	1	No	O	NA/TC	N	N/N	
	NERV	Headache/ headache#	3	02FEB2021	6/1	1	Yes		NA/TC	R (02FEB2021)	N/N	
	GENRL	Chills/ chills#	3	18FEB2021	22/2	1	Yes		NA	R (19FEB2021)	N/N	
		Fatigue/ fatigue#	3	18FEB2021	22/2	1	Yes		NA	R (19FEB2021)	N/N	
	NERV	Headache/ headache#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N	
	RESP	Rhinorrhoea/ runny nose#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N	
16-55/ C4591001 1136 11361039	GENRL	Injection site pain/ injection site pain#	2	03FEB2021	143/2	1	Yes		NA	R (04FEB2021)	N/N	
16-55/ C4591001	MUSC	Pain in extremity/ sore arm after vaccine#	2	28JAN2021	140/3	1	Yes		NA	R (30JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1136 11361040	INFEC	Diverticulitis/ WORSENING OF DIVERTICULITIS	2	07OCT2020	20/8	2	No	O	NA	R (14OCT2020)	N/N	
1136 11361054	PSYCH	Insomnia/ insomnia#	3	26FEB2021	16/C	2	Yes		NA/TC	N	N/N	
1136 11361058	GENRL	Fatigue/ fatigue*		14SEP2020	1/5	1	Yes		NA	R (18SEP2020)	N/N	
1136 11361062	NERV	Headache/ headache*		14SEP2020	1/5	1	Yes		NA	R (18SEP2020)	N/N	
1136 11361065	GENRL	Fatigue/ MILD FATIGUE	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N	
1136 11361065	NERV	Headache/ mild headache#	2	20JAN2021	107/2	1	Yes		NA	R (21JAN2021)	N/N	
1136 11361072	GENRL	Fatigue/ FATIGUE#	3	20JAN2021	1/5	1	Yes		NA	R (24JAN2021)	N/N	
1136 11361072	NERV	Headache/ HEADACHE#	3	20JAN2021	1/1	1	Yes		NA	R (20JAN2021)	N/N	
1136 11361072	GENRL	Fatigue/ fatigue#	2	25FEB2021	107/3	1	Yes		NA	R (27FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1136 11361073		Injection site pain/ sore left arm at injection site#	2	25FEB2021	107/3	1	Yes		NA	R (27FEB2021)	N/N	
16-55/ C4591001 1136 11361076	GENRL	Injection site pain/ injection site pain, left arm*		22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N	
16-55/ C4591001 1136 11361082	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	2	01DEC2020	13/C	2	No	O	NA	UNK	N/N	
16-55/ C4591001 1136 11361083	IMMUN	Seasonal allergy/ seasonal allergies	2	15DEC2020	28/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1136 11361086	GENRL	Injection site pain/ injection site pain	1	29OCT2020	2/5	2	Yes		NA	R (02NOV2020)	N/N	
	GASTR	Diarrhoea/ diarrhea	1	30OCT2020	3/1	1	Yes		NA	R (30OCT2020)	N/N	
16-55/ C4591001 1136 11361091	PSYCH	Depression/ worsening depression	2	01JAN2021	47/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1136 11361092	GENRL	Pyrexia/ fever	1	31OCT2020	4/1	1	Yes		NA	R (31OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1136 11361094	GENRL	Pain/ body aches	1	16NOV2020	20/1	1	Yes		NA	R (16NOV2020)	N/N	
		Pyrexia/ fever	1	16NOV2020	20/1	1	Yes		NA	R (16NOV2020)	N/N	
		Fatigue/ fatigue	1	30OCT2020	2/4	2	No	O	NA	R (02NOV2020)	N/N	
		NERV	Headache/ headache	1	30OCT2020	2/4	2	No	O	NA	R (02NOV2020)	N/N
		RESP	Paranasal sinus discomfort/ sinus pressure	1	30OCT2020	2/4	2	No	O	NA	R (02NOV2020)	N/N
			Sneezing/ sneezing	1	30OCT2020	2/4	1	No	O	NA	R (02NOV2020)	N/N
		GENRL	Chills/ chills#	4	18FEB2021	2/4	1	Yes		NA	R (21FEB2021)	N/N
			Fatigue/ fatigue#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
			Pain/ body aches#	4	18FEB2021	2/4	1	Yes		NA	R (21FEB2021)	N/N
			Pyrexia/ fever#	4	18FEB2021	2/4	1	Yes		NA	R (21FEB2021)	N/N
		MUSC	Myalgia/ muscle aches#	4	18FEB2021	2/4	1	Yes		NA	R (21FEB2021)	N/N
		NERV	Hyperaesthesia/ skin sensitivity#	4	18FEB2021	2/4	1	Yes		NA	R (21FEB2021)	N/N
	16-55/ C4591001 1136 11361099	GENRL	Injection site pain/ injection site pain, left arm	1	30OCT2020	2/3	1	Yes		NA/TC	R (01NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Chills/ chills	2	17NOV2020	1/3	2	Yes		NA	R (19NOV2020)	N/N	
		Fatigue/ fatigue	2	17NOV2020	1/3	2	Yes		NA	R (19NOV2020)	N/N	
		Injection site pain/ injection site pain	2	17NOV2020	1/3	2	Yes		NA/TC	R (19NOV2020)	N/N	
		Pyrexia/ fever	2	17NOV2020	1/3	2	Yes		NA/TC	R (19NOV2020)	N/N	
16-55/ C4591001 1136 11361101	NERV	Headache/ mild headache#	3	01MAR2021	5/2	1	Yes		NA	R (02MAR2021)	N/N	
16-55/ C4591001 1136 11361108	GENRL	Injection site pain/ injection site pain	1	30OCT2020	2/3	2	Yes		NA/TC	R (01NOV2020)	N/N	
16-55/ C4591001 1136 11361111	GENRL	Injection site induration/ induration by injection site	1	31OCT2020	3/7	1	Yes		NA	R (06NOV2020)	N/N	
		Injection site pain/ pain at injection site	1	31OCT2020	3/7	1	Yes		NA	R (06NOV2020)	N/N	
16-55/ C4591001 1139 11391015	GASTR	Abdominal pain/ Abdominal Pain	2	28AUG2020	8/7	1	No	O	NA	R (03SEP2020)	N/N	
16-55/ C4591001 1139 11391037	GENRL	Injection site bruising/ Bruising at injection site	1	04AUG2020	1/9	1	Yes		NA	R (12AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1139 11391041	RESP	Dyspnoea/ Incomplete Breaths on Inspiration	2	08SEP2020	16/18	2	No	O	NA/TC	R (25SEP2020)	N/N	
16-55/ C4591001 1139 11391071	REPRO	Prostatitis/ Acute prostatitis	2	01SEP2020	5/C	3	No	O	NA/TC/TCN	RG	N/N	
	INFEC	Urinary tract infection/ Urinary tract infection	2	03SEP2020	7/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1139 11391089	MUSC	Musculoskeletal discomfort/ Left Shoulder discomfort	1	26AUG2020	15/12	1	Yes		NA	R (06SEP2020)	N/N	
16-55/ C4591001 1139 11391090	GASTR	Abdominal pain/ Abdominal pain	1	12AUG2020	1/4	2	Yes		NA	R (15AUG2020)	N/N	
	MUSC	Arthralgia/ Joint Pain	2	05SEP2020	2/59	2	Yes		NA/TC	R (02NOV2020)	N/N	
	NERV	Headache/ Intermittent Headaches	2	27SEP2020	24/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1139 11391106	MUSC	Back pain/ lower back pain	1	03NOV2020	22/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1139 11391138	INFEC	Sinusitis/ sinusitis	2	08JAN2021	23/18	2	No	O	NA/TC	R (25JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1140 11401009	GENRL	Injection site pain/ Injection Site Pain	1	31JUL2020	1/2	1	Yes		NA	R (01AUG2020)	N/N
		Injection site swelling/ Injection Site Swelling	1	31JUL2020	1/2	2	Yes		NA	R (01AUG2020)	N/N
	IMMUN	Anaphylactic reaction/ Anaphylaxis Status Post Bee Sting	2	28AUG2020	9/1	4	No	O	NA/TC	R (28AUG2020)	Y/N
	INFEC	Infected bite/ Cellulitis Status Post Bee Sting	2	30AUG2020	11/11	2	No	O	NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1140 11401011	MUSC	Neck pain/ Neck Pain#	3	13FEB2021	2/C	1	Yes		NA	N	N/N
16-55/ C4591001 1140 11401016	MUSC	Myalgia/ Myalgia	1	31JUL2020	1/2	2	Yes		NA	R (01AUG2020)	N/N
	GASTR	Nausea/ nausea	2	22AUG2020	2/3	1	Yes		NA	R (24AUG2020)	N/N
16-55/ C4591001 1140 11401017	GENRL	Fatigue/ Fatigue#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
	MUSC	Pain in extremity/ Left arm pain#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1140 11401020	NEOPL	B-cell lymphoma/ B-Cell Lymphoma	2	03DEC2020	101/C	2	No	O	NA/TC	N	Y/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1140 11401021	PSYCH	Insomnia/ Insomnia	2	12SEP2020	19/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1140 11401031	INJ&P	Skin laceration/ Laceration to left hand#	2	19JAN2021	149/25	1	No	O	NA	R (12FEB2021)	N/N	
16-55/ C4591001 1140 11401050	GASTR	Diarrhoea/ Diarrhea	1	17AUG2020	13/1	1	Yes		NA	R (17AUG2020)	N/N	
16-55/ C4591001 1140 11401057	GENRL	Injection site pain/ pain at injection site#	3	23DEC2020	2/1	1	Yes		NA	R (23DEC2020)	N/N	
16-55/ C4591001 1140 11401061	GENRL	Injection site pain/ pain at injection site#	3	29DEC2020	2/2	1	Yes		NA	R (30DEC2020)	N/N	
16-55/ C4591001 1140 11401062	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	1/2	2	Yes		NA	R (19DEC2020)	N/N	
16-55/ C4591001 1140 11401088	GENRL	Injection site pain/ Pain at injection site#	3	29DEC2020	1/3	1	Yes		NA	R (31DEC2020)	N/N	
	GENRL	Fatigue/ fatigue#	3	30DEC2020	2/1	1	Yes		NA	R (30DEC2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1140 11401092	GENRL	Pain/ Body Aches#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N	
	MUSC	Pain in extremity/ Sore Left Arm#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	09JAN2021	2/1	2	Yes		NA	R (09JAN2021)	N/N	
			Pyrexia/ Fever 103F#	4	09JAN2021	2/1	3	Yes		NA	R (09JAN2021)	N/N
	NERV		Lethargy/ lethargy#	4	09JAN2021	2/1	2	Yes		NA	R (09JAN2021)	N/N
	GENRL		Injection site pain/ Pain at injection site#	4	12JAN2021	2/4	2	Yes		NA/TC	R (15JAN2021)	N/N
	MUSC		Myalgia/ Generalized Muscle Aches	1	24AUG2020	11/7	2	No	O	NA	R (30AUG2020)	N/N
	GENRL		Fatigue/ Fatigue	1	26AUG2020	13/5	2	No	O	NA	R (30AUG2020)	N/N
	RESP		Upper-airway cough syndrome/ Post-nasal Drip	1	27AUG2020	14/8	1	No	O	NA	R (03SEP2020)	N/N
	GENRL		Injection site pain/ Left Arm Injection Site Pain#	3	30DEC2020	1/2	1	Yes		NA/TC	R (31DEC2020)	N/N
	NERV		3	30DEC2020	1/2	1	Yes		NA/TC	R (31DEC2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1140 11401137	GENRL	Injection site pain/ Pain at Injection site#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1140 11401144	GENRL	Injection site pain/ Pain at Injection Site*		04SEP2020	1/1	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1140 11401149	GENRL	Injection site pain/ pain at injection site	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Chills/ chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Fatigue/ fatigue	2	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N
	MUSC	Myalgia/ myalgias	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1140 11401153	GENRL	Chills/ Chills	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Fatigue/ Fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	3	10FEB2021	2/3	2	Yes		NA	R (12FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1140 11401157		Fatigue/ Fatigue#	3	10FEB2021	2/3	1	Yes		NA	R (12FEB2021)	N/N
		Injection site pain/ Pain at injection site#	3	10FEB2021	2/3	1	Yes		NA	R (12FEB2021)	N/N
		Pyrexia/ Fever#	3	10FEB2021	2/3	2	Yes		NA	R (12FEB2021)	N/N
	NERV	Headache/ Headache#	3	10FEB2021	2/3	2	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1140 11401160	GENRL	Chills/ chills	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ headache	2	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1140 11401164	GENRL	Injection site pain/ Injection site pain#	4	04FEB2021	1/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1140 11401177	GENRL	Fatigue/ Fatigue	1	21AUG2020	1/C	1	No	O	NA	N	N/N
16-55/ C4591001 1140 11401180	REPRO	Ovarian cyst/ Ovarian Cyst#	3	22FEB2021	8/C	2	No	O	NA	N	N/N
		Pelvic pain/ Pelvic Pain#	3	22FEB2021	8/C	2	No	O	NA	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1140 11401184	BLOOD	Lymphadenopathy/ Lymphadenopathy above Left Clavicle#	4	09MAR2021	2/C	1	Yes		NA	N	N/N
	REPRO	Breast cyst/ Breast Cyst#	4	09MAR2021	2/C	1	No	O	NA	N	N/N
	EAR	Hyperacusis/ Increased Sense of Hearing	2	16SEP2020	1/6	1	No	O	NA	R (21SEP2020)	N/N
	GASTR	Dyspepsia/ Heartburn	2	16SEP2020	1/6	1	No	O	NA	R (21SEP2020)	N/N
		Nausea/ Nausea	2	16SEP2020	1/6	1	No	O	NA	R (21SEP2020)	N/N
	NERV	Dizziness/ Lightheadedness	2	16SEP2020	1/6	1	No	O	NA	R (21SEP2020)	N/N
		Parosmia/ Increased Sense of Smell	2	16SEP2020	1/6	1	No	O	NA	R (21SEP2020)	N/N
16-55/ C4591001 1140 11401187	PSYCH	Anxiety/ Anxiety	2	16SEP2020	1/6	1	No	O	NA	R (21SEP2020)	N/N
16-55/ C4591001 1140 11401187	NERV	Headache/ Headache	2	13OCT2020	29/4	2	No	O	NA	R (16OCT2020)	N/N
16-55/ C4591001 1140 11401198	MUSC	Myalgia/ muscle aches	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1140 11401203	GENRL	Pyrexia/ Fever	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1140 11401206	NERV	Headache/ Headache	1	27AUG2020	1/1	2	Yes		NA	R (27AUG2020)	N/N
16-55/ C4591001 1140 11401209	GENRL	Malaise/ General Malaise	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1140 11401214	GASTR	Nausea/ Nausea	1	30AUG2020	3/1	1	No	O	NA	R (30AUG2020)	N/N
		Vomiting/ Vomiting	1	30AUG2020	3/1	1	No	O	NA	R (30AUG2020)	N/N
16-55/ C4591001 1140 11401219	NERV	Hypoesthesia/ jaw numbness	2	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1140 11401224	GENRL	Chills/ Chills	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1140 11401231	INJ&P	Limb injury/ Left shoulder strain	2	01NOV2020	41/4	2	No	O	NA	R (04NOV2020)	N/N
		Road traffic accident/ Motor Vehicle Accident	2	01NOV2020	41/1	2	No	O	NA	R (01NOV2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever#	3	11FEB2021	1/2	2	Yes		NA	R (12FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1140 11401241	GENRL	Chills/ Chills	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 1140 11401243	GENRL	Fatigue/ Fatigue Pyrexia/ Fever	2	24SEP2020	2/1	2	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 1140 11401246	MUSC	Pain in extremity/ sore arm- lasted less than 1 day#	3	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N	
16-55/ C4591001 1140 11401249	GENRL	Injection site pain/ Pain at injection site	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N	
16-55/ C4591001 1140 11401250	GENRL	Injection site pain/ pain at injection site#	3	28DEC2020	1/2	1	Yes		NA/TC	R (29DEC2020)	N/N	
16-55/ C4591001 1140 11401252	GENRL	Fatigue/ fatigue	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N	
	MUSC	Arthralgia/ joint pain	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N	
	MUSC	Myalgia/ Muscle aches	2	24SEP2020	1/3	3	Yes		NA/TC	R (26SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GASTR	Diarrhoea/ diarrhea	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N	
		Nausea/ nausea	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
		Vomiting/ vomiting	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N	
	VASC	Hypertension/ Hypertension#	2	30JAN2021	129/C	2	No	O	NA	N	N/N	
16-55/ C4591001 1140 11401279	GENRL	Injection site pain/ Pain at injection site#	3	21DEC2020	1/1	1	Yes		NA/TC	R (21DEC2020)	N/N	
16-55/ C4591001 1140 11401281	GENRL	Injection site pain/ Pain at Injection Site	1	13OCT2020	1/1	1	Yes		NA	R (13OCT2020)	N/Y	
	NERV	Headache/ headache	1	13OCT2020	1/1	1	Yes		NA	R (13OCT2020)	N/Y	
16-55/ C4591001 1140 11401282	RESP	Asthma exercise induced/ Exercise induced Asthma	2	NOV2020	1/C	2	No	O	NA/TC	RG	N/N	
	GASTR	Abdominal pain upper/ Right Upper Quadrant Abdominal Pain#	4	14FEB2021	11/4	3	No	O	NA	R (17FEB2021)	N/N	
	RESP	Pulmonary embolism/ Bilateral Pulmonary Embolisms#	4	15FEB2021	12/C	4	No	O	NA	RG	Y/N	
	VASC	Deep vein thrombosis/ Deep Vein Thrombosis Left Leg#	4	15FEB2021	12/C	4	No	O	NA	RG	Y/N	
16-55/ C4591001	GASTR	Diarrhoea/ Diarrhea#	3	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1140 11401285	BLOOD	Lymphadenopathy/ enlarged lymph node axilla (R)#	4	04FEB2021	2/7	2	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1140 11401290	GENRL	Injection site pain/ Tenderness at Injection Site	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
		Pyrexia/ Fever	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	06NOV2020	1/3	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C4591001 1140 11401294	GENRL	Injection site pain/ Pain at injection site	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
	MUSC	Myalgia/ myalgias	2	03NOV2020	1/4	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1140 11401298	MUSC	Arthralgia/ Diffuse Arthralgia's	2	06NOV2020	1/3	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C4591001 1140 11401304	GENRL	Injection site pain/ Pain at injection site	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1140 11401306	EYE	Eye pain/ Bilateral Eye Pain	1	07NOV2020	17/56	1	No	O	NA	R (01JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Visual impairment/ Change in Visual Perception	1	07NOV2020	17/3	3	No	O	P/W	R (09NOV2020)	Y/N
		Amnesia/ short term memory loss	1	07NOV2020	17/4	1	No	O	P/TC/TCN	R (10NOV2020)	Y/N
		Paraparesis/ Worsening of Chronic Spastic Paraparesis	1	07NOV2020	17/C	3	No	O	P/TC/TCN	N	N/N
16-55/ C4591001 1140 11401311	GENRL	Chills/ Chills#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
		Fatigue/ Fatigue#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
		Pain/ Body Aches#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1140 11401321	GENRL	Injection site pain/ Pain at injection site#	3	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1141 11411005	NEOPL	Fibroadenoma of breast/ Left breast fibroadenoma	2	10SEP2020	21/1	2	No	O	NA/TC	R (10SEP2020)	N/N
	SKIN	Acne cystic/ Cystic Acne on Face	2	02NOV2020	74/8	1	No	O	NA/TC	R (09NOV2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	28DEC2020	1/2	1	Yes		NA/TC	R (29DEC2020)	N/N
		Injection site swelling/ injection site swelling#	3	28DEC2020	1/2	1	Yes		NA	R (29DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	20JAN2021	1/3	1	Yes		NA/TC	R (22JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1141 11411006	MUSC	Back pain/ Back Pain	1	31JUL2020	1/10	3	Yes		NA/TC	R (09AUG2020)	N/N	
	INFEC	Gingivitis/ Gum Infection	2	01DEC2020	103/72	1	No	O	NA/TC	R (10FEB2021)	N/N	
16-55/ C4591001 1141 11411007	GENRL	Injection site pain/ Injection Site Pain#	3	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N	
		Injection site pain/ Injection Site Tenderness#	3	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N	
	MUSC	Joint range of motion decreased/ Decreased upward range of motion in vaccinated arm#	3	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N	
	NERV	Headache/ Headache#	4	12FEB2021	1/1	1	Yes		NA	R (12FEB2021)	N/N	
16-55/ C4591001 1141 11411008	GENRL	Injection site pain/ injection site pain	1	31JUL2020	1/26	3	Yes		NA	R (25AUG2020)	N/N	
	MUSC	Tendonitis/ Shoulder tendonitis	1	31JUL2020	1/67	1	Yes		NA	R (05OCT2020)	N/N	
	GASTR	Gastroesophageal reflux disease/ worsening epigastric pain r/t acid reflux#	2	09FEB2021	173/C	2	No	O	NA/TCN	N	N/N	
16-55/ C4591001 1141 11411010	PSYCH	Anxiety/ Anxiousness	2	14SEP2020	14/93	2	No	O	NA/TCN	R (15DEC2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1141 11411012	GENRL	Depressed mood/ Low Mood	2	14SEP2020	14/93	2	No	O	NA/TCN	R (15DEC2020)	N/N	
		Vessel puncture site pain/ pinching sensation in left lower arm after blood draw*		31JUL2020	1/38	1	No	O	NA	R (06SEP2020)	N/N	
		Vessel puncture site paraesthesia/ Tingling on lower left arm at blood draw site.*		31JUL2020	1/20	1	No	O	NA	R (19AUG2020)	N/N	
16-55/ C4591001 1141 11411016	GENRL	Injection site pain/ injection site pain#	3	01FEB2021	1/4	1	Yes		NA	R (04FEB2021)	N/N	
		GASTR	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N	
		INV	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N	
		MUSC	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N	
16-55/ C4591001 1141 11411019	GENRL	Injection site pain/ Injection site pain#	3	23DEC2020	1/3	1	Yes		NA	R (25DEC2020)	N/N	
		Fatigue/ Fatigue#	3	24DEC2020	2/1	1	Yes		NA/TCN	R (24DEC2020)	N/N	
		Malaise/ Generalized malaise#	3	24DEC2020	2/1	1	Yes		NA	R (24DEC2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411020	GENRL	Chills/ chills#	4	15JAN2021	2/1	2	Yes		NA	R (15JAN2021)	N/N
	INV	Body temperature increased/ elevated body temperature t max 99.7#	4	15JAN2021	2/1	1	Yes		NA/TC	R (15JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	15JAN2021	2/1	2	Yes		NA/TC	R (15JAN2021)	N/N
	NERV	Headache/ headache#	4	15JAN2021	2/1	2	Yes		NA/TC	R (15JAN2021)	N/N
	GASTR	Nausea/ nausea#	3	28JAN2021	2/1	2	Yes		NA	R (28JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
		Injection site pain/ injection site pain#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Arthralgia/ generalized joint pain#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
	MUSC	Arthralgia/ Joint pain#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1141 11411021	GENRL	Injection site pain/ muscle soreness injection area	2	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
16-55/ C4591001 1141 11411022	GENRL	Injection site pain/ injection site soreness#	3	21DEC2020	1/2	2	Yes		NA	R (22DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1141 11411023	GENRL	Inflammation/ acute bilateral hand inflammation	1	AUG2020	1/C	2	No	O	NA	RG	N/N	
	NERV	Paraesthesia/ Tingling sensation left hand	1	10AUG2020	7/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1141 11411024	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N	
	GENRL	Injection site pain/ injection site soreness#	4	12JAN2021	2/2	2	Yes		NA	R (13JAN2021)	N/N	
	INV	Body temperature increased/ elevated body temperature (99.6F)#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N	
	MUSC	Myalgia/ mild myalgia#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N	
	NERV	Headache/ Headache#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N	
16-55/ C4591001 1141 11411029	MUSC	Arthralgia/ Arthralgias	2	17SEP2020	23/12	2	Yes		NA/TC/TCN	R (28SEP2020)	N/N	
	PSYCH	Anxiety/ Anxiety Flare up	2	18SEP2020	24/C	1	Yes		NA/TC/TCN	N	N/N	
16-55/ C4591001 1141 11411030	MUSC	Arthralgia/ right wrist pain	2	19SEP2020	25/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1141 11411032		Injection site pain/ Injection site pain left deltoid#	3	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N	
16-55/ C4591001 1141 11411036	GENRL	Injection site pain/ injection site pain#	3	18DEC2020	1/4	2	Yes		NA/TC	R (21DEC2020)	N/N	
	GENRL	Fatigue/ fatigue#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N	
	GENRL	Fatigue/ Fatigue#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N	
		Feeling abnormal/ brain fog#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N	
	NERV	Head discomfort/ minor head pressure#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	07JAN2021	2/1	2	Yes		NA/TC	R (07JAN2021)	N/N	
		Chills/ Rigors#	4	07JAN2021	2/1	2	Yes		NA/TC	R (07JAN2021)	N/N	
	INV	Body temperature increased/ elevated body temperature#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N	
16-55/ C4591001 1141 11411041	GENRL	Fatigue/ Fatigue#	3	22DEC2020	1/5	1	Yes		NA	R (26DEC2020)	N/N	
		Malaise/ Malaise#	3	22DEC2020	1/4	1	Yes		NA	R (25DEC2020)	N/N	
	NERV	Headache/ Headache#	2	22DEC2020	120/2	1	Yes		NA/TC	R (23DEC2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site pain#	3	23DEC2020	2/4	1	Yes		NA/TC	R (26DEC2020)	N/N
16-55/ C4591001 1141 11411042	SKIN	Dermatitis/ Dermatitis torso area#	2	22DEC2020	119/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1141 11411045	GENRL	Injection site pain/ muscle soreness left arm injection site#	3	18DEC2020	2/3	1	Yes		NA	R (20DEC2020)	N/N
16-55/ C4591001 1141 11411046	EAR	Tympanic membrane perforation/ Perforated ear drum right ear	2	27AUG2020	2/14	2	Yes		NA/TC	R (09SEP2020)	N/N
	INFEC	Otitis media acute/ Acute Otitis media	2	27AUG2020	2/14	2	Yes		NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1141 11411048	INJ&P	Ankle fracture/ left bimalleolar fracture	1	22AUG2020	16/82	3	No	O	NA/TC	R (11NOV2020)	N/N
		Fall/ Fall	1	22AUG2020	16/1	3	No	O	NA/TC	R (22AUG2020)	N/N
	MUSC	Myalgia/ Myalgia#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1141 11411050	GASTR	Diverticulum/ Diverticulosis	2	14SEP2020	19/C	1	No	O	NA	N	N/N
		Large intestine polyp/ colon polyp	2	14SEP2020	19/1	1	No	O	NA/TC	R (14SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411051	GENRL	Injection site pain/ injection site pain#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
	NERV	Headache/ headache#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1141 11411051	GENRL	Injection site pain/ injection site soreness#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ headaches#	3	09FEB2021	8/3	2	No	O	NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1141 11411053	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/4	2	Yes		NA	R (25FEB2021)	N/N
	PSYCH	Anxiety/ Worsening Anxiety	2	02DEC2020	99/62	2	No	O	NA/TC/TCN	R (01FEB2021)	N/N
16-55/ C4591001 1141 11411054	NERV	Depression/ Worsening depression	2	02DEC2020	99/62	2	No	O	NA/TC/TCN	R (01FEB2021)	N/N
	NERV	Headache/ Headache#	4	15FEB2021	1/3	1	Yes		NA	R (17FEB2021)	N/Y
16-55/ C4591001 1141 11411054	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	GENRL	Feeling hot/ warm sensation#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1141 11411056	MUSC	Injection site pain/ injection site pain#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N	
		Myalgia/ myalgia#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N	
	GENRL	Injection site hyperaesthesia/ Hyperesthesia left deltoid region on injection site	2	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/Y	
16-55/ C4591001 1141 11411061	GENRL	Chills/ chills#	4	26JAN2021	1/2	2	Yes		NA	R (27JAN2021)	N/N	
16-55/ C4591001 1141 11411064		Injection site pain/ injection site soreness deltoid#	4	26JAN2021	1/4	1	Yes		NA	R (29JAN2021)	N/N	
	INV	Body temperature increased/ elevated body temperature (99.6F)#	4	26JAN2021	1/3	1	Yes		NA/TC	R (28JAN2021)	N/N	
	MUSC	Myalgia/ myalgia#	4	26JAN2021	1/3	1	Yes		NA/TC	R (28JAN2021)	N/N	
	NERV	Headache/ headache#	4	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N	
	GENRL	Feeling cold/ Cold Sensation#	3	04JAN2021	1/1	2	Yes		NA	R (04JAN2021)	N/N	
16-55/ C4591001 1141 11411064		Injection site pain/ Injection Site Pain#	3	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/N	
	NERV	Headache/ Headache#	3	04JAN2021	1/2	2	Yes		NA/TC	R (05JAN2021)	N/N	
	PSYCH	Insomnia/ Insomnia#	3	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411067	GENRL	Feeling cold/ Cold Sensation#	4	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
		Malaise/ Malaise#	4	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Left Shoulder Area Myalgia#	4	27JAN2021	1/3	1	Yes		NA/TC	R (29JAN2021)	N/N
	NERV	Headache/ Headache#	4	27JAN2021	1/3	1	Yes		NA/TC	R (29JAN2021)	N/N
	MUSC	Flank pain/ Right sided flank pain#	4	28JAN2021	2/2	1	Yes		NA/TC	R (29JAN2021)	N/N
	MUSC	Plantar fasciitis/ worsening of plantar fasciitis left foot	2	14SEP2020	13/C	2	No	O	NA/TC	RG	N/N
	GENRL	Fatigue/ fatigue#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
		Injection site pain/ injection site pain#	3	21DEC2020	1/6	1	Yes		NA	R (26DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	13JAN2021	1/4	2	Yes		NA	R (16JAN2021)	N/N
	NERV	Headache/ Headache (worse than typical)#	4	13JAN2021	1/2	2	Yes		NA/TC	R (14JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	14JAN2021	2/2	1	Yes		NA/TC	R (15JAN2021)	N/N
MUSC	Myalgia/ Generalized Myalgia#	4	14JAN2021	2/2	2	Yes		NA	R (15JAN2021)	N/N	
GENRL	Injection site pain/ Arm Pain (injection)#	4	16JAN2021	4/2	1	Yes		NA	R (17JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411068	GENRL	Injection site pain/ muscle soreness injection site#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1141 11411070	GENRL	Chills/ chills#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N
		Fatigue/ fatigue#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N
		Injection site pain/ injection site pain#	3	23DEC2020	1/2	2	Yes		NA/TC	R (24DEC2020)	N/N
	GENRL	Pyrexia/ Fever#	4	15JAN2021	2/1	1	Yes		NA/TC	R (15JAN2021)	N/N
16-55/ C4591001 1141 11411074	GASTR	Abdominal discomfort/ Stomach discomfort#	4	25FEB2021	2/1	2	Yes		NA	R (25FEB2021)	N/N
	GENRL	Chills/ chills#	4	25FEB2021	2/1	2	Yes		NA	R (25FEB2021)	N/N
		Malaise/ Malaise#	4	25FEB2021	2/1	2	Yes		NA	R (25FEB2021)	N/N
		Pyrexia/ Fever (101 F)#	4	25FEB2021	2/1	2	Yes		NA/TC	R (25FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	25FEB2021	2/1	3	Yes		NA/TC	R (25FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/1	2	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Post Injection Upper Arm Pain	2	09SEP2020	1/4	1	Yes		NA	R (12SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411077	GENRL	Injection site bruising/ Injection Site Bruise	2	10SEP2020	2/12	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1141 11411079	PSYCH	Gastrointestinal somatic symptom disorder/ Stress related gastroesophageal reflux	1	21AUG2020	8/31	1	No	O	NA/TC/TCN	R (20SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	29DEC2020	1/2	3	Yes		NA	R (30DEC2020)	N/N
	GENRL	Chills/ Chills#	4	19JAN2021	1/2	2	Yes		NA	R (20JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	19JAN2021	1/C	2	Yes		NA	RG	N/N
	MUSC	Myalgia/ Myalgias#	4	19JAN2021	1/3	2	Yes		NA	R (21JAN2021)	N/N
	NERV	Headache/ Headache#	4	19JAN2021	1/3	2	Yes		NA	R (21JAN2021)	N/N
	SKIN	Night sweats/ Night sweats#	4	19JAN2021	1/2	2	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1141 11411080	GENRL	Injection site pain/ injection site pain#	3	28DEC2020	1/3	2	Yes		NA	R (30DEC2020)	N/Y
	GASTR	Nausea/ Nausea#	4	21JAN2021	2/1	2	Yes		NA	R (21JAN2021)	N/N
	NERV	Headache/ Headache#	4	21JAN2021	2/2	2	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001	MUSC	Arthralgia/ Generalized Arthralgia#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411082	INJ&P	Chest injury/ trauma left rib cage	2	09SEP2020	8/8	1	No	O	NA/TC/TCN	R (16SEP2020)	N/N
1141 11411084	VASC	Hot flush/ Hot flushes after vaccination#	3	21DEC2020	1/1	1	Yes		NA	R (21DEC2020)	N/Y
	GENRL	Injection site pain/ injection site pain#	3	22DEC2020	2/2	2	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
1141 11411087	MUSC	Myalgia/ muscle aches	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	24DEC2020	2/3	1	Yes		NA	R (26DEC2020)	N/N
1141 11411088											
16-55/ C4591001	MUSC	Myalgia/ myalgia low back	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N
1141 11411089	NERV	Headache/ Post vaccination headache	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Pain/ Body Aches	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411091 16-55/ C4591001 1141 11411092 16-55/ C4591001 1141 11411093 16-55/ C4591001 1141 11411094	NERV	Headache/ Headache	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
	VASC	Flushing/ Facial Flushing	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	17AUG2020	1/3	2	Yes		NA	R (19AUG2020)	N/N
	CARD	Tachycardia/ tachycardia	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
	INV	Body temperature increased/ Elevated Body Temperature	2	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N
	GENRL	Chills/ Chills#	4	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Lower back myalgia#	4	28JAN2021	2/2	1	Yes		NA/TC	R (29JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	16SEP2020	7/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	19DEC2020	2/2	2	Yes		NA	R (20DEC2020)	N/N
		Injection site pain/ Injection site pain#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N
INV	Body temperature increased/ Elevated body temperature#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ myalgia#	3	19DEC2020	2/2	2	Yes		NA	R (20DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
		Pyrexia/ Fever (102F)#	4	07JAN2021	2/1	2	Yes		NA	R (07JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	07JAN2021	2/1	2	Yes		NA	R (07JAN2021)	N/N
	NERV	Headache/ Headache#	4	07JAN2021	2/1	2	Yes		NA	R (07JAN2021)	N/N
	HEPAT	Cholelithiasis/ cholelithiasis#	4	02FEB2021	28/7	2	No	O	NA/TC/TCN	R (08FEB2021)	N/N
16-55/ C4591001 1141 11411096	INJ&P	Arthropod bite/ Insect bite left ankle	1	31AUG2020	14/16	2	No	O	NA/TC	R (15SEP2020)	N/N
	SKIN	Erythema/ Erythema left ankle	1	31AUG2020	14/16	2	No	O	NA/TC	R (15SEP2020)	N/N
		Urticaria/ urticaria left ankle	1	31AUG2020	14/16	2	No	O	NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1141 11411098	GASTR	Nausea/ Nausea#	4	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
	INV	Body temperature increased/ Body Temperature Increased#	4	20JAN2021	2/1	1	Yes		NA/TC	R (20JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	20JAN2021	2/1	1	Yes		NA/TC	R (20JAN2021)	N/N
16-55/ C4591001	MUSC	Pain in extremity/ Post vaccination left upper arm pain#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411099	GENRL	Injection site pain/ injection site pain	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1141 11411102	NERV	Headache/ headache	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
	CARD	Tachycardia/ tachycardia	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	NERV	Dizziness/ lightheadedness	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1141 11411103	GASTR	Hypoaesthesia oral/ numbness of tongue	2	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N
		Hypoaesthesia teeth/ numbness of teeth	2	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain left arm	2	09SEP2020	1/5	2	Yes		NA	R (13SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N
		Nausea/ nausea	2	10SEP2020	2/3	2	Yes		NA/TC	R (12SEP2020)	N/N
		Toothache/ toothache	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site bruising/ bruising at injection site	2	10SEP2020	2/5	1	Yes		NA	R (14SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411104	MUSC	Myalgia/ body aches (myalgia)	2	10SEP2020	2/3	1	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Headache/ headache	2	10SEP2020	2/3	2	Yes		NA/TC	R (12SEP2020)	N/N
	INJ&P	Ligament sprain/ Sprained L Ankle	2	07OCT2020	30/C	1	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ injection site pain#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1141 11411106	GENRL	Injection site pain/ Injection Site Pain#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgia#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	2/4	2	Yes		NA/TC/TCN	R (23AUG2020)	N/N
	NERV	Nerve compression/ Pinched nerve right leg	1	26AUG2020	8/C	2	No	O	NA/TC/TCN	RG	N/N
	GENRL	Injection site pain/ Left Arm Pain at injection site	1	11SEP2020	24/3	1	Yes		NA/TC/TCN	R (13SEP2020)	N/N
16-55/ C4591001 1141 11411108	GENRL	Fatigue/ Fatigue	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Pain/ Body Aches	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1141 11411110	NERV	Dizziness/ Lightheadedness	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N	
	NERV	Headache/ Headache, worsening	2	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N	
			Injection site pain/ Injection site tenderness#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
	GENRL		Pyrexia/ Fever (100.0F)#	4	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N
	INJ&P		Injection related reaction/ upper shoulder pain (injection-related)#	4	18FEB2021	1/3	1	Yes		NA/TC	R (20FEB2021)	N/N
			Injection related reaction/ upper arm bicep pain (injection-related)#	4	18FEB2021	1/3	1	Yes		NA/TC	R (20FEB2021)	N/N
	NERV		Headache/ headache#	4	18FEB2021	1/3	1	Yes		NA/TC	R (20FEB2021)	N/N
	16-55/ C4591001 1141 11411113	GENRL	Injection site pain/ injection site pain	2	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
		BLOOD	Lymphadenopathy/ swollen left axillary lymph node	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001 1141 11411114	GENRL	Injection site pain/ injection site tenderness	1	22AUG2020	2/3	1	Yes		NA	R (24AUG2020)	N/N	
	GENRL	Injection site pain/ Injection Site Soreness	2	11SEP2020	1/5	2	Yes		NA/TC	R (15SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411116	NERV	Headache/ Headache	2	11SEP2020	1/2	2	Yes		NA	R (12SEP2020)	N/N
	GENRL	Pain/ Body Aches	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	18DEC2020	2/2	1	Yes		NA	R (19DEC2020)	N/N
	GASTR	Nausea/ Nausea#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Chills/ Chills#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Fatigue/ Fatigue#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Arthralgia#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Myalgia/ Generalized Myalgia#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1141 11411118	NERV	Headache/ Headache#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Injection site pain/ injection site soreness#	3	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/Y
	GENRL	Injection site pain/ injection site pain#	4	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
	GENRL	Injection site pain/ Injection Pain	1	21AUG2020	1/3	2	Yes		NA/TC	R (23AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1141 11411119	GASTR	Nausea/ nausea	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N	
1141 11411120	GENRL	Asthenia/ generalized weakness	2	12SEP2020	2/3	2	Yes		NA	R (14SEP2020)	N/N	
		Chills/ chills	2	12SEP2020	2/3	2	Yes		NA	R (14SEP2020)	N/N	
	INV	Body temperature increased/ elevated body temperature	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N	
16-55/ C4591001	GENRL	Injection site induration/ induration at injection Site	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N	
1141 11411121	GENRL	Injection site pain/ Pain at injection Site	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N	
	GASTR	Nausea/ Nausea	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N	
	GENRL	Pain/ Body Aches	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N	
	NERV	Headache/ Headache	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N	
	MUSC	Joint range of motion decreased/ limited range of motion left arm#	3	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N	
		Myalgia/ left upper arm pain at deltoid muscle#	3	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N	
	GENRL	Asthenia/ Lack of energy#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411122	IMMUN	Fatigue/ Fatigue#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N
		Pyrexia/ Fever (102F)#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
		Seasonal allergy/ Exacerbation of seasonal allergies	2	21SEP2020	8/7	1	No	O	NA/TC	R (27SEP2020)	N/N
	RESP	Nasal congestion/ nasal congestion	2	21SEP2020	8/7	1	No	O	NA/TC	R (27SEP2020)	N/N
	NERV	Headache/ headache#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
	INFEC	Urinary tract infection/ urinary tract infection#	4	10MAR2021	29/C	2	No	O	NA/TC	N	N/N
	16-55/ C4591001 1141 11411123	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/4	1	Yes		NA	R (25DEC2020)
GENRL	Fatigue/ Fatigue#	3	23DEC2020	2/1	1	Yes		NA	R (23DEC2020)	N/N	
GENRL	Injection site pain/ Injection site pain#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N	
GASTR	Nausea/ Nausea#	4	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N	
GENRL	Chills/ Chills#	4	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N	
16-55/ C4591001 1141 11411127	GENRL	Injection site pain/ injection site pain	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411128	CARD	Tachycardia/ Tachycardia	1	31AUG2020	8/44	2	No	O	NA	R (13OCT2020)	N/N
	GENRL	Chills/ chills (rigors)#	3	27JAN2021	2/1	2	Yes		NA/TC	R (27JAN2021)	N/N
		Injection site erythema/ erythema (injection site)#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
		Injection site pain/ injection site tenderness#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
		Injection site erythema/ erythema at injection site#	4	18FEB2021	2/4	1	Yes		NA	R (21FEB2021)	N/N
		Injection site pain/ Sore deltoid (injection site pain)#	4	18FEB2021	2/4	1	Yes		NA/TC	R (21FEB2021)	N/N
	INV	Body temperature increased/ elevated body temperature (99.3F)#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	18FEB2021	2/4	1	Yes		NA	R (21FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/3	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1141 11411129	GENRL	Injection site pain/ Injection site pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1141 11411130	GENRL	Injection site pain/ injection site pain	1	25AUG2020	1/5	2	Yes		NA/TCN	R (29AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1141 11411131	GENRL	Pyrexia/ low grade fever	1	25AUG2020	1/4	1	Yes	NA	NA	R (28AUG2020)	N/N	
		Injection site pain/ Injection Site Pain Left Arm	2	15SEP2020	1/5	2	Yes	NA	NA	R (19SEP2020)	N/N	
		INV	Body temperature increased/ Elevated Body Temperature	2	15SEP2020	1/3	2	Yes	NA/TC	NA/TC	R (17SEP2020)	N/N
		GENRL	Chills/ Chills	2	16SEP2020	2/2	2	Yes	NA/TC/TCN	NA/TC/TCN	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	26AUG2020	2/2	1	Yes	NA	NA	R (27AUG2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain Right Arm	2	14SEP2020	1/2	1	Yes	NA	NA	R (15SEP2020)	N/N	
	16-55/ C4591001 1141 11411132	GENRL	Fatigue/ fatigue#	3	29DEC2020	1/3	2	Yes	NA	NA	R (31DEC2020)	N/N
	MUSC	Injection site pain/ injection site pain#	3	29DEC2020	1/3	1	Yes	NA	NA	R (31DEC2020)	N/N	
	NERV	Myalgia/ myalgia#	3	29DEC2020	1/3	2	Yes	NA	NA	R (31DEC2020)	N/N	
	GENRL	Headache/ headache#	3	29DEC2020	1/3	2	Yes	NA	NA	R (31DEC2020)	N/N	
16-55/ C4591001 1141 11411132	GENRL	Fatigue/ Fatigue#	4	20JAN2021	1/2	1	Yes	NA	NA	R (21JAN2021)	N/N	
	MUSC	Injection site pain/ Injection site pain#	4	20JAN2021	1/3	1	Yes	NA	NA	R (22JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	20JAN2021	1/2	1	Yes	NA	NA	R (21JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	20JAN2021	1/2	1	Yes	NA	NA	R (21JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411135	NERV	Headache/ Headache#	4	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N
	MUSC	Myalgia/ Body Muscle Aches	2	17SEP2020	1/2	2	Yes		NA/TC	R (18SEP2020)	N/N
	INV	Body temperature increased/ Elevated Body Temperature	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site PAin	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	17SEP2020	4/4	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1141 11411136		Pyrexia/ Fever	2	17SEP2020	4/4	1	Yes		NA	R (20SEP2020)	N/N
	INV	Weight increased/ Adverse Drug Reaction-Weight Gain	2	NOV2020	49/	1	No	O	NA	R	N/N
	GASTR	Gastritis/ Gastritis#	2	25JAN2021	134/6	1	No	O	NA	R (30JAN2021)	N/N
		Irritable bowel syndrome/ Worsening Irritable Bowel Syndrome#	2	25JAN2021	134/30	1	No	O	NA	R (23FEB2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411137	GENRL	Injection site pain/ Injection Site Pain Left Arm	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1141 11411139	GENRL	Fatigue/ Fatigue#	4	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N
		Injection site pain/ injection site pain#	4	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	MUSC	Arthralgia/ generalized joint pain#	4	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
		Myalgia/ myalgia#	4	06FEB2021	2/2	1	Yes		NA/TC	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	4	06FEB2021	2/2	1	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1141 11411140	GENRL	Injection site pain/ Injection Site Pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	INJ&P	Thermal burn/ Burn Injury, left hand#	3	10JAN2021	20/6	1	No	O	NA/TC	R (15JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	12JAN2021	2/6	1	Yes		NA	R (17JAN2021)	N/N
	MUSC	Myalgia/ muscle achiness#	4	12JAN2021	2/4	1	Yes		NA/TC	R (15JAN2021)	N/N
	PSYCH	Irritability/ irritability#	4	12JAN2021	2/4	1	Yes		NA	R (15JAN2021)	N/N
	SKIN	Cold sweat/ cold sweats#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	BLOOD	Lymphadenopathy/ lymphadenopathy (left axillary, clavicle, elbow)#	4	13JAN2021	3/5	2	Yes		NA	R (17JAN2021)	N/N
16-55/ C4591001 1141 11411141	GASTR	Diarrhoea/ Diarrhea	2	19SEP2020	3/1	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1141 11411142	GASTR	Abdominal pain/ Acute Abdominal Pain	2	22NOV2020	67/4	3	No	O	NA/TC	R (25NOV2020)	N/N
	GENRL	Injection site pain/ left deltoid pain at injection site#	3	18DEC2020	1/3	2	Yes		NA	R (20DEC2020)	N/N
	GENRL	Pyrexia/ Fever#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	09JAN2021	2/2	2	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1141 11411146	GENRL	Chills/ Chills#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Chills/ Chills#	4	17FEB2021	1/1	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1141 11411148	GENRL	Injection site pain/ arm pain at injection site	1	28AUG2020	1/3	2	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site pain/ injection site pain left arm	2	18SEP2020	1/4	2	Yes		NA	R (21SEP2020)	N/N
	GENRL	Pain/ body aches	2	19SEP2020	2/3	2	Yes		NA/TC	R (21SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INV	Body temperature increased/ elevated body temperature, max temp 99.8	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ headache	2	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1141 11411149	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C4591001 1141 11411151	GENRL	Pyrexia/ low grade fever	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
	MUSC	Myalgia/ whole body myalgia	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	INV	Body temperature increased/ elevated body temperature#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	INV	Body temperature increased/ Elevated Body Temperature#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ Headache#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	MUSC	Back pain/ Mid-region back pain#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1141 11411152	GENRL	Injection site pain/ injection site pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411153	GENRL	Fatigue/ Fatigue#	4	06JAN2021	1/3	3	Yes		NA	R (08JAN2021)	N/N
	GENRL	Fever (tmax 102.7 F) and sweats#	4	07JAN2021	2/1	3	Yes		NA/TC	R (07JAN2021)	N/N
	MUSC		Myalgia/ myalgia#	4	07JAN2021	2/2	2	Yes		NA	R (08JAN2021)
	CARD	Junctional ectopic tachycardia/ Junctional ectopic tachycardia	2	02OCT2020	12/97	4	No	O	NA/TC/TCN	RS (06JAN2021)	Y/N
	NERV	Dizziness/ Lightheadedness	2	02OCT2020	12/C	3	No	O	NA/TC	RG	N/N
	CARD	Tachycardia/ Tachycardia	2	03OCT2020	13/C	3	No	O	NA/TC	RG	N/N
	CARD	Tachycardia/ Tachycardia	2	13JAN2021	115/C	2	No	O	NA/TC	N	N/N
	NERV	Dizziness/ Dizziness	2	14JAN2021	116/16	2	No	CD	NA	R (29JAN2021)	N/N
	NERV	Dizziness/ Lightheadedness	2	14JAN2021	116/16	2	No	CD	NA	R (29JAN2021)	N/N
	NERV	Headache/ Headache	2	14JAN2021	116/16	3	No	CD	NA	R (29JAN2021)	N/N
	NERV	Presyncope/ Near syncopal episode#	3	2021	1/C	2	No	O	NA	N	N/N
	GENRL	Fatigue/ Fatigue#	3	15FEB2021	7/11	3	No	CD	NA	R (25FEB2021)	N/N
NERV	Dizziness/ Dizziness#	3	15FEB2021	7/11	3	No	CD	NA	R (25FEB2021)	N/N	
NERV	Headache/ Headache#	3	15FEB2021	7/11	3	No	CD	NA	R (25FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411154	GENRL	Injection site pain/ injection site pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001 1141 11411156	NERV	Headache/ headache	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N
	INV	Body temperature increased/ Elevated Body Temperature	1	20SEP2020	21/4	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain (Neck, Bilateral Hands)	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
		Hyperaesthesia/ bilateral hand increased sensation to touch	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1141 11411158	GENRL	Feeling hot/ warmth sensation#	3	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
		Injection site pain/ injection site tenderness#	3	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
		Malaise/ malaise#	3	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1141 11411159	GENRL	Injection site pain/ Injection site pain left arm	1	02SEP2020	2/3	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Chills/ chills	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411161	NERV	Pain/ body aches	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
		Headache/ headache	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
	RESP	Dyspnoea exertional/ shortness of breathe while exercising	1	21SEP2020	20/17	1	No	O	NA/TC	R (07OCT2020)	N/N
	MUSC	Myalgia/ muscle pain (generalized right arm)#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/Y
16-55/ C4591001 1141 11411162	NERV	Dizziness/ Transient episodes lightheadedness#	3	15FEB2021	7/C	2	No	O	NA	RG	N/N
	NERV	Dizziness/ Lightheadedness	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	16OCT2020	24/7	2	No	O	NA	R (22OCT2020)	N/N
	GENRL	Pyrexia/ fever#	3	27JAN2021	1/2	2	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
NERV	Headache/ Headache#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1141 11411163	MUSC	Arthralgia/ Worsening bilateral knee pain (persistent)	1	SEP2020	1/C	2	No	O	NA	N	N/N	
	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N	
	GENRL	Injection site pain/ injection site pain left arm	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N	
	INV	Body temperature increased/ elevated body temperature, temp. max 99.7	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N	
	MUSC	Myalgia/ muscle aches	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N	
16-55/ C4591001 1141 11411164	GENRL	Injection site pain/ Injection pain left arm.	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N	
	MUSC	Tendonitis/ tendonitis left arm	1	02SEP2020	1/39	1	Yes		NA	R (10OCT2020)	N/N	
	GENRL	Fatigue/ fatigue#	2	13JAN2021	1/4	2	Yes		NA	R (16JAN2021)	N/N	
		Injection site pain/ sore arm (injection site)#	2	13JAN2021	1/5	1	Yes		NA	R (17JAN2021)	N/N	
	INV	Body temperature increased/ body temperature increased (F)#	2	14JAN2021	2/2	2	Yes		NA	R (15JAN2021)	N/N	
	NERV	Dizziness/ lightheaded#	2	14JAN2021	2/1	2	Yes		NA	R (14JAN2021)	N/N	
16-55/ C4591001 1141 11411165	GENRL	Injection site pain/ injection site pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1141 11411166	GENRL	Fatigue/ Fatigue#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
	INV	Body temperature increased/ body temperature increased (tmax 100.1F)#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	1/3	2	Yes		NA/TC	R (04SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N	
	GENRL	Chills/ Chills	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N	
	INV	Body temperature increased/ Elevated body temperature	2	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain.	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N	
16-55/ C4591001 1141 11411167	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N	
	INV	Body temperature increased/ Elevated Body Temperature	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
	MUSC	Myalgia/ Muscle Pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
	SKIN	Hyperhidrosis/ Sweating	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411168	GENRL	Injection site pain/ injection site soreness#	3	03FEB2021	1/4	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1141 11411169	GENRL	Injection site pain/ Injection site pain	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1141 11411170	GASTR	Nausea/ Nausea#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Asthenia/ Lack of Energy#	3	12FEB2021	2/2	2	Yes		NA	R (13FEB2021)	N/N
		Fatigue/ Fatigue#	3	12FEB2021	2/2	2	Yes		NA	R (13FEB2021)	N/N
		Injection site swelling/ Swelling at injection site#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
		Malaise/ Malaise#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	3	12FEB2021	2/2	2	Yes		NA	R (13FEB2021)	N/N
	NERV	Headache/ Headache#	3	12FEB2021	2/2	2	Yes		NA	R (13FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	13FEB2021	3/1	2	Yes		NA	R (13FEB2021)	N/N
	GENRL	Pyrexia/ Fever (T Max 104 F)#	3	13FEB2021	3/1	3	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection pain left upper arm	1	03SEP2020	1/4	1	Yes		NA	R (06SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411171	GENRL	Injection site pain/ injection site pain	1	20SEP2020	18/6	2	Yes	NA	NA	R (25SEP2020)	N/N
	GASTR	Abdominal pain upper/ gastralgia	2	23SEP2020	2/3	1	Yes	NA	NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	23SEP2020	2/C	2	Yes	NA	NA	RG	N/N
	INV	Body temperature increased/ elevated body temperature	2	23SEP2020	2/3	2	Yes	NA	NA	R (25SEP2020)	N/N
	MUSC	Back pain/ back pain	2	23SEP2020	2/3	2	Yes	NA	NA	R (25SEP2020)	N/N
	NERV	Dizziness/ dizziness	2	23SEP2020	2/3	1	Yes	NA	NA	R (25SEP2020)	N/N
	RESP	Nasal congestion/ nasal congestion	2	23SEP2020	2/3	1	Yes	NA	NA	R (25SEP2020)	N/N
16-55/ C4591001 1141 11411172	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/2	2	Yes	NA	NA	R (17FEB2021)	N/N
		Malaise/ Malaise#	4	16FEB2021	2/2	2	Yes	NA	NA	R (17FEB2021)	N/N
	MUSC	Myalgia/ Generalized Myalgia#	4	16FEB2021	2/2	2	Yes	NA	NA	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	2/2	2	Yes	NA	NA	R (17FEB2021)	N/N
16-55/ C4591001 1141 11411173	GENRL	Injection site pain/ Injection Site Pain	1	04SEP2020	1/2	1	Yes	NA	NA	R (05SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411174	GENRL	Injection site pain/ injection site pain	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
	GENRL	Chills/ chills	2	25SEP2020	1/3	3	Yes		NA/TC	R (27SEP2020)	N/N
		Fatigue/ fatigue	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
		Pain/ body aches	2	25SEP2020	1/3	3	Yes		NA/TC	R (27SEP2020)	N/N
	INV	Body temperature increased/ elevated body temperature, max temp 99.0	2	25SEP2020	1/3	1	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1141 11411175	GENRL	Injection site pain/ Injection Site Pain#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1141 11411176	MUSC	Myalgia/ Myalgia#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N
16-55/ C4591001 1141 11411177	GASTR	Diarrhoea/ Diarrhea	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	NERV	Headache/ Headache	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N
	INV	Body temperature increased/ Elevated Body Temperature	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411179	GENRL	Injection site pain/ Injection Site Soreness	2	25SEP2020	2/4	2	Yes		NA/TC	R (28SEP2020)	N/N
	MUSC	Arthralgia/ Bilateral Knee Arthralgia	2	25SEP2020	2/4	1	Yes		NA/TC	R (28SEP2020)	N/N
		Back pain/ Back Ache	2	25SEP2020	2/4	1	Yes		NA/TC	R (28SEP2020)	N/N
	GENRL	Injection site erythema/ Erythema at Injection Site	2	26SEP2020	3/3	1	Yes		NA	R (28SEP2020)	N/N
	GENRL	Injection site swelling/ Swelling at the Injection Site	2	27SEP2020	4/2	1	Yes		NA	R (28SEP2020)	N/N
	GENRL	Injection site pain/ muscle soreness injection arm	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	NERV	Headache/ Headaches	1	14SEP2020	7/11	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ injection site soreness	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	BLOOD	Lymph node pain/ tender left lymph node axillary	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	INV	Body temperature increased/ elevated body temperature, max temp 103.3	2	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1141 11411181	GENRL	Injection site pain/ Left arm injection site Pain	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Injection site soreness#	3	22JAN2021	1/2	1	Yes		NA/TCN	R (23JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411182	GENRL	Chills/ Chills#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
		Feeling hot/ Warm Sensation#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
	MUSC	Back pain/ back pain	1	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
	INFEC	Vaginal infection/ Vaginal Infection	1	17SEP2020	10/8	1	No	O	NA/TC	R (24SEP2020)	N/N
	INJ&P	Limb injury/ puncture injury (stepped on nail) left foot	2	09DEC2020	70/15	1	No	O	NA/TC	R (23DEC2020)	N/N
16-55/ C4591001 1141 11411184	NERV	Headache/ Headaches	1	25SEP2020	17/8	1	No	O	NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1141 11411185	GENRL	Injection site pain/ injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
	NERV	Headache/ headache#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
	GENRL	Chills/ Chills	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Fatigue/ Fatigue	1	09SEP2020	1/4	1	Yes		NA	R (12SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411186	MUSC	Injection site swelling/ Injection Site Swelling	1	09SEP2020	1/2	1	Yes	NA	R	(10SEP2020)	N/N
		Pain/ Body Aches	1	09SEP2020	1/4	1	Yes	NA	R	(12SEP2020)	N/N
		Myalgia/ Muscle Soreness	1	09SEP2020	1/4	1	Yes	NA	R	(12SEP2020)	N/N
	GENRL	Chills/ Chills	2	29SEP2020	2/2	1	Yes	NA	R	(30SEP2020)	N/N
		Fatigue/ Fatigue	2	29SEP2020	2/3	2	Yes	NA	R	(01OCT2020)	N/N
	MUSC	Injection site pain/ Injection Site Pain	2	29SEP2020	2/2	1	Yes	NA	R	(30SEP2020)	N/N
		Myalgia/ Muscle Aches	2	29SEP2020	2/3	2	Yes	NA	R	(01OCT2020)	N/N
	NERV	Headache/ Headache	1	10SEP2020	2/5	2	Yes	NA/TC	R	(14SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	30SEP2020	2/3	1	Yes	NA	R	(02OCT2020)	N/N
	NERV	Injection site pain/ Injection Site Soreness Left Arm	2	30SEP2020	2/3	1	Yes	NA	R	(02OCT2020)	N/N
Headache/ Headache		2	30SEP2020	2/3	2	Yes	NA/TC	R	(02OCT2020)	N/N	
16-55/ C4591001 1141 11411187	GENRL	Injection site swelling/ Injection site swelling	1	09SEP2020	1/2	1	Yes	NA	R	(10SEP2020)	N/N
	GENRL	Chills/ Chills	1	10SEP2020	2/2	1	Yes	NA	R	(11SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411188	NERV	Fatigue/ Fatigue	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Headache/ Headache	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	12SEP2020	4/2	2	Yes		NA	R (13SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	02OCT2020	2/1	2	Yes		NA/TC	R (02OCT2020)	N/N
	NERV	Headache/ Headache	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
	GENRL	Injection site pain/ injection site soreness	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1141 11411192	GENRL	Injection site pain/ Injection Site Pain	2	28SEP2020	1/2	2	Yes		NA/TC	R (29SEP2020)	N/N
	MUSC	Myalgia/ Generalized Myalgia	2	29SEP2020	2/1	2	Yes		NA	R (29SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	NERV	Injection site pain/ Injection site pain left arm deltoid	1	10SEP2020	1/3	1	Yes		NA/TC	R (12SEP2020)	N/N
		Headache/ Headache	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	INV	Body temperature increased/ Elevated body Temperature	1	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
GENRL	Fatigue/ Fatigue	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411194	NERV	Injection site pain/ Injection Site Pain	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		Pyrexia/ Fever	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
	GENRL	Headache/ Headache	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		Chills/ Chills	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	10SEP2020	1/3	2	Yes		NA	R (12SEP2020)	N/N
	NERV	Injection site pain/ injection site pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Headache/ Headache	1	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	22DEC2020	1/2	1	Yes		NA/TC	R (23DEC2020)	N/N
	GENRL	Injection site pain/ injection site soreness#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
INV	Body temperature increased/ elevated body temperature 101.3F#	4	12JAN2021	2/1	1	Yes		NA/TC	R (12JAN2021)	N/N	
16-55/ C4591001 1141 11411195	INFEC	Sinusitis/ Sinus Infection	1	30SEP2020	21/10	2	No	O	NA/TC	R (09OCT2020)	N/N
	SKIN	Alopecia/ patchy hair loss	2	28FEB2021	138/C	1	No	O	NA	N	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411197	GENRL	Fatigue/ fatigue	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		Injection site pain/ injection site pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1141 11411198	GENRL	Injection site pain/ Injection site pain	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
		Injection site swelling/ swelling injection area	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Chills/ Chills	2	01OCT2020	2/3	2	Yes		NA/TC	R (03OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	01OCT2020	2/5	2	Yes		NA	R (05OCT2020)	N/N
	INV	Body temperature increased/ Elevated Body Temperature	2	01OCT2020	2/3	1	Yes		NA/TC	R (03OCT2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	01OCT2020	2/4	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Injection site erythema/ Erythema at Injection Site	2	04OCT2020	5/4	2	Yes		NA	R (07OCT2020)	N/N
		Injection site macule/ Skin Macule at Injection Site	2	04OCT2020	5/4	2	Yes		NA	R (07OCT2020)	N/N
		Injection site swelling/ Swelling at Injection Site	2	04OCT2020	5/4	2	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1141 11411199		Injection site pain/ injection site pain#	4	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N	
	MUSC	Myalgia/ Generalized myalgia#	4	29JAN2021	1/3	1	Yes		NA/TC	R (31JAN2021)	N/N	
	NERV	Headache/ Worsening headache (from baseline)#	4	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N	
16-55/ C4591001 1141 11411201	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N	
16-55/ C4591001 1141 11411202	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/Y	
	GENRL	Fatigue/ Fatigue	1	14SEP2020	4/11	1	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N	
16-55/ C4591001 1141 11411203	GENRL	Fatigue/ Fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	
		Injection site pain/ Injection site pain left extremity	1	12SEP2020	2/3	2	Yes		NA	R (14SEP2020)	N/N	
	INV	Body temperature increased/ Elevated body temperature	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	
	GENRL	Injection site pain/ injection site pain	1	30SEP2020	20/3	1	Yes		NA	R (02OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1141 11411204	SKIN	Pityriasis rosea/ Neck rash pityriasis rosea	2	07DEC2020	68/55	1	No	O	NA/TC	R (30JAN2021)	N/N	
		Pityriasis rosea/ Truncal rash pityriasis rosea	2	07DEC2020	68/55	1	No	O	NA/TC	R (30JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	2	09FEB2021	132/1	1	Yes		NA	R (09FEB2021)	N/N	
		Injection site pain/ injection site sore arm deltoid area#	3	09FEB2021	1/3	2	Yes		NA	R (11FEB2021)	N/N	
	NERV	Headache/ headache#	2	09FEB2021	132/1	2	Yes		NA	R (09FEB2021)	N/N	
16-55/ C4591001 1141 11411205	GENRL	Injection site pain/ Injection Site Pain left arm	1	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N	
	NERV	Headache/ Headache	1	15SEP2020	2/3	2	Yes		NA/TC	R (17SEP2020)	N/N	
	NERV	Headache/ headache	1	29SEP2020	16/2	1	No	O	NA/TC	R (30SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N	
	NERV	Headache/ headache	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N	
16-55/ C4591001 1141 11411206	GENRL	Fatigue/ Fatigue#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1141 11411208	MUSC	Injection site pain/ Injection site pain#	3	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N	
		Myalgia/ myalgias#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N	
	NERV	Headache/ Headache#	3	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N	
		Pyrexia/ fever#	3	13JAN2021	2/2	2	Yes		NA/TC	R (14JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	01FEB2021	1/4	2	Yes		NA	R (04FEB2021)	N/N	
		Pyrexia/ Fever#	4	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N	
	MUSC	Myalgia/ Myalgias#	4	01FEB2021	1/4	2	Yes		NA/TC	R (04FEB2021)	N/N	
		Headache/ Headache#	4	01FEB2021	1/4	2	Yes		NA/TC	R (04FEB2021)	N/N	
	GENRL	Chills/ Chills (Rigors)#	4	14JAN2021	2/1	2	Yes		NA	R (14JAN2021)	N/N	
	16-55/ C4591001 1141 11411209	GENRL	Pyrexia/ Fever (103.1)#	4	14JAN2021	2/1	2	Yes		NA	R (14JAN2021)	N/N
Injection site pain/ Injection Site Pain			1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N	
GENRL		Injection site pain/ injection site pain	2	07OCT2020	1/3	2	Yes		NA	R (09OCT2020)	N/N	
GENRL		Pyrexia/ low grade fever, max temp 99.9	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411211	MUSC	Myalgia/ left deltoid muscle soreness#	3	18DEC2020	1/2	2	Yes		NA	R (19DEC2020)	N/N
	GENRL	Pyrexia/ Fever (100.6 F)#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1141 11411212	GENRL	Injection site pain/ Injection Site Pain	1	15SEP2020	1/4	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Injection site bruising/ Bruise at Injection Site	1	16SEP2020	2/6	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	06OCT2020	1/4	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Pain/ Body Aches	2	07OCT2020	2/2	2	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1141 11411213	GENRL	Injection site pain/ injection site pain left upper arm	1	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ Fever	1	16SEP2020	2/1	2	Yes		NA/TC	R (16SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
		Myalgia/ Muscle Pain	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411214	GASTR	Tooth impacted/ Impacted Wisdom Teeth	2	16OCT2020	4/1	2	No	O	NA/TC/TCN	R (16OCT2020)	N/N
	INFEC	Endometritis/ Endometritis#	2	08MAR2021	147/C	2	No	O	NA/TC	RG	N/N
	INV	Body temperature increased/ elevated body temperature, max temp 99.3	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
	NERV	Headache/ headache	2	08OCT2020	2/2	2	Yes		NA	R (09OCT2020)	N/N
	PSYCH	Mental fatigue/ Mental fatigue	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	4	04FEB2021	1/3	2	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1141 11411215	GENRL	Injection site pain/ tenderness at injection site#	4	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Fatigue/ fatigue	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
	MUSC	Myalgia/ Myalgias#	4	19JAN2021	1/2	2	Yes		NA/TC	R (20JAN2021)	N/N
	GENRL	Chills/ Chills#	4	20JAN2021	2/1	3	Yes		NA/TC	R (20JAN2021)	N/N
16-55/ C4591001	INV	Body temperature increased/ body temperature increased (99.1)#	4	20JAN2021	2/1	3	Yes		NA/TC	R (20JAN2021)	N/N
	GENRL	Fatigue/ fatigue	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411217		Injection site pain/ injection site pain	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
		Injection site pain/ injection site pain	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
		Pyrexia/ low grade fever	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
	INV	Body temperature increased/ elevated body temperature, temperature 100.4	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	MUSC	Muscular weakness/ muscle weakness	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1141 11411218	GENRL	Injection site erythema/ Injection site erythema	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Injection site myalgia	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	METAB	Decreased appetite/ Loss of Appetite	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ injection site soreness	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
	GENRL	Injection site pain/ injection site tenderness#	3	02FEB2021	1/4	1	Yes		NA/TC	R (05FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411219	GENRL	Fatigue/ Fatigue#	3	03FEB2021	2/3	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	24FEB2021	2/2	1	Yes		NA	R (25FEB2021)	N/N
		Injection site pain/ injection site pain#	4	24FEB2021	2/2	3	Yes		NA/TC	R (25FEB2021)	N/N
	INV	Body temperature increased/ elevated body temperature (99.6F)#	4	24FEB2021	2/2	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness Right Arm	1	16SEP2020	1/3	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Injection site warmth/ Warm Sensation at Injection Site	2	08OCT2020	1/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	VASC	Flushing/ General Flushing	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain left arm	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/Y
	GENRL	Chills/ Chills	1	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Pain/ Body aches	1	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1141 11411220	GENRL	Fatigue/ Fatigue	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Pain/ Body Aches	2	09OCT2020	1/2	2	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	11OCT2020	3/3	1	Yes		NA	R (13OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	11OCT2020	3/3	1	Yes		NA	R (13OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1141 11411221	GENRL	Chills/ chills#	3	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N	
		Fatigue/ Fatigue#	3	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N	
		Pyrexia/ Fever (100.9 F)#	3	21JAN2021	2/2	1	Yes		NA/TC	R (22JAN2021)	N/N	
	BLOOD	Lymphadenopathy/ left axillary lymph node enlargement#	3	23JAN2021	4/3	1	Yes		NA	R (25JAN2021)	N/N	
	NERV	Headache/ headache#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N	
16-55/ C4591001 1141 11411222	GENRL	Fatigue/ Fatigue	1	17SEP2020	2/3	1	Yes		NA/TC	R (19SEP2020)	N/N	
	MUSC	Arthralgia/ Arthralgia, Bilateral Knees	1	17SEP2020	2/3	1	Yes		NA/TC	R (19SEP2020)	N/N	
		Myalgia/ Myalgia	1	17SEP2020	2/3	1	Yes		NA/TC	R (19SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N	
		Injection site pain/ Injection Site Soreness	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N	
16-55/ C4591001 1141 11411223	GENRL	Injection site pain/ Injection Site Soreness	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411224	NERV	Headache/ Headache	1	17SEP2020	2/7	1	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1141 11411226	GENRL	Fatigue/ Fatigue	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1141 11411227	GENRL	Injection site pain/ Pain at injection site left arm	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/Y
	GENRL	Fatigue/ Fatigue	1	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
GENRL	PSYCH	Anxiety/ Worsening anxiety	1	18SEP2020	2/4	1	Yes		NA/TC	R (21SEP2020)	N/N
	PSYCH	Depression/ Worsening depression	1	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/Y
MUSC	Myalgia/ Generalized Myalgias	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411229	GENRL	Fatigue/ Fatigue	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
	PSYCH	Depression/ Worsening depression	2	24OCT2020	16/C	2	No	O	NA/TC	N	N/N
	GASTR	Nausea/ nausea (in evening)#	4	06JAN2021	1/3	2	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1141 11411230	GENRL	Injection site pain/ injection site soreness#	4	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Injection site pain/ injection site soreness left arm	1	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	1	18SEP2020	1/14	1	Yes		NA	R (01OCT2020)	N/N
	INV	Body temperature increased/ elevated body temperature, temperature 99.1	1	20SEP2020	3/1	1	Yes		NA	R (20SEP2020)	N/N
	BLOOD	Lymphadenopathy/ enlarged left interior neck lymph node	1	30SEP2020	13/C	1	Yes		NA	N	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	16OCT2020	1/4	1	Yes		NA	R (19OCT2020)	N/Y
	MUSC	Back pain/ Myalgia in Entire Back	2	17OCT2020	2/3	1	Yes		NA	R (19OCT2020)	N/N
		Back pain/ Right Sided Upper Back Pain	2	17OCT2020	2/1	2	No	O	NA	R (17OCT2020)	N/N
16-55/ C4591001 1141 11411231	GENRL	Injection site pain/ Injection Site Pain Right Arm	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1141 11411235	GENRL	Injection site pain/ injection site soreness	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1141 11411236	NERV	Paraesthesia/ Facial Tingling	1	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain Left Arm	1	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
	GENRL	Injection site erythema/ Erythema at Injection Site	2	10OCT2020	2/5	1	Yes		NA	R (14OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1141 11411237	GENRL	Fatigue/ Fatigue	1	23SEP2020	3/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Injection site soreness#	4	01FEB2021	1/1	1	Yes		NA	R (01FEB2021)	N/N
16-55/ C4591001 1141 11411238	MUSC	Myalgia/ generalized myalgias#	3	12FEB2021	1/1	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001	MUSC	Arthralgia/ Right wrist pain	1	SEP2020	1/C	1	No	O	NA/TCN	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411239 16-55/ C4591001 1141 11411240	GENRL	Injection site pain/ Injection Site Pain Left Arm	1	22SEP2020	1/3	2	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Injection site swelling/ Swelling at Injection Site	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	IMMUN	Seasonal allergy/ Seasonal Allergies	1	01OCT2020	10/32	1	No	O	NA/TC	R (01NOV2020)	N/N
	GENRL	Chills/ Chills	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	13OCT2020	1/3	2	Yes		NA/TC	R (15OCT2020)	N/N
		Injection site swelling/ Swelling at Injection Site	2	13OCT2020	1/34	1	Yes		NA	R (15NOV2020)	N/N
		Malaise/ Malaise	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1141 11411241	GENRL	Injection site pain/ Injection Site Pain	1	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N
	INV	Body temperature increased/ body temperature increased	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
	NERV	Headache/ Headache	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411242	INFEC	Puncture site infection/ infected ear piercing right ear	2	27OCT2020	13/12	1	No	O	NA/TC	R (07NOV2020)	N/N
	GENRL	Injection site pain/ sore deltoid left arm (injection area)#	3	05FEB2021	1/3	2	Yes		NA/TC	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	3	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1141 11411243	GENRL	Injection site pain/ Injection Site Pain Left Arm	1	24SEP2020	1/3	2	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	INV	Body temperature increased/ Elevated Body Temperature	1	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Axillary pain/ Left Sided Axilla Pain	2	15OCT2020	2/4	1	Yes		NA	R (18OCT2020)	N/N
	MUSC	Neck pain/ L Sided Cervical Pain	2	15OCT2020	2/5	1	Yes		NA	R (19OCT2020)	N/N
16-55/ C4591001 1141 11411245	GENRL	Fatigue/ fatigue#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N
		Injection site pain/ injection site pain#	3	16DEC2020	1/2	2	Yes		NA/TC	R (17DEC2020)	N/N
	GENRL	Chills/ chills (rigor)#	4	04JAN2021	1/2	1	Yes		NA/TC	R (05JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1141 11411246	MUSC	Injection site pain/ injection site pain#	4	04JAN2021	1/2	1	Yes		NA/TC	R (05JAN2021)	N/N	
		Myalgia/ myalgia#	4	04JAN2021	1/2	1	Yes		NA/TC	R (05JAN2021)	N/N	
	GENRL	Injection site pain/ Injection Site Pain Right Arm	1	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N	
	GENRL	Pain/ Body Aches	1	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N	
		Injection site pain/ injection site soreness	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N	
		Fatigue/ fatigue	1	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N	
	16-55/ C4591001 1141 11411248	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/3	2	Yes		NA/TC	R (19DEC2020)	N/N
	16-55/ C4591001 1141 11411249	GENRL	Injection site pain/ Injection site myalgia left arm	1	25SEP2020	1/3	1	Yes		NA/TC	R (27SEP2020)	N/N
GENRL	Injection site swelling/ Swelling at Injection Site Left Arm	1	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N		
	Injection site warmth/ Warm Sensation at injection site left Arm	1	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N		

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1141 11411250	GENRL	Injection site erythema/ Erythema at Injection Site	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N	
		Injection site swelling/ Swelling at Injection Site	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N	
		Injection site warmth/ Warmth at Injection Site	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N	
	MUSC	Musculoskeletal stiffness/ L Upper Arm Stiffness	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N	
	GENRL	Feeling cold/ Feeling Cold	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N	
	MUSC	Arthralgia/ L Sided Shoulder Pain	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N	
		Neck pain/ L Sided Neck Pain	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N	
	NERV	Dizziness/ Lightheaded	2	14OCT2020	2/1	2	Yes		NA/TCN	R (14OCT2020)	N/N	
		Fatigue/ Fatigue after blood draw*		05OCT2020	1/1	1	No	O	NA	R (05OCT2020)	N/N	
		GENRL	Injection site pain/ injection site pain#	3	03FEB2021	1/3	2	Yes		NA/TC	R (05FEB2021)	N/N
		GENRL	Fatigue/ fatigue#	3	04FEB2021	2/3	2	Yes		NA	R (06FEB2021)	N/N
		MUSC	Myalgia/ generalized body aches (myalgia)#	3	04FEB2021	2/3	2	Yes		NA/TC	R (06FEB2021)	N/N
	NERV	Headache/ headache#	3	04FEB2021	2/3	1	Yes		NA/TC	R (06FEB2021)	N/N	
	MUSC	Myalgia/ generalized body aches (myalgia)#	4	24FEB2021	1/4	2	Yes		NA/TC	R (27FEB2021)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1141 11411251	NERV	Headache/ headache#	3	24FEB2021	22/4	1	Yes		NA	R (27FEB2021)	N/N	
	GENRL	Injection site pain/ injection site pain#	4	25FEB2021	2/3	1	Yes		NA	R (27FEB2021)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N	
16-55/ C4591001 1141 11411255	GENRL	Injection site pain/ injection site pain left arm	1	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/Y	
	GENRL	Injection site pain/ Injection site soreness	2	29OCT2020	1/1	1	Yes		NA	R (29OCT2020)	N/N	
16-55/ C4591001 1141 11411256	GENRL	Injection site pain/ Injection site soreness#	3	17FEB2021	1/3	2	Yes		NA	R (19FEB2021)	N/Y	
	GENRL	Injection site bruising/ Bruising at injection site	1	05NOV2020	2/4	1	Yes		NA	R (08NOV2020)	N/N	
	MUSC	Muscle spasms/ Muscle cramping in right shoulder	1	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N	
	NERV	Headache/ Headache	1	08NOV2020	5/2	2	Yes		NA/TC	R (09NOV2020)	N/N	
MUSC	Musculoskeletal chest pain/ Localized Rib pain#	2	29DEC2020	26/35	2	No	O		NA/TC	R (01FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411257	GENRL	Chills/ Chills#	3	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	3	06FEB2021	2/1	1	Yes		NA/TC	R (06FEB2021)	N/N
	GENRL	Chills/ Chills	1	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
	INV	Body temperature increased/ Elevated Body Temperature	1	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
	MUSC	Arthralgia/ Joint Pain	1	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	02NOV2020	1/5	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1141 11411260	GENRL	Injection site erythema/ Erythema at injection site	2	03NOV2020	2/5	2	Yes		NA	R (07NOV2020)	N/N
		Injection site swelling/ Swelling at injection site	2	03NOV2020	2/5	2	Yes		NA	R (07NOV2020)	N/N
	GENRL	Injection site pain/ left deltoid muscle pain (injection site) (woke her in the night)#	3	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	30JAN2021	2/2	2	Yes		NA	R (31JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N
GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411262	INV	Body temperature increased/ elevated body temperature (99.9F)#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N
	RESP	Rhinorrhoea/ Rhinorrhea#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Injection site bruising/ Bruise at injection site#	4	20FEB2021	4/C	1	Yes		NA	N	N/N
	GENRL	Injection site pain/ injection site pain#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Injection site pain/ Left Arm Soreness at Injection Site	1	19OCT2020	1/3	2	Yes		NA	R (21OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
	INV	Body temperature increased/ Elevated Body Temperature	2	10NOV2020	2/1	1	Yes		NA/TC	R (10NOV2020)	N/N
	MUSC	Myalgia/ Generalized Myalgia	2	10NOV2020	2/2	2	Yes		NA/TC	R (11NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11NOV2020	3/2	2	Yes		NA	R (12NOV2020)	N/N
	MUSC	Pain in extremity/ Upper Arm Soreness L Side, deltoid muscle area	1	20OCT2020	1/4	1	Yes		NA	R (23OCT2020)	N/N
GENRL	Injection site haemorrhage/ Ecchymosis at Injection Site	1	22OCT2020	3/5	1	Yes		NA	R (26OCT2020)	N/N	
EAR	Otorrhoea/ Ear discharge	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills	2	10NOV2020	1/2	2	Yes		NA	R (11NOV2020)	N/N
		Injection site pain/ Injection site soreness	2	10NOV2020	1/9	1	Yes		NA	R (18NOV2020)	N/N
	INV	Body temperature increased/ Elevated body temperature	2	10NOV2020	1/2	1	Yes		NA/TC	R (11NOV2020)	N/N
	NERV	Headache/ Headache	2	10NOV2020	1/2	1	Yes		NA/TC	R (11NOV2020)	N/N
	GENRL	Injection site haemorrhage/ Ecchymosis at injection site	2	11NOV2020	2/8	1	Yes		NA	R (18NOV2020)	N/N
		Injection site swelling/ Swelling at injection site	2	11NOV2020	2/8	1	Yes		NA	R (18NOV2020)	N/N
	SKIN	Hyperhidrosis/ Diaphoresis	2	11NOV2020	2/1	2	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1141 11411265	GENRL	Injection site pain/ injection site pain#	3	02FEB2021	1/4	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1141 11411266	MUSC	Arthralgia/ Left Shoulder Pain in vaccinated arm	1	21OCT2020	1/4	2	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N
		Injection site swelling/ Swelling at injection site	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N
	NERV	Headache/ Headache	2	11NOV2020	2/1	1	Yes		NA/TC	R (11NOV2020)	N/N
16-55/ C4591001	GENRL	Injection site erythema/ Slight Erythema at Injection Site	1	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1141 11411269		Injection site pain/ injection site soreness	1	27OCT2020	1/2	2	Yes		NA	R (28OCT2020)	N/N	
	GENRL	Chills/ Chills	2	18NOV2020	1/2	1	Yes		NA/TC	R (19NOV2020)	N/N	
		Injection site pain/ Injection Site Pain	2	18NOV2020	1/2	1	Yes		NA/TC	R (19NOV2020)	N/N	
	NERV	Dizziness/ Light Headed	2	18NOV2020	1/2	1	Yes		NA/TC	R (19NOV2020)	N/N	
16-55/ C4591001 1141 11411270	GENRL	Injection site pain/ injection site pain#	3	23DEC2020	1/3	1	Yes		NA/TC	R (25DEC2020)	N/N	
	GENRL	Injection site pain/ injection site soreness left deltoid#	4	13JAN2021	1/2	1	Yes		NA/TC	R (14JAN2021)	N/N	
	GENRL	Chills/ chills#	4	14JAN2021	2/1	2	Yes		NA/TC	R (14JAN2021)	N/N	
		Fatigue/ Fatigue#	4	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N	
		Malaise/ malaise#	4	14JAN2021	2/1	2	Yes		NA/TC	R (14JAN2021)	N/N	
	INV	Body temperature increased/ elevated body temperature tmax 100.0F#	4	14JAN2021	2/1	1	Yes		NA/TC	R (14JAN2021)	N/N	
	MUSC	Myalgia/ muscles aches#	4	14JAN2021	2/1	2	Yes		NA/TC	R (14JAN2021)	N/N	
	BLOOD	Lymphadenopathy/ enlarged lymph node left arm axillary#	4	15JAN2021	3/3	1	Yes		NA	R (17JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1142 11421007	SKIN	Pruritus/ Diffuse itching#	3	30DEC2020	1/2	2	Yes		NA	R (31DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	31DEC2020	2/7	1	Yes		NA	R (06JAN2021)	N/N
		Pain/ Body aches#	3	31DEC2020	2/3	1	Yes		NA	R (02JAN2021)	N/N
	GENRL	Pain/ Body Aches#	4	21JAN2021	2/4	2	Yes		NA	R (24JAN2021)	N/N
	NERV	Headache/ Headache#	4	21JAN2021	2/1	2	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1142 11421010	GENRL	Injection site pain/ Injection site pain#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1142 11421020	GENRL	Injection site pain/ injection site pain#	3	18DEC2020	2/5	1	Yes		NA	R (22DEC2020)	N/N
	GASTR	Nausea/ nausea#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Myalgia/ muscle aches#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ headache#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1142 11421022	GENRL	Injection site pain/ injection site pain#	3	31DEC2020	2/1	1	Yes		NA	R (31DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1142 11421041	GENRL	Malaise/ malaise#	4	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
		Pyrexia/ fever#	4	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
		Injection site pain/ injection site pain#	2	20DEC2020	114/5	1	Yes		NA	R (24DEC2020)	N/N
	GASTR	Nausea/ Nausea#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Pain/ Body aches#	4	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1142 11421045	GENRL	Injection site pain/ injection site pain#	4	04FEB2021	23/2	2	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain#	3	26FEB2021	1/2	2	Yes		NA	R (27FEB2021)	N/N
	SKIN	Ecchymosis/ ecchymosis at left antecubital fossa#	3	27FEB2021	2/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1142 11421049	NERV	Headache/ headache#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1142 11421051	GENRL	Injection site pain/ injection site pain#	3	19DEC2020	2/3	1	Yes		NA	R (21DEC2020)	N/N
	GENRL	Pain/ body aches#	4	30JAN2021	2/2	2	Yes		NA	R (31JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1142 11421052	SKIN	Rash/ rash	1	18AUG2020	13/8	2	No	O	NA/TC	R (25AUG2020)	N/N
16-55/ C4591001 1142 11421056	GENRL	Injection site pain/ injection site pain#	3	30DEC2020	1/3	2	Yes		NA	R (01JAN2021)	N/N
	GENRL	Chills/ chills#	4	23JAN2021	2/2	2	Yes		NA	R (24JAN2021)	N/N
		Malaise/ malaise#	4	23JAN2021	2/2	2	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1142 11421059	GENRL	Injection site pain/ injection site pain#	3	29DEC2020	1/2	2	Yes		NA	R (30DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	4	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
		Injection site pain/ injection site pain#	4	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
		Pain/ body aches#	4	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1142 11421060	GENRL	Fatigue/ fatigue#	3	17DEC2020	2/1	1	Yes		NA	R (17DEC2020)	N/N
		Injection site pain/ injection site pain#	3	17DEC2020	2/1	1	Yes		NA	R (17DEC2020)	N/N
		Pain/ body aches#	3	17DEC2020	2/1	1	Yes		NA	R (17DEC2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1142 11421066	GENRL	Injection site pain/ injection site pain#	3	05JAN2021	1/2	2	Yes		NA	R (06JAN2021)	N/N
	GENRL	Chills/ chills#	4	26JAN2021	1/1	2	Yes		NA	R (26JAN2021)	N/Y
		Injection site pain/ injection site pain#	4	26JAN2021	1/1	2	Yes		NA	R (26JAN2021)	N/Y
16-55/ C4591001 1142 11421067	GENRL	Fatigue/ fatigue#	4	19JAN2021	8/8	3	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1142 11421078	GENRL	Injection site pain/ injection site pain#	3	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1142 11421079	GENRL	Injection site pain/ injection site pain#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N
16-55/ C4591001 1142 11421084	INJ&P	Craniocerebral injury/ Closed head injury	1	19AUG2020	8/1	3	No	O	NA	R (19AUG2020)	N/N
	PSYCH	Suicidal ideation/ Suicidal Ideation	1	19AUG2020	8/3	4	No	O	NA/TC	R (21AUG2020)	Y/N
16-55/ C4591001 1142 11421090	GENRL	Injection site pain/ injection site pain#	3	17DEC2020	1/2	1	Yes		NA/TC/TCN	R (18DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1142 11421092	NERV	Headache/ headache#	3	30DEC2020	14/2	1	No	O	NA/TCN	R (31DEC2020)	N/N	
	GENRL	Chills/ chills#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N	
	NERV	Headache/ headache#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N	
	GENRL	Chills/ chills#	3	18DEC2020	1/3	2	Yes		NA/TC/TCN	R (20DEC2020)	N/N	
			Fatigue/ fatigue#	3	18DEC2020	1/3	1	Yes		NA/TC/TCN	R (20DEC2020)	N/N
			Injection site pain/ injection site pain#	2	18DEC2020	107/3	3	Yes		NA/TC/TCN	R (20DEC2020)	N/N
	MUSC	Arthralgia/ Generalized joint pain#	3	18DEC2020	1/3	2	Yes		NA/TC	R (20DEC2020)	N/N	
16-55/ C4591001 1142 11421096		Myalgia/ muscle aches#	3	18DEC2020	1/3	2	Yes		NA/TC/TCN	R (20DEC2020)	N/N	
	SKIN	Hyperhidrosis/ sweating#	3	18DEC2020	1/3	2	Yes		NA/TC/TCN	R (20DEC2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	02FEB2021	1/2	2	Yes		NA	R (03FEB2021)	N/N	
16-55/ C4591001 1142 11421107	GENRL	Injection site pain/ injection site pain#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N	
	INJ&P	Thermal burn/ 2 in burn to left calf	2	17NOV2020	71/	2	No	O	NA/TC/TCN	R	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INJ&P	Muscle strain/ muscle strain#	2	07MAR2021	181/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1142 11421115	MUSC	Myalgia/ muscle ache#	3	30DEC2020	2/2	1	Yes		NA	R (31DEC2020)	N/N
	GENRL	Pain/ body aches#	4	22JAN2021	2/4	2	Yes		NA	R (25JAN2021)	N/N
	NERV	Headache/ headache#	4	22JAN2021	2/4	2	Yes		NA	R (25JAN2021)	N/N
16-55/ C4591001 1142 11421119	GENRL	Injection site pain/ injection site pain#	3	17DEC2020	1/2	2	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1142 11421130	GENRL	Injection site pain/ injection site pain#	3	18DEC2020	1/3	2	Yes		NA	R (20DEC2020)	N/N
	GENRL	Chills/ chills#	4	09JAN2021	2/1	3	Yes		NA	R (09JAN2021)	N/N
		Pain/ body aches#	4	09JAN2021	2/1	3	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1142 11421138	GENRL	Swelling face/ Facial swelling#	3	26JAN2021	14/2	3	No	O	NA/TC	R (27JAN2021)	N/N
	IMMUN	Hypersensitivity/ Allergic reaction#	3	26JAN2021	14/2	3	No	O	NA/TC	R (27JAN2021)	N/N
	GENRL	Pyrexia/ fever#	4	04FEB2021	2/2	2	Yes		NA	R (05FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1142 11421142	NERV	Paraesthesia/ generalized tingling sensation#	4	04FEB2021	2/2	2	Yes		NA	R (05FEB2021)	N/N
	MUSC	Arthralgia/ left shoulder pain	1	28AUG2020	8/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1142 11421153	GENRL	Pyrexia/ fever#	4	05FEB2021	2/3	2	Yes		NA	R (07FEB2021)	N/N
	MUSC	Arthralgia/ worsening right shoulder pain#	4	05FEB2021	2/8	2	Yes		NA	R (12FEB2021)	N/N
	MUSC	Back pain/ worsening back pain#	4	05FEB2021	2/8	2	Yes		NA	R (12FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1142 11421157	GENRL	Chills/ chills#	4	26JAN2021	2/1	2	Yes		NA	R (26JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	26JAN2021	2/1	2	Yes		NA	R (26JAN2021)	N/N
	GENRL	Pain/ body aches#	4	26JAN2021	2/1	2	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1142 11421158	GENRL	Pyrexia/ fever#	4	26JAN2021	2/1	2	Yes		NA	R (26JAN2021)	N/N
	GENRL	Axillary pain/ left axillary pain	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1142 11421161	GENRL	Injection site erythema/ Redness at injection site	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ Soreness at injection site	2	21SEP2020	1/3	2	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1142 11421163	GENRL	Chills/ chills	1	01SEP2020	2/2	2	Yes		NA/TC	R (02SEP2020)	N/N
		Injection site erythema/ injection site redness	1	01SEP2020	2/11	2	Yes		NA/TC/TCN	R (11SEP2020)	N/N
		Injection site pain/ injection site pain	1	02SEP2020	3/6	2	Yes		NA/TC/TCN	R (07SEP2020)	N/N
		Injection site swelling/ injection site swelling	1	02SEP2020	3/6	2	Yes		NA/TC/TCN	R (07SEP2020)	N/N
		Chills/ chills	2	24SEP2020	2/2	2	Yes		NA/TC/TCN	R (25SEP2020)	N/N
		Pain/ body aches	2	24SEP2020	2/3	2	Yes		NA/TC/TCN	R (26SEP2020)	N/N
		Pyrexia/ fever of 101.4 F	2	25SEP2020	3/2	2	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1142 11421166	GENRL	Nausea/ nausea	2	23SEP2020	2/3	2	Yes		NA	R (25SEP2020)	N/N
		Fatigue/ fatigue	2	23SEP2020	2/3	2	Yes		NA/TCN	R (25SEP2020)	N/N
		Pain/ full body aches	2	24SEP2020	3/3	2	Yes		NA/TCN	R (26SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1142 11421173	GENRL	Injection site pain/ injection site pain	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/Y
	GENRL	Injection site bruising/ injection site bruising	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	18DEC2020	1/2	2	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1142 11421175	GENRL	Injection site pain/ injection site pain#	3	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	06FEB2021	2/2	2	Yes		NA	RS (07FEB2021)	N/N
16-55/ C4591001 1142 11421181	GENRL	Injection site pain/ injection site pain	1	03SEP2020	1/15	2	Yes		NA	R (17SEP2020)	N/Y
	GENRL	Injection site swelling/ injection site swelling	1	04SEP2020	2/3	2	Yes		NA	R (06SEP2020)	N/N
	GENRL	Malaise/ malaise	2	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N
		Pain/ generalized body aches	2	26SEP2020	2/2	2	Yes		NA/TC	R (27SEP2020)	N/N
		Pyrexia/ fever of 100.5 F	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	4	08JAN2021	2/1	2	Yes		NA	R (08JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1142 11421182	MUSC	Myalgia/ muscle pain#	4	08JAN2021	2/1	2	Yes		NA	R (08JAN2021)	N/N	
16-55/ C4591001 1142 11421183	GENRL	Chills/ chills#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N	
16-55/ C4591001 1142 11421184	GENRL	Pyrexia/ fever#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N	
16-55/ C4591001 1142 11421184	GENRL	Asthenia/ generalized weakness	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
	MUSC	Pyrexia/ fever of 101.0 F	1	24SEP2020	22/3	2	Yes		NA	R (26SEP2020)	N/N	
	MUSC	Myalgia/ generalized muscle aches	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
	NERV	Headache/ headache	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1142 11421185	GENRL	Fatigue/ fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
	NERV	Pain/ body aches	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
	NERV	Headache/ headache	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1142 11421188 16-55/ C4591001 1142 11421202	GENRL	Injection site pain/ Injection site pain	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N	
	NERV	Headache/ Headache	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N	
	INFEC	Appendicitis/ Acute Appendicitis	2	05DEC2020	68/2	3	No	O	NA/TCN	R (06DEC2020)	Y/N	
16-55/ C4591001 1142 11421205	GENRL	Injection site pain/ injection site pain#	3	01JAN2021	2/3	2	Yes		NA	R (03JAN2021)	N/N	
	GENRL	Injection site pain/ injection site pain#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N	
16-55/ C4591001 1142 11421212	GENRL	Injection site pain/ injection site pain#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N	
16-55/ C4591001 1142 11421219	GENRL	Chills/ Chills	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N	
		Pain/ Body aches	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N	
16-55/ C4591001 1142 11421222	GENRL	Fatigue/ Fatigue	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills	2	06OCT2020	2/3	2	Yes		NA	R (08OCT2020)	N/N
	SKIN	Rash/ Rash on neck	2	06OCT2020	2/4	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Chills/ chills#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ headache#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1142 11421230	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	2/3	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1142 11421231	GENRL	Injection site pain/ Injection site pain	2	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N
	GENRL	Malaise/ Malaise	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1142 11421233	GENRL	Injection site pain/ Injection Site Pain	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
		Pain/ Body aches	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1142 11421234	GENRL	Injection site pain/ injection site pain#	3	03MAR2021	2/3	2	Yes		NA	R (05MAR2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site (left deltoid) soreness	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1142 11421235	GENRL	Injection site pain/ injection site (left deltoid) soreness	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1142 11421244	GENRL	Injection site pain/ injection site pain#	3	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1142 11421245	GENRL	Pain/ Body aches	2	10OCT2020	2/2	2	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1142 11421248	GENRL	Injection site pain/ injection site (left deltoid) soreness	1	21SEP2020	1/4	2	Yes		NA/TCN	R (24SEP2020)	N/N
	SKIN	Hyperhidrosis/ profuse sweating	2	13OCT2020	1/2	2	Yes		NA/TC	R (14OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	14OCT2020	2/2	2	Yes		NA	R (15OCT2020)	N/N
	MUSC	Muscular weakness/ muscle weakness	2	14OCT2020	2/2	2	Yes		NA/TC	R (15OCT2020)	N/N
	GENRL	Injection site erythema/ injection site redness	2	16OCT2020	4/2	2	Yes		NA/TC	R (17OCT2020)	N/N
		Injection site pruritus/ injection site itching	2	16OCT2020	4/2	2	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 1142 11421250	GENRL	Injection site erythema/ Redness at injection site	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ injection site pain#	3	18DEC2020	1/2	2	Yes		NA/TC	R (19DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	4	08JAN2021	1/6	2	Yes		NA/TC	R (13JAN2021)	N/N
	MUSC	Neck pain/ unilateral neck pain#	4	09JAN2021	2/5	2	Yes		NA/TC	R (13JAN2021)	N/N
	NERV	Headache/ headache#	4	10JAN2021	3/3	2	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1142 11421251	GENRL	Injection site pain/ injection site pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Pain/ body aches#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1142 11421253	GENRL	Injection site pain/ Injection site pain	1	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	NERV	Headache/ Headache	1	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	14OCT2020	2/2	2	Yes		NA	R (15OCT2020)	N/N
	NERV	Headache/ Headache	2	14OCT2020	2/2	2	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1142 11421256	BLOOD	Lymphadenopathy/ left axillary lymph node swelling#	3	17DEC2020	2/3	2	Yes		NA	R (19DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1142 11421258	BLOOD	Lymphadenopathy/ right cervical lymph node swelling#	3	24DEC2020	9/2	2	Yes		NA	R (25DEC2020)	N/N	
	BLOOD	Lymphadenopathy/ swollen left axillary lymph node#	4	07JAN2021	3/4	2	Yes		NA	R (10JAN2021)	N/N	
	BLOOD	Lymphadenopathy/ swollen right cervical lymph node#	4	12JAN2021	8/8	2	No	O	NA	R (19JAN2021)	N/N	
	GENRL	Malaise/ Malaise	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N	
	16-55/ C4591001 1142 11421264	NERV	Somnolence/ sleepiness#	3	18DEC2020	1/1	2	Yes		NA/TCN	R (18DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	19DEC2020	2/3	3	Yes		NA	R (21DEC2020)	N/N	
	GENRL	Chills/ chills#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N	
	GENRL	Pain/ body aches#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N	
	GENRL	Pyrexia/ fever#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N	
	16-55/ C4591001 1142 11421265	GENRL	Malaise/ malaise#	4	30JAN2021	2/1	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1142 11421271	BLOOD	Blood loss anaemia/ anemia secondary to menorrhoea	1	2020	1/C	2	No	O	NA/TC/TCN	RG	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chest pain/ chest pain, atypical	2	05DEC2020	41/2	2	No	O	NA/TC	R (06DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	06JAN2021	2/1	1	Yes		NA	R (06JAN2021)	N/N
	GASTR	Nausea/ nausea#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N
		Vomiting/ vomiting#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N
	GENRL	Chills/ chills#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N
		Fatigue/ fatigue#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N
		Pain/ body aches#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N
		Pyrexia/ fever#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1142 11421276	GENRL	Injection site pain/ injection site pain#	3	29DEC2020	1/2	2	Yes		NA	R (30DEC2020)	N/N
	NERV	Dizziness/ light-headedness#	4	20JAN2021	1/C	1	Yes		NA	N	N/Y
	GENRL	Pain/ body aches#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
	NERV	Headache/ headache#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1142 11421284	SURG	Injection/ injection#	3	26FEB2021	1/2	1	Yes		NA	R (27FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1142 11421287	GENRL	Injection site pain/ injection site pain#	4	13JAN2021	2/1	2	Yes		NA	R (13JAN2021)	N/N
		Malaise/ malaise#	4	13JAN2021	2/1	2	Yes		NA	R (13JAN2021)	N/N
	NERV	Headache/ headache#	4	13JAN2021	2/1	2	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1142 11421289	GENRL	Asthenia/ weakness	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
		Fatigue/ fatigue	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
		Injection site pain/ injection site pain	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
		Pain/ generalized body aches	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C4591001 1142 11421292	GENRL	Pain/ body aches#	3	22DEC2020	2/2	2	Yes		NA	R (23DEC2020)	N/N
		Chills/ chills#	4	13JAN2021	2/3	3	Yes		NA	R (15JAN2021)	N/N
	GENRL	Pain/ body aches#	4	13JAN2021	2/3	3	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1142 11421295	GENRL	Injection site pain/ injection site pain#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue#	4	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
		Injection site pain/ injection site pain#	4	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1142 11421306	GENRL	Injection site pain/ injection site pain#	3	30DEC2020	1/3	1	Yes		NA	R (01JAN2021)	N/N
	GENRL	Chills/ chills#	3	20JAN2021	22/2	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1142 11421313	GENRL	Fatigue/ fatigue#	4	12JAN2021	2/4	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1145 11451002	INJ&P	Chemical burns of eye/ chemical injury to Right Eye#	2	23JAN2021	144/5	2	No	O	NA	R (27JAN2021)	N/N
16-55/ C4591001 1145 11451017	GENRL	Fatigue/ fatigue	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1145 11451019	GENRL	Fatigue/ Fatigue	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08SEP2020	1/2	3	Yes		NA	R (09SEP2020)	N/N
		Injection site pain/ Injection site pain	2	08SEP2020	1/6	3	Yes		NA	R (13SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1145 11451022	MUSC	Myalgia/ Generalized Muscle Aches	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ Headache	2	08SEP2020	1/3	3	Yes		NA	R (10SEP2020)	N/N
	MUSC	Arthralgia/ Joint pain	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Chills/ Chills	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N
16-55/ C4591001 1145 11451025		Fatigue/ Fatigue	1	18AUG2020	1/3	1	Yes		NA	R (20AUG2020)	N/N
		Injection site pain/ Injection site pain	1	18AUG2020	1/3	2	Yes		NA/TC	R (20AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	19AUG2020	2/2	3	Yes		NA	R (20AUG2020)	N/N
16-55/ C4591001 1145 11451026		Injection site pain/ Injection site pain	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
	NERV	Headache/ Headache	1	19AUG2020	2/2	2	Yes		NA	R (20AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	18AUG2020	1/1	1	Yes		NA	R (18AUG2020)	N/Y
	GENRL	Injection site swelling/ injection site swelling	2	11SEP2020	3/7	1	Yes		NA	R (17SEP2020)	N/N
	IMMUN	Seasonal allergy/ worsening of seasonal allergies	2	28SEP2020	20/2	1	No	O	NA	R (29SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1145 11451030	GENRL	Chills/ chills	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N
	MUSC	Myalgia/ muscle aches	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N
	NERV	Headache/ headache	1	22AUG2020	2/1	2	Yes		NA	R (22AUG2020)	N/N
	MUSC	Myalgia/ muscle aches	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		Pain in extremity/ left arm pain	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ headache	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1145 11451031	RESP	Paranasal sinus discomfort/ Sinus pressure	1	21AUG2020	1/1	1	No	O	NA	R (21AUG2020)	N/Y
16-55/ C4591001 1145 11451033	GENRL	Fatigue/ Fatigue	1	21AUG2020	1/2	1	No	O	NA	R (22AUG2020)	N/N
	SKIN	Rash/ Rash	1	24AUG2020	4/8	1	No	O	NA	R (31AUG2020)	N/N
16-55/ C4591001 1145 11451034	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	1/1	2	Yes		NA	R (15SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1145 11451037	GENRL	Injection site erythema/ Injection site redness	2	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Injection site pain	2	15SEP2020	1/1	2	Yes		NA	R (15SEP2020)	N/N
		Fatigue/ Fatigue	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N
16-55/ C4591001 1145 11451042	GENRL	Injection site pain/ Arm pain at injection site	2	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N
	GASTR	Ileus/ Ileus	2	25DEC2020	102/4	3	No	O	NA	R (28DEC2020)	Y/N
16-55/ C4591001 1145 11451043	GENRL	Injection site pain/ left arm injection site pain	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Injection site pain/ left arm injection site pain	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1145 11451053	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
		Fatigue/ Fatigue	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Arthralgia/ Joint pain	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1145 11451057	GENRL	Injection site pain/ left arm injection site pain	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001 1145 11451059	EYE	Photophobia/ Photophobia	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/Y
	GENRL	Injection site pain/ Injection site pain	1	28AUG2020	1/4	2	Yes		NA	R (31AUG2020)	N/Y
	NERV	Headache/ Headache	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/Y
	MUSC	Arthralgia/ Knee pain	1	08SEP2020	12/4	2	No	O	NA	R (11SEP2020)	N/N
	MUSC	Joint swelling/ Knee swelling	1	11SEP2020	15/1	2	No	O	NA	R (11SEP2020)	N/N
	INFEC	Appendicitis/ appendicitis	2	04JAN2021	109/4	3	No	O	NA/TC/TCN	R (07JAN2021)	Y/N
16-55/ C4591001 1145 11451063	MUSC	Intervertebral disc protrusion/ disc herniation	1	14SEP2020	15/C	2	No	O	NA/TC	RG	N/N
	NERV	Paraesthesia/ Paresthesias of Skin	1	21SEP2020	22/8	3	No	CD	NA/TC	R (28SEP2020)	Y/N
	NERV	Dizziness/ dizziness	1	24SEP2020	25/2	2	No	CD	NA	R (25SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at injection site	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1145 11451064		Pyrexia/ fever	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1145 11451067	GENRL	Injection site pain/ left arm injection site pain#	3	22JAN2021	2/2	2	Yes		NA/TC	R (23JAN2021)	N/N
16-55/ C4591001 1145 11451068	GENRL	Injection site pain/ mild pain on injection site in left arm	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Pain in extremity/ Left arm soreness#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1145 11451071	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	1/2	2	Yes		NA	R (05SEP2020)	N/N
	GENRL	Chills/ chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		Fatigue/ fatigue	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ fever	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1145 11451074	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1145 11451075	GENRL	Fatigue/ Fatigue	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1145 11451079	NERV	Headache/ Headache	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	MUSC	Pain in extremity/ Arm pain	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1145 11451080	GENRL	Chills/ chills	2	25SEP2020	2/2	3	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ fever	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1145 11451081	GENRL	Fatigue/ fatigue	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1145 11451081	GENRL	Injection site pain/ Injection site pain*		09SEP2020	1/3	2	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1145 11451081	GENRL	Chills/ chills	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ injection site pain	1	29SEP2020	21/2	2	Yes		NA	R (30SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1145 11451086	MUSC	Myalgia/ muscle ache	2	29SEP2020	1/2	3	Yes		NA	R (30SEP2020)	N/N
	GASTR	Nausea/ nausea*		09SEP2020	1/23	2	Yes		NA	R (01OCT2020)	N/N
	GENRL	Fatigue/ fatigue	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1145 11451088		Injection site pain/ injection site pain	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ headache	1	29SEP2020	21/3	2	Yes		NA	R (01OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N
	RESP	Upper-airway cough syndrome/ post nasal drip	2	19OCT2020	21/3	1	Yes		NA	R (21OCT2020)	N/N
	GENRL	Pain/ aches#	4	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/Y
16-55/ C4591001 1145 11451090	MUSC	Pain in extremity/ right arm pain#	4	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Chills/ chills#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	SKIN	Fixed eruption/ fixed drug eruption:	2	01OCT2020	3/9	2	Yes		NA	R (09OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1145 11451091	GENRL	Chills/ chills*		10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N	
		Injection site pain/ injection site pain*		10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N	
	GENRL	Chills/ chills	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N	
		Injection site pain/ injection site pain	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N	
16-55/ C4591001 1145 11451093		Pyrexia/ fever	2	29SEP2020	1/3	2	Yes		NA	R (01OCT2020)	N/N	
	GENRL	Chills/ chills	1	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N	
	SKIN	Hyperhidrosis/ sweating	1	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N	
	GENRL	Chills/ chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N	
16-55/ C4591001 1145 11451094		Fatigue/ fatigue	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N	
		Injection site pain/ injection site pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N	
	MUSC	Pain in extremity/ Left arm pain#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ injection site pain left arm	1	18SEP2020	1/4	2	Yes		NA	R (21SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1145 11451107	GENRL	Chills/ shivering	2	08OCT2020	1/2	2	Yes		NA	R (09OCT2020)	N/N	
		Injection site pain/ left arm injection site pain	1	08OCT2020	21/2	1	Yes		NA	R (09OCT2020)	N/N	
		Pain/ body aches	1	08OCT2020	21/2	2	Yes		NA	R (09OCT2020)	N/N	
	GASTR	Vomiting/ vomitting	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N	
16-55/ C4591001 1145 11451108	MUSC	Arthralgia/ joint pain	1	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N	
16-55/ C4591001 1145 11451112	GENRL	Fatigue/ fatigue	1	23OCT2020	2/3	2	Yes		NA	R (25OCT2020)	N/N	
		Injection site pain/ injection site pain	1	23OCT2020	2/3	1	Yes		NA	R (25OCT2020)	N/N	
16-55/ C4591001 1146 11461002	INV	Blood pressure increased/ Elevation of baseline blood pressure	2	15SEP2020	15/58	2	No	O	NA/TC	R (11NOV2020)	N/N	
	NERV	Headache/ Headache#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N	
16-55/ C4591001 1146 11461004	EYE	Conjunctivitis allergic/ Allergic conjunctivitis	2	25NOV2020	85/8	2	No	O	NA/TC	R (02DEC2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461007	EYE	Eye irritation/ Burning eyes status post injection #1	1	12AUG2020	1/5	1	Yes		NA	R (16AUG2020)	N/N
	EYE	Eye irritation/ Burning eyes status post injection #2	2	31AUG2020	1/5	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1146 11461020	GENRL	Fatigue/ Fatigue#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	NERV	Headache/ Headache#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1146 11461021	GENRL	Fatigue/ Fatigue	1	14AUG2020	1/8	2	Yes		NA	R (21AUG2020)	N/N
	NERV	Headache/ Headache	1	14AUG2020	1/8	2	Yes		NA	R (21AUG2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	20AUG2020	7/2	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001 1146 11461044	EYE	Eye pain/ Bilateral eye pain	2	06OCT2020	29/14	1	No	O	NA	R (19OCT2020)	N/N
	INV	Blood pressure increased/ blood pressure elevation	2	20OCT2020	43/C	2	No	O	NA/TC	N	N/N
	GENRL	Chills/ Chills#	4	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N
		Fatigue/ Fatigue#	4	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461054	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/5	1	Yes		NA	R (23AUG2020)	N/Y
	GENRL	Injection site pain/ Injection sit pain post 2nd injection	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1146 11461055	MUSC	Pain in extremity/ Arm Pain#	3	10FEB2021	1/2	1	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1146 11461058	GENRL	Injection site pain/ injection site pain left arm	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/Y
16-55/ C4591001 1146 11461061	GASTR	Diarrhoea/ Diarrhea	1	20AUG2020	2/5	1	Yes		NA	R (24AUG2020)	N/N
16-55/ C4591001 1146 11461063	GENRL	Pyrexia/ Fever#	4	26JAN2021	1/2	2	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1146 11461070	GENRL	Chills/ Chills#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
		Pain/ Body aches#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1146 11461071	INFEC	Hordeolum/ sty left eye	2	15SEP2020	8/22	1	No	O	NA/TC	R (06OCT2020)	N/N	
1146 11461075	GENRL	Fatigue/ Fatigue#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	
1146 11461076	GENRL	Chills/ Chills#	4	29JAN2021	1/2	1	Yes		NA/TC	R (30JAN2021)	N/N	
1146 11461078	NERV	Headache/ Headache#	4	29JAN2021	1/2	1	Yes		NA/TC	R (30JAN2021)	N/N	
1146 11461082	GENRL	Injection site pain/ injection site pain occurring >30 min after injection	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N	
1146 11461083	GENRL	Chills/ Chills occurring >30 minutes post injection	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	
1146 11461083	GENRL	Chills/ Chills#	3	05FEB2021	1/4	1	Yes		NA	R (08FEB2021)	N/N	
	GASTR	Diarrhoea/ Diarrhea#	3	08FEB2021	4/3	1	Yes		NA	R (10FEB2021)	N/N	
	GASTR	Nausea/ Nausea#	4	26FEB2021	1/3	1	Yes		NA/TC	R (28FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Chills/ Chills#	4	26FEB2021	1/3	1	Yes		NA/TC	R (28FEB2021)	N/N	
		Pyrexia/ Fever#	4	26FEB2021	1/3	1	Yes		NA	R (28FEB2021)	N/N	
16-55/ C4591001 1146 11461084	GENRL	Injection site pain/ Injection site pain > 30 minutes post injection	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N	
16-55/ C4591001 1146 11461085	RESP	Sinus congestion/ Congested Sinuses	2	08NOV2020	59/4	1	No	O	NA	R (11NOV2020)	N/N	
16-55/ C4591001 1146 11461086	GENRL	Chills/ Chills#	3	25JAN2021	1/2	1	Yes		NA/TC	R (26JAN2021)	N/N	
	MUSC	Pain in extremity/ Arm Pain, left#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N	
16-55/ C4591001 1146 11461091	GENRL	Injection site pain/ Injection site pain >30 minutes post vaccine	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N	
16-55/ C4591001 1146 11461092	GASTR	Diarrhoea/ Diarrhea	1	28AUG2020	8/2	1	Yes		NA	R (29AUG2020)	N/N	
	GENRL	Injection site pain/ Injection site pain >30 minutes post vaccine	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1146 11461096	GENRL	Chills/ Chills	2	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
		Fatigue/ Fatigue	2	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
		Injection site pain/ Injection site pain	2	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1146 11461102	MUSC	Myalgia/ Muscle Aches#	3	27JAN2021	2/3	2	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1146 11461116	GENRL	Pain/ Body aches > 30 minutes post vaccine 2	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1146 11461117	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ Chills starting > 30 minutes post vaccine 2	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		Pain/ Body aches	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ headache >30 minutes post vaccine 2	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1146 11461118	GENRL	Injection site pain/ injection site pain	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Pyrexia/ fever of 100.7F	1	28AUG2020	3/2	2	Yes		NA/TC	R (29AUG2020)	N/N	
	GENRL	Fatigue/ fatigue post vaccine	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N	
		Injection site pain/ injection site pain >30 minutes post vaccine	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N	
	INV	Body temperature increased/ elevated temp post injection to 99.5	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001 1146 11461119	GENRL	Pyrexia/ Fever#	4	02MAR2021	1/2	1	Yes		NA	R (03MAR2021)	N/N	
16-55/ C4591001 1146 11461123	GASTR	Diarrhoea/ diarrhea	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N	
	GENRL	Chills/ chills	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N	
16-55/ C4591001 1146 11461124	INJ&P	Post procedural haemorrhage/ Mild nose bleed s/p nasal swab*		27AUG2020	1/1	1	No	O	NA/TCN	R (27AUG2020)	N/N	
	MUSC	Pain in extremity/ Arm Pain#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N	
16-55/ C4591001 1146 11461130	MUSC	Back pain/ Right mid to low back pain	2	14OCT2020	30/3	1	No	O	NA/TCN	R (16OCT2020)	N/N	
16-55/ C4591001	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	2021	106/C	3	No	O	NA	N	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1146 11461133	PREG	Abortion spontaneous/ spontaneous abortion#	2	21JAN2021	126/1	3	No	O	NA	R (21JAN2021)	Y/N
	REPRO	Vaginal haemorrhage/ Vaginal Bleeding#	2	21JAN2021	126/2	2	No	O	NA	R (22JAN2021)	Y/N
16-55/ C4591001 1146 11461141	GENRL	Injection site pain/ Injection site pain began >30 minutes after vaccine administration	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C4591001 1146 11461144	GENRL	Pain/ Body Aches#	4	05FEB2021	1/3	1	Yes		NA/TC	R (07FEB2021)	N/N
		Pyrexia/ Low grade fever#	4	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N
	MUSC	Pain in extremity/ Arm Pain#	4	05FEB2021	1/3	1	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1146 11461146	GENRL	Injection site pain/ Injection site pain#	4	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1146 11461150	NERV	Headache/ headache- day 8-9 post vaccine	1	05SEP2020	9/3	1	Yes		NA	R (07SEP2020)	N/N
	EYE	Vitreous detachment/ Posterior Vitriol Detachment	2	21SEP2020	6/C	2	No	O	NA	N	N/N
	SKIN	Dermatitis contact/ Poison Ivy Rash	2	08OCT2020	23/17	1	No	O	NA/TC	R (24OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461155	GENRL	Injection site pain/ Throbbing at injection site#	3	30JAN2021	2/1	1	Yes		NA/TCN	R (30JAN2021)	N/N
	MUSC	Pain in extremity/ Left Arm Pain#	3	30JAN2021	2/1	1	Yes		NA/TCN	R (30JAN2021)	N/N
	GENRL	Chills/ Chills#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ Site injection pain#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1146 11461157	GENRL	Pain/ Body aches#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Chills/ Chills#	4	09FEB2021	2/1	1	Yes		NA/TC	R (09FEB2021)	N/N
16-55/ C4591001 1146 11461159	MUSC	Pain in extremity/ Arm Pain#	4	09FEB2021	2/1	1	Yes		NA/TC	R (09FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain >30 minutes after vaccine administration	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Fatigue/ fatigue >30 minutes after vaccine administration	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain >30 minutes post vaccine administration	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Pyrexia/ Fever 99.5 occurred after vaccine	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461170	MUSC	Myalgia/ Muscle aches >30 minutes after vaccine	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Arthralgia/ Pain in left knee	1	SEP2020	1/	2	No	O	NA	R	N/N
16-55/ C4591001 1146 11461176	GASTR	Food poisoning/ food poisoning	1	15SEP2020	15/2	1	No	O	NA	R (16SEP2020)	N/N
		Nausea/ Nausea	1	15SEP2020	15/2	1	No	O	NA	R (16SEP2020)	N/N
16-55/ C4591001 1146 11461176	GENRL	Vaccination site induration/ 6cm induration secondary to flu vaccine	2	06OCT2020	16/5	2	No	CND	NA	R (10OCT2020)	N/N
16-55/ C4591001 1146 11461177	RENAL	Haematuria/ Hematuria#	4	20FEB2021	6/1	1	No	O	NA	R (20FEB2021)	N/N
16-55/ C4591001 1146 11461183	GENRL	Chills/ Chills	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1146 11461184		Pain/ Body aches	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Pain/ Body aches#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
	MUSC	Pain in extremity/ Sore arm#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1146 11461187	INFEC	Herpes simplex/ Herpes Simplex 1	1	14SEP2020	13/8	1	No	O	NA/TC	R (21SEP2020)	N/N	
16-55/ C4591001 1146 11461197	MUSC	Bursitis/ Bursitis of the knee	1	22SEP2020	20/29	2	No	O	NA/TC	R (20OCT2020)	N/N	
16-55/ C4591001 1146 11461200	CARD	Atrioventricular block first degree/ 1 Degree AV block	2	27SEP2020	3/1	2	No	O	NA	R (27SEP2020)	N/N	
		Bradycardia/ Acute Bradycardia	2	27SEP2020	3/2	3	No	O	NA/TC	R (28SEP2020)	Y/N	
	NERV	Syncope/ syncope	2	27SEP2020	3/3	2	No	O	NA	R (29SEP2020)	Y/N	
16-55/ C4591001 1146 11461201	GENRL	Fatigue/ Fatigue#	4	04FEB2021	1/2	1	Yes		NA/TC	R (05FEB2021)	N/N	
		Pain/ Body Aches#	4	04FEB2021	1/2	1	Yes		NA/TC	R (05FEB2021)	N/N	
	MUSC	Pain in extremity/ Arm Pain#	4	04FEB2021	1/2	1	Yes		NA/TC	R (05FEB2021)	N/N	
16-55/ C4591001 1146 11461204	PSYCH	Depression/ Worsening of depression	2	13OCT2020	22/14	2	No	O	NA/TC	R (26OCT2020)	N/N	
16-55/ C4591001	RESP	Upper-airway cough syndrome/ Post nasal drip	2	27OCT2020	35/4	1	No	O	NA	R (30OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1146 11461206 16-55/ C4591001	INFEC	Urinary tract infection/ Urinary Tract Infection	2	07OCT2020	15/8	2	No	O	NA/TC	R (14OCT2020)	N/N	
1146 11461212 16-55/ C4591001	INFEC	Hordeolum/ Stye of the left eye	1	23SEP2020	20/8	1	No	O	NA/TCN	R (30SEP2020)	N/N	
1146 11461218 16-55/ C4591001	NERV	Headache/ Mild Headache	1	23SEP2020	20/1	1	No	O	NA/TC	R (23SEP2020)	N/N	
1146 11461219 16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N	
1146 11461237		Injection site pain/ Injection site pain	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N	
		Pain/ Body aches	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N	
16-55/ C4591001 1146 11461238	GENRL	Chills/ Chills	2	07OCT2020	2/3	1	Yes		NA/TC	R (09OCT2020)	N/N	
		Pain/ Body aches	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N	
		Pyrexia/ Low grade fever of 100.8	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461239	GENRL	Pain/ Bodyaches	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/Y
	NERV	Headache/ Headaches post vaccine #2	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1146 11461241	GENRL	Chills/ Chills	2	07OCT2020	2/3	1	Yes		NA/TC	R (09OCT2020)	N/N
		Fatigue/ Fatigue	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N
		Injection site pain/ Injection site pain	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1146 11461243	GASTR	Nausea/ Nausea#	4	02MAR2021	1/3	1	Yes		NA/TC	R (04MAR2021)	N/N
	GENRL	Chills/ Chills#	4	02MAR2021	1/3	1	Yes		NA	R (04MAR2021)	N/N
		Fatigue/ Fatigue#	4	02MAR2021	1/3	1	Yes		NA	R (04MAR2021)	N/N
		Pain/ Body Aches#	4	02MAR2021	1/3	1	Yes		NA/TC	R (04MAR2021)	N/N
16-55/ C4591001 1146 11461245	INV	Blood pressure increased/ Elevated blood pressure	2	02NOV2020	28/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1146 11461248		Pyrexia/ Fever of 101.5 post injection #2	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N	
16-55/ C4591001 1146 11461250	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	1/5	1	Yes		NA	R (10OCT2020)	N/N	
16-55/ C4591001 1146 11461255	GENRL	Chills/ Chills	2	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N	
		Fatigue/ Fatigue	2	10OCT2020	2/2	2	Yes		NA	R (11OCT2020)	N/N	
		Injection site pain/ Injection site pain	2	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N	
	NERV	Headache/ Headache	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N	
16-55/ C4591001 1146 11461270	GENRL	Chills/ Chills#	4	09FEB2021	1/3	2	Yes		NA/TC	R (11FEB2021)	N/N	
		Fatigue/ Fatigue#	4	09FEB2021	1/3	1	Yes		NA/TC	R (11FEB2021)	N/N	
		Pain/ Body aches#	4	09FEB2021	1/3	1	Yes		NA/TC	R (11FEB2021)	N/N	
		Pyrexia/ Fever (100.2)#	4	09FEB2021	1/3	1	Yes		NA/TC	R (11FEB2021)	N/N	
	NERV	Headache/ Headache#	4	09FEB2021	1/3	1	Yes		NA/TC	R (11FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461271	GENRL	Injection site pain/ injection site pain left arm	2	09NOV2020	1/4	1	Yes		NA	R (12NOV2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	09NOV2020	1/4	1	Yes		NA	R (12NOV2020)	N/N
	NERV	Headache/ headache	2	09NOV2020	1/2	1	Yes		NA/TC	R (10NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	10NOV2020	2/3	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1146 11461272	GENRL	Chills/ Chills	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
		Pain/ Bodyaches	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ Headache	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1146 11461273	GASTR	Diarrhoea/ Diarrhea	2	14NOV2020	2/3	1	Yes		NA/TC	R (16NOV2020)	N/N
	NERV	Headache/ Headache	2	14NOV2020	2/3	1	Yes		NA/TC	R (16NOV2020)	N/N
	MUSC	Myalgia/ Muscle Pain#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	05FEB2021	2/3	2	Yes		NA	R (07FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1146 11461274	MUSC	Injection site pain/ Injection Site Pain#	4	05FEB2021	2/3	1	Yes		NA/TC/TCN	R (07FEB2021)	N/N	
		Pain/ Body Aches#	4	05FEB2021	2/4	2	Yes		NA	R (08FEB2021)	N/N	
		Pain in extremity/ Pain upper left thigh	1	28OCT2020	10/C	2	No	O		NA	RG	N/N
		Chills/ Chills#	4	26JAN2021	2/1	1	Yes			NA/TC	R (26JAN2021)	N/N
		Pain/ Body aches#	4	26JAN2021	2/1	1	Yes			NA/TC	R (26JAN2021)	N/N
16-55/ C4591001 1146 11461276	GASTR	Diarrhoea/ Diarrhea	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N	
		Injection site pain/ Injection site pain, left side	2	09NOV2020	1/3	1	Yes		NA/TC	R (11NOV2020)	N/N	
		Fatigue/ Fatigue	2	10NOV2020	2/2	1	Yes			NA	R (11NOV2020)	N/N
		Diarrhoea/ Diarrhea#	3	12JAN2021	2/1	1	Yes			NA	R (12JAN2021)	N/N
		Chills/ Chills#	3	12JAN2021	2/2	1	Yes			NA	R (13JAN2021)	N/N
		Fatigue/ Fatigue#	3	12JAN2021	2/2	1	Yes			NA	R (13JAN2021)	N/N
		Parosmia/ Increased smell sensitivty	2	13NOV2020	5/41	1	Yes			NA	R (23DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461279	GENRL	Chills/ Chills post vaccination #1	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/Y
		Fatigue/ Fatigue post vaccination #1	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/Y
	NERV	Injection site pain/ Injection site pain post vaccination #1	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/Y
		Headache/ Headache post vaccination #1	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/Y
		GENRL	Chills/ Chills	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)
	NERV	Fatigue/ Fatigue	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N
		Injection site pain/ Injection site pain	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1146 11461280	GASTR	Headache/ Headache	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N
		Flatulence/ Gas	2	12NOV2020	3/3	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Nausea/ Nausea	2	12NOV2020	3/3	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1146 11461281	GENRL	Headache/ Headache	2	12NOV2020	3/3	1	Yes		NA	R (14NOV2020)	N/N
		Injection site pain/ injection site pain, left deltoid	1	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/Y



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461285	GENRL	Chills/ Chills post vaccine 2	2	10NOV2020	1/3	2	Yes		NA	R (12NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1146 11461287	GASTR	Diarrhoea/ Diarrhea day 2 following vaccination #1	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N
		Nausea/ Nausea on day 2 following vaccination#1	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1146 11461288	GASTR	Nausea/ Nausea day 2 following vaccine 2	2	13NOV2020	2/3	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Fatigue/ Fatigue day 2 following vax 2	2	13NOV2020	2/3	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	19NOV2020	1/2	1	Yes		NA	R (20NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	20NOV2020	2/1	1	Yes		NA	R (20NOV2020)	N/N
	GENRL	Fatigue/ Fatigue post vax 2	2	20NOV2020	2/5	1	Yes		NA	R (24NOV2020)	N/N
	MUSC	Myalgia/ Muscle Soreness	2	20NOV2020	2/1	1	Yes		NA	R (20NOV2020)	N/N
	NERV	Headache/ Headache	2	20NOV2020	2/2	1	Yes		NA	R (21NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461291	GENRL	Injection site pain/ Injection Site Pain#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Chills/ Chills#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1146 11461293	GASTR	Large intestine polyp/ Colon Polyp	1	16NOV2020	28/1	1	No	O	NA	R (16NOV2020)	N/N
16-55/ C4591001 1146 11461294	GENRL	Fatigue/ Fatigue	1	22OCT2020	2/4	1	Yes		NA	R (25OCT2020)	N/N
		Injection site pain/ Injection site pain, left side	1	22OCT2020	2/4	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Chills/ Chills	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
		Injection site pain/ Injection site pain, left arm	2	11NOV2020	1/2	1	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1146 11461295	GENRL	Chills/ Chills	2	12NOV2020	2/5	1	Yes		NA	R (16NOV2020)	N/N
		Fatigue/ Fatigue	2	12NOV2020	2/5	1	Yes		NA	R (16NOV2020)	N/N
		Pyrexia/ Fever	2	12NOV2020	2/2	1	Yes		NA/TC	R (13NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1146 11461297	NERV	Headache/ Headache	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N	
	GENRL	Fatigue/ Fatigue#	4	28FEB2021	3/5	1	Yes		NA	R (04MAR2021)	N/N	
	MUSC	Myalgia/ Muscle aches#	4	28FEB2021	3/5	1	Yes		NA	R (04MAR2021)	N/N	
16-55/ C4591001 1146 11461299	NERV	Headache/ Headache#	4	28FEB2021	3/5	1	Yes		NA	R (04MAR2021)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	12NOV2020	2/33	1	Yes		NA	R (14DEC2020)	N/N	
	NERV	Headache/ Headache	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N	
16-55/ C4591001 1146 11461300	GENRL	Pain/ Body Aches#	3	23JAN2021	2/2	2	Yes		NA	R (24JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N	
	GENRL	Pain/ Body Aches#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N	
16-55/ C4591001 1146 11461302	GENRL	Injection site pain/ Injection site pain, left arm	2	10NOV2020	1/2	1	Yes		NA/TC	R (11NOV2020)	N/N	
	INFEC	COVID-19/ COVID-19	2	14JAN2021	66/7	2	No	O	NA	R (20JAN2021)	Y/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461305	MUSC	Pain in extremity/ Arm Pain#	3	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/4	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Chills/ Chills	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1146 11461306		Pyrexia/ fever	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ headache	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	14NOV2020	3/3	1	Yes		NA	R (16NOV2020)	N/N
16-55/ C4591001 1146 11461308	GASTR	Diarrhoea/ Diarrhea#	4	06MAR2021	2/1	1	Yes		NA	R (06MAR2021)	N/N
	NERV	Headache/ Headache#	4	06MAR2021	2/1	1	Yes		NA	R (06MAR2021)	N/N
	GENRL	Pain/ Bodyaches	1	24OCT2020	3/3	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C4591001	MUSC	Myalgia/ muscle aches	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
	NERV	Headache/ headache	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain day 1 post vaccine*		22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1146 11461313	GENRL	Chills/ Chills	2	14NOV2020	2/4	1	Yes		NA	R (17NOV2020)	N/N	
		Injection site pain/ Injection site pain	2	14NOV2020	2/4	1	Yes		NA	R (17NOV2020)	N/N	
16-55/ C4591001 1146 11461315	GENRL	Chills/ Chills	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N	
		Pain/ Bodyaches	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N	
	NERV	Headache/ Headache	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N	
16-55/ C4591001 1146 11461316	GENRL	Injection site pain/ Left sided injection site pain.	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N	
	GASTR	Diarrhoea/ Diarrhea	1	26OCT2020	5/2	1	Yes		NA	R (27OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N	
	GASTR	Diarrhoea/ Diarrhea	2	12NOV2020	2/5	1	Yes		NA	R (16NOV2020)	N/N	
	GENRL	Fatigue/ fatigue	2	12NOV2020	2/5	1	Yes		NA	R (16NOV2020)	N/N	
		Pain/ Body aches	2	12NOV2020	2/5	1	Yes		NA	R (16NOV2020)	N/N	
16-55/ C4591001	GASTR	Diarrhoea/ Mild diarrhea evening of vax 1	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1146 11461317	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
	NERV	Headache/ Headache day 2 after vax 1	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
		Injection site pain/ Injection site pain	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Pain in extremity/ Arm Pain after vaccination#	3	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N
	INFEC	Ear infection/ Ear Infection#	3	10FEB2021	16/2	1	No	O	NA/TC	R (11FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue post vaccination 1	1	24OCT2020	3/2	1	Yes		NA	R (25OCT2020)	N/N
1146 11461318	GENRL	Pain/ Body aches#	3	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N
	NERV	Headache/ Headache#	3	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Chills/ Chills#	4	16FEB2021	1/1	1	Yes		NA	R (16FEB2021)	N/N
		Pain/ Body aches#	4	16FEB2021	1/1	1	Yes		NA	R (16FEB2021)	N/N
	MUSC	Pain in extremity/ Arm Pain#	4	16FEB2021	1/1	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1146 11461320		Fatigue/ Fatigue	2	12NOV2020	1/3	2	Yes		NA	R (14NOV2020)	N/N
		Pyrexia/ Fever of 100.0F	2	12NOV2020	1/3	2	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ Mild Steady headache	2	12NOV2020	1/3	1	Yes		NA/TC	R (14NOV2020)	N/N
16-55/ C4591001 1146 11461323	SKIN	Urticaria/ Generalized hives#	2	05FEB2021	85/13	1	No	O	NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1146 11461324	NERV	Dizziness/ Dizziness	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
	GASTR	Diarrhoea/ Diarrhea/Loose Stool#	3	26JAN2021	5/4	2	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1146 11461325	GENRL	Injection site pain/ Injection Site Pain#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Arthralgia/ Joint pain knees, bilateral#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ Headache#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	26JAN2021	2/4	2	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	27JAN2021	3/3	2	Yes		NA	R (29JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1146 11461326	GENRL	Chills/ Chills#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N	
		Injection site pain/ Injection Site Pain#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N	
		Pyrexia/ Fever#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N	
		Injection site pain/ Injection site pain right arm	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/Y	
		Fatigue/ Fatigue	1	24OCT2020	2/3	1	Yes		NA	R (26OCT2020)	N/N	
		Injection site pain/ Injection site pain	2	11NOV2020	1/4	1	Yes		NA	R (14NOV2020)	N/N	
		Dizziness/ Dizziness	2	11NOV2020	1/4	1	Yes		NA	R (14NOV2020)	N/N	
16-55/ C4591001 1146 11461327	NERV	Headache/ Headache	2	11NOV2020	1/4	1	Yes		NA/TC	R (14NOV2020)	N/N	
	INFEC	Ear infection/ Ear Infection	2	08JAN2021	59/7	1	No	O	NA/TC	R (14JAN2021)	N/N	
	GENRL	Chills/ Chills	2	13NOV2020	1/1	1	Yes		NA	R (13NOV2020)	N/N	
		Injection site pain/ Right arm tenderness (injection site)	2	13NOV2020	1/1	1	Yes		NA	R (13NOV2020)	N/N	
		Pain/ Body aches	2	13NOV2020	1/1	1	Yes		NA	R (13NOV2020)	N/N	
	Pyrexia/ Fever	2	13NOV2020	1/3	2	Yes		NA/TC	R (15NOV2020)	N/N		



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461328	NERV	Headache/ Headache	2	13NOV2020	1/3	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	20JAN2021	1/4	1	Yes		NA	R (23JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	08FEB2021	1/3	2	Yes		NA/TC	R (10FEB2021)	N/N
	GENRL	Chills/ Chills#	4	08FEB2021	1/3	2	Yes		NA/TC	R (10FEB2021)	N/N
16-55/ C4591001 1146 11461329	GENRL	Injection site pain/ injection site pain	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	15NOV2020	3/3	1	Yes		NA	R (17NOV2020)	N/N
16-55/ C4591001 1146 11461331	GASTR	Nausea/ Nausea	2	15NOV2020	3/3	1	Yes		NA	R (17NOV2020)	N/N
	NERV	Dizziness/ Dizziness	2	15NOV2020	3/3	1	Yes		NA	R (17NOV2020)	N/N
	MUSC	Pain in extremity/ Arm Pain#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461337	GENRL	Fatigue/ Fatigue	2	14NOV2020	2/3	1	Yes		NA	R (16NOV2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain	2	14NOV2020	2/3	1	Yes		NA	R (16NOV2020)	N/N
	NERV		Headache/ Headache	2	14NOV2020	2/3	2	Yes		NA	R (16NOV2020)
	GENRL	Fatigue/ Fatigue	2	13NOV2020	1/8	2	Yes		NA	R (20NOV2020)	N/N
	EAR	Vertigo/ Vertigo	2	14NOV2020	2/5	1	Yes		NA/TC	R (18NOV2020)	N/N
	GENRL	Fatigue/ fatigue#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
	NERV		Pyrexia/ Feverish feeling	1	26OCT2020	1/1	1	Yes		NA	R (26OCT2020)
	NERV	Dizziness/ Dizziness	1	26OCT2020	1/1	1	Yes		NA	R (26OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
NERV	Headache/ Headache		1	27OCT2020	2/2	1	Yes		NA/TC	R (28OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461343	GENRL	Injection site pain/ Injection site pain	2	17NOV2020	2/2	1	Yes		NA/TC	R (18NOV2020)	N/N
	INFEC	Urinary tract infection/ UTI	2	06DEC2020	21/6	1	No	O	NA/TC	R (11DEC2020)	N/N
	GENRL	Chills/ Chills#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Pain/ Body Aches#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Chills/ Chills#	2	25JAN2021	69/1	1	Yes		NA/TC	R (25JAN2021)	N/N
	GENRL	Pyrexia/ Fever 100.5 F	2	18NOV2020	1/2	1	Yes		NA	R (19NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	19NOV2020	2/2	2	Yes		NA	R (20NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	19NOV2020	2/3	1	Yes		NA	R (21NOV2020)	N/N
	NERV	Headache/ Headache	2	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1146 11461348	GENRL	Chills/ Chills	2	16NOV2020	1/6	1	Yes		NA	R (21NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	16NOV2020	1/3	1	Yes		NA	R (18NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461349	MUSC	Pyrexia/ Fever	2	16NOV2020	1/6	1	Yes		NA	R (21NOV2020)	N/N
		Myalgia/ Muscle aches	2	17NOV2020	2/5	2	Yes		NA	R (21NOV2020)	N/N
	NERV	Dizziness/ Very mild dizziness after vaccine 1	1	26OCT2020	1/1	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C4591001 1146 11461351	GENRL	Injection site pain/ Injection site pain	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1146 11461354	GENRL	Fatigue/ Fatigue post vaccine 1	1	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001 1146 11461354	GENRL	Injection site pain/ Injection site pain	1	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
		Pain/ Body aches post vaccine 1	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
	Chills/ Chills	2	16NOV2020	1/2	2	Yes		NA	R (17NOV2020)	N/N	
	Fatigue/ Fatigue	2	16NOV2020	1/3	2	Yes		NA	R (18NOV2020)	N/N	
	Pain/ Body aches	2	16NOV2020	1/2	2	Yes		NA	R (17NOV2020)	N/N	
	Pyrexia/ Fever 99.4 F	2	16NOV2020	1/2	2	Yes		NA	R (17NOV2020)	N/N	
	GENRL	Injection site pain/ Injection site pain of left arm	1	27OCT2020	1/4	2	Yes		NA	R (30OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1146 11461356	GENRL	Chills/ Chills	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N
		Injection site pain/ Injection site pain	2	18NOV2020	2/3	1	Yes		NA	R (20NOV2020)	N/N
		Pain/ Bodyaches	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N
	NERV	Headache/ Headache	2	18NOV2020	2/2	2	Yes		NA/TC	R (19NOV2020)	N/N
16-55/ C4591001 1146 11461358	MUSC	Pain in extremity/ Arm Pain#	3	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1146 11461359	GENRL	Fatigue/ Fatigue	2	18NOV2020	1/2	2	Yes		NA	R (19NOV2020)	N/N
		Injection site pain/ Injection site pain post vaccine	2	18NOV2020	1/2	2	Yes		NA	R (19NOV2020)	N/N
16-55/ C4591001 1146 11461360	NERV	Headache/ Worsening Headaches	1	27OCT2020	1/2	1	Yes		NA/TC	R (28OCT2020)	N/Y
	GENRL	Injection site pain/ Injection Site Pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Chills/ Chills#	4	16FEB2021	1/1	1	Yes		NA	R (16FEB2021)	N/N
		Pain/ Body aches#	4	16FEB2021	1/1	1	Yes		NA	R (16FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461364	GENRL	Chills/ Chills	1	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1146 11461366	NERV	Headache/ Headache	2	17NOV2020	2/4	2	No	O	NA/TC	R (20NOV2020)	N/N
	RESP	Cough/ Cough	2	17NOV2020	2/4	1	No	O	NA	R (20NOV2020)	N/N
		Nasal congestion/ Nasal congestion	2	17NOV2020	2/4	2	No	O	NA/TC	R (20NOV2020)	N/N
16-55/ C4591001 1146 11461369	GENRL	Fatigue/ Fatigue	2	16NOV2020	1/2	2	Yes		NA	R (17NOV2020)	N/N
		Feeling abnormal/ Felt foggy	2	16NOV2020	1/2	1	Yes		NA	R (17NOV2020)	N/N
		Injection site pain/ Injection site pain	2	16NOV2020	1/2	1	Yes		NA	R (17NOV2020)	N/N
16-55/ C4591001 1146 11461372	GENRL	Chills/ Chills	1	28OCT2020	1/3	1	Yes		NA	R (30OCT2020)	N/N
		Injection site pain/ Injection site pain	1	28OCT2020	1/3	1	Yes		NA	R (30OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	16NOV2020	1/5	1	Yes		NA	R (20NOV2020)	N/N
	GENRL	Chills/ Chills	2	17NOV2020	2/4	1	Yes		NA	R (20NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461373	MUSC	Neck pain/ Neck pain	2	17NOV2020	2/4	1	Yes		NA	R (20NOV2020)	N/N
16-55/ C4591001 1146 11461373	MUSC	Pain in extremity/ Arm Pain#	3	03FEB2021	1/2	1	Yes		NA/TC	R (04FEB2021)	N/N
16-55/ C4591001 1146 11461374	GENRL	Injection site pain/ Injection site pain post vaccine 1	1	28OCT2020	1/3	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1146 11461375	GASTR	Nausea/ Nausea	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N
16-55/ C4591001 1146 11461375	GENRL	Injection site pain/ Pain at injection site#	3	28JAN2021	1/1	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1146 11461376	GENRL	Injection site pain/ Injection site pain post vaccine 1	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1146 11461379	MUSC	Pain in extremity/ Mild Arm Pain#	3	08FEB2021	1/1	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever#	4	01MAR2021	1/2	1	Yes		NA/TC	R (02MAR2021)	N/N
16-55/ C4591001	MUSC	Pain in extremity/ Arm Soreness#	4	01MAR2021	1/2	1	Yes		NA	R (02MAR2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1146 11461381 16-55/ C4591001 1146 11461382	MUSC	Muscle spasms/ leg cramping both calves	1	30OCT2020	2/4	1	Yes		NA	R (02NOV2020)	N/N
	MUSC	Muscle twitching/ muscle twitching in chest area post vaccine 2	2	17NOV2020	1/1	1	Yes		NA	R (17NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	18NOV2020	2/3	1	Yes		NA	R (20NOV2020)	N/N
		Pain/ Bodyaches	2	18NOV2020	2/3	2	Yes		NA	R (20NOV2020)	N/N
	MUSC	Muscle spasms/ leg cramping both calves	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N
	NERV	Headache/ Headache	2	18NOV2020	2/3	2	Yes		NA/TC	R (20NOV2020)	N/N
16-55/ C4591001 1146 11461386	GENRL	Chills/ Chills	2	18NOV2020	1/2	1	Yes		NA	R (19NOV2020)	N/N
		Fatigue/ Fatigue	2	18NOV2020	1/3	1	Yes		NA	R (20NOV2020)	N/N
		Pain/ Body Aches	2	18NOV2020	1/3	2	Yes		NA/TC	R (20NOV2020)	N/N
16-55/ C4591001 1146 11461387	GASTR	Diarrhoea/ Diarrhea	2	20NOV2020	1/4	2	Yes		NA	R (23NOV2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1146 11461388	NERV	Headache/ Headache	2	20NOV2020	1/2	1	Yes		NA/TC	R (21NOV2020)	N/N	
	MUSC	Myalgia/ Muscle aches	2	21NOV2020	2/2	1	Yes		NA	R (22NOV2020)	N/N	
	NERV	Headache/ Headache#	3	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N	
	GENRL	Pyrexia/ Fever after vaccine#	4	16FEB2021	1/1	1	Yes		NA/TC	R (16FEB2021)	N/N	
	GASTR	Diarrhoea/ Diarrhea post vaccine 1	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain post vaccine 1	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N	
	INFEC	Hordeolum/ Stye right eye	2	18NOV2020	1/8	1	No	O	NA	R (25NOV2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	3	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N	
	GENRL	Injection site pain/ Injection Site Pain#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N	
16-55/ C4591001 1146 11461390	GENRL	Injection site pain/ injection site pain	1	30OCT2020	2/3	1	Yes		NA	R (01NOV2020)	N/N	
GENRL	Chills/ Chills	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N		

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461391	MUSC	Fatigue/ Fatigue/Tiredness	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N
		Myalgia/ Muscle Pain	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N
	NERV	Headache/ headache day 2 post vaccine 1 (lasted 4 hours)	1	30OCT2020	2/2	1	Yes		NA	R (31OCT2020)	N/N
	MUSC	Muscle twitching/ Intermittent muscle twitching left chest	2	01DEC2020	15/21	1	No	O	NA	R (21DEC2020)	N/N
	GENRL	Chills/ Chills#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	MUSC	Myalgia/ Muscle Pain#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	NERV	Headache/ Headache#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1146 11461395	GENRL	Chills/ Chills	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/Y
	GENRL	Fatigue/ Fatigue	2	19NOV2020	2/3	1	Yes		NA	R (21NOV2020)	N/N
			2	19NOV2020	2/4	2	Yes		NA	R (22NOV2020)	N/N
		Injection site pain/ Injection site pain	2	19NOV2020	2/3	1	Yes		NA	R (21NOV2020)	N/N
			2	19NOV2020	2/4	2	Yes		NA	R (22NOV2020)	N/N
	Pain/ Body aches	2	19NOV2020	2/4	2	Yes		NA	R (22NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1146 11461397	MUSC	Myalgia/ Muscle aches	2	19NOV2020	2/3	1	Yes		NA	R (21NOV2020)	N/N	
	GENRL	Chills/ Chills#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N	
	MUSC	Back pain/ Back ache#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N	
16-55/ C4591001 1147 11471003	NERV	Headache/ Headache#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N	
	VASC	Essential hypertension/ essential hypertension	2	21AUG2020	3/C	1	No	O	NA/TC	N	N/N	
	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	NOV2020	70/C		No	O	NA	UNK	N/N	
16-55/ C4591001 1147 11471019	GASTR	Diarrhoea/ Diarrhea#	2	12MAR2021	201/2	1	No	O	NA	R (13MAR2021)	N/N	
	MUSC	Myalgia/ Muscle ache	2	24AUG2020	1/5	3	Yes		NA/TC	R (28AUG2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	3	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N	
16-55/ C4591001 1147 11471021	MUSC	Myalgia/ Myalgia#	3	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1147 11471046	GENRL	Malaise/ Malaise#	4	10MAR2021	1/2	1	Yes		NA	R (11MAR2021)	N/N	
		Pyrexia/ Fever#	4	10MAR2021	1/2	1	Yes		NA	R (11MAR2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	10MAR2021	1/2	1	Yes		NA	R (11MAR2021)	N/N	
16-55/ C4591001 1147 11471047	PSYCH	Anxiety/ Anxiety (New Diagnosis)	2	28AUG2020	3/C	1	No	O	NA/TCN	N	N/N	
16-55/ C4591001 1147 11471049	INV	Blood thyroid stimulating hormone increased/ elevated TSH	2	18SEP2020	22/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1147 11471053	NERV	Migraine/ migraine (exacerbation)	2	10OCT2020	44/2	1	No	O	NA	R (11OCT2020)	N/N	
16-55/ C4591001 1147 11471073	INV	Blood creatinine decreased/ Decreased Creatinine (31.6)	2	02SEP2020	3/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1147 11471092	RESP	Rhinitis allergic/ Allergic Rhinitis	2	11SEP2020	11/8	1	No	O	NA/TC	R (18SEP2020)	N/N	
16-55/ C4591001	RESP	Oropharyngeal pain/ Sore throat*		12AUG2020	-12/13	1	No	O	NA	R (24AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1147 11471112 16-55/ C4591001	INFEC	Abscess neck/ Nape abscess	2	25SEP2020	22/2	1	No	O	NA/TC	R (26SEP2020)	N/N	
1147 11471121 16-55/ C4591001	INFEC	Influenza/ Flu A&B	2	21SEP2020	12/C	1	No	O	NA/TC	RG	N/N	
1147 11471153 16-55/ C4591001	INV	Blood cholesterol increased/ elevated cholesterol	2	06OCT2020	26/C	1	No	O	NA	N	N/N	
1147 11471166 16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	09SEP2020	17/6	1	Yes		NA	R (14SEP2020)	N/N	
1147 11471180 16-55/ C4591001	GENRL	Chills/ Chills#	3	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N	
1147 11471211	GENRL	Chills/ Chills#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N	
	MUSC	Myalgia/ Muscle pain#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N	
16-55/ C4591001 1147 11471216	BLOOD	Anaemia/ anemia (new diagnosis)	1	11SEP2020	9/C	1	No	O	NA/TC	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1147 11471258	GENRL	Injection site pain/ Pain at injection site#	3	26FEB2021	1/3	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001 1147 11471259	EYE	Eye pain/ Ocular pain, bilateral	2	05JAN2021	25/C	1	No	O	NA/TC	N	N/N
		Ocular hyperaemia/ Ocular redness, bilateral	2	05JAN2021	25/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1147 11471272	INJ&P	Ligament sprain/ Sprained Ankle	2	14JAN2021	18/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1149 11491001	GENRL	Pyrexia/ Fever	2	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/N
	MUSC	Pain in extremity/ Pain in left arm	2	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N
16-55/ C4591001 1149 11491012	GENRL	Chills/ Chills	2	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
		Pyrexia/ Fever	2	25AUG2020	1/19	1	Yes		NA	R (12SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	01SEP2020	8/25	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Flank pain/ Flank Pain	2	15SEP2020	22/8	1	No	CND	NA	R (22SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491020	NERV	Headache/ Headache	2	20SEP2020	27/3	1	No	CND	NA	R (22SEP2020)	N/N
	GENRL	Chills/ chills	2	31AUG2020	5/2	1	Yes		NA	R (01SEP2020)	N/N
		Fatigue/ fatigue	2	31AUG2020	5/2	1	Yes		NA	R (01SEP2020)	N/N
16-55/ C4591001 1149 11491025	GENRL	Injection site pain/ Pain at injection site#	3	01FEB2021	1/1	1	Yes		NA	R (01FEB2021)	N/N
	GENRL	Fatigue/ fatigue	1	08AUG2020	2/3	1	Yes		NA	R (10AUG2020)	N/N
	GENRL	Injection site erythema/ injection site redness	1	12AUG2020	6/2	1	Yes		NA	R (13AUG2020)	N/N
16-55/ C4591001 1149 11491030	GENRL	Injection site pain/ Soreness at injection site#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1149 11491033	NERV	Headache/ Headache#	4	28JAN2021	3/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Left arm soreness at injection site#	3	19JAN2021	1/3	1	Yes		NA	R (21JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491037	GENRL	Chills/ Chills#	4	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
		Pyrexia/ Fever 100.2#	4	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
	GENRL	Injection site pain/ Tenderness at injection site#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	22FEB2021	1/3	1	Yes		NA/TC	R (24FEB2021)	N/N
	GASTR	Nausea/ nausea	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ left arm pain at injection site with touch	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		Pyrexia/ fever	2	10SEP2020	1/3	1	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Injection site pain/ Tenderness at injection site#	3	11FEB2021	1/1	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1149 11491047	GENRL	Injection site pain/ Pain at injection site#	4	11FEB2021	3/2	1	Yes		NA/TC	R (12FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491054	MUSC	Myalgia/ Myalgia#	4	11FEB2021	3/2	1	Yes		NA/TC	R (12FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	21DEC2020	1/3	1	Yes		NA/TC	R (23DEC2020)	N/N
16-55/ C4591001 1149 11491057	GENRL	Injection site pain/ Soreness at injection site#	4	11JAN2021	1/4	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ Headache#	4	11JAN2021	1/4	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1149 11491057	GASTR	Diarrhoea/ loose stool	1	12AUG2020	1/1	1	Yes		NA	R (12AUG2020)	N/N
16-55/ C4591001 1149 11491069	GENRL	Injection site pain/ Pain at Injection site#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1149 11491070	NERV	Headache/ Headache#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1149 11491070	MUSC	Pain in extremity/ Arm pain#	3	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
	NERV	Headache/ Headache#	3	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/Y
	GENRL	Chills/ Chills#	3	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491075	GENRL	Pain/ Body aches#	3	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
		Pyrexia/ Fever#	3	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
		Injection site pain/ Tenderness at injection site#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1149 11491076	MUSC	Pain in extremity/ right arm pain	1	17AUG2020	1/3	2	Yes		NA	R (19AUG2020)	N/N
16-55/ C4591001 1149 11491077	GENRL	Injection site pain/ Pain at injection site, right arm#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Pyrexia/ Fever#	4	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Chills/ Chills	1	18AUG2020	2/3	1	Yes		NA	R (20AUG2020)	N/N
16-55/ C4591001 1149 11491083	MUSC	Pain/ Body Aches	1	18AUG2020	2/3	1	Yes		NA	R (20AUG2020)	N/N
		Pyrexia/ Fever	1	18AUG2020	2/3	1	Yes		NA	R (20AUG2020)	N/N
		Myalgia/ Myalgia	2	09SEP2020	2/28	2	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Tenderness at injection site#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1149 11491085	GENRL	Injection site pain/ left arm pain at injection site related to motion	1	18AUG2020	1/3	1	Yes		NA	R (20AUG2020)	N/N
1149 11491086	GENRL	Fatigue/ fatigue	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ left arm pain at injection site related to motion	2	09SEP2020	2/6	1	Yes		NA	R (14SEP2020)	N/N
		Pain/ body aches	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1149 11491088	GASTR	Abdominal discomfort/ Upset Stomach	1	18AUG2020	1/3	1	Yes		NA	R (20AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	18AUG2020	1/3	1	Yes		NA	R (20AUG2020)	N/N
		Injection site pain/ Left arm pain at injection site	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/Y
16-55/ C4591001 1149 11491089	GENRL	Injection site pain/ Left arm pain at injection site	1	19AUG2020	1/2	1	Yes		NA	R (20AUG2020)	N/N
	GASTR	Vomiting/ Emesis	1	06SEP2020	19/31	1	No	O	NA	R (06OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491092	GASTR	Nausea/ Nausea#	4	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Pain/ Body Aches#	4	05FEB2021	2/1	1	Yes		NA/TC	R (05FEB2021)	N/N
		Pyrexia/ Fever (99.9)#	4	05FEB2021	2/2	1	Yes		NA/TC	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	4	05FEB2021	2/1	1	Yes		NA/TC	R (05FEB2021)	N/N
	INFEC	Herpes simplex/ Herpes outbreak#	4	06FEB2021	3/2	1	No	O	NA/TC	R (07FEB2021)	N/N
	NERV	Lethargy/ Lethargic	1	23AUG2020	5/1	1	Yes		NA	R (23AUG2020)	N/N
	GENRL	Fatigue/ Tired	1	26AUG2020	8/1	1	Yes		NA	R (26AUG2020)	N/N
	PSYCH	Insomnia/ Difficulty sleeping	1	31AUG2020	13/2	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Fatigue/ Tired	1	01SEP2020	14/1	1	Yes		NA	R (01SEP2020)	N/N
	16-55/ C4591001 1149 11491093	MUSC	Musculoskeletal pain/ joint/muscle pain in arms and legs	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)
16-55/ C4591001 1149 11491098		Myalgia/ left triceps pain	1	20AUG2020	2/5	1	Yes		NA	R (24AUG2020)	N/N
	GENRL	Injection site pain/ injection site pain with motion	1	19AUG2020	1/2	1	Yes		NA	R (20AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491114	GENRL	Injection site pain/ Pain at Injection site#	3	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/Y
16-55/ C4591001 1149 11491115	GENRL	Injection site pain/ Soreness at injection site#	4	20JAN2021	1/4	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1149 11491116	MUSC	Pain in extremity/ Left arm pain*		20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001 1149 11491120	GENRL	Injection site pain/ Soreness at injection site#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1149 11491121	MUSC	Myalgia/ Generalized myalgia	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	12SEP2020	2/4	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1149 11491125	GENRL	Injection site pain/ Soreness at injection site#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001	MUSC	Pain in extremity/ left arm soreness	1	24AUG2020	1/2	2	Yes		NA/TC	R (25AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1149 11491128 16-55/ C4591001 1149 11491133	GENRL	Fatigue/ Fatigue#	4	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1149 11491136	MUSC	Pyrexia/ Low grade fever 100.1# Myalgia/ left arm muscle pain with motion	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
16-55/ C4591001 1149 11491140	GASTR	Nausea/ nausea	1	27AUG2020	3/1	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C4591001 1149 11491140	NERV	Headache/ headache/ left-post occipital pain	1	27AUG2020	3/1	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C4591001 1149 11491140	GENRL	Fatigue/ Fatigue#	3	17FEB2021	1/1	1	Yes		NA	R (17FEB2021)	N/Y
16-55/ C4591001 1149 11491146	GENRL	Injection site pain/ Pain at injection site# Injection site haemorrhage/ Left arm bleeding at injection site	3	17FEB2021	1/1	1	Yes		NA	R (17FEB2021)	N/Y
16-55/ C4591001 1149 11491146	GENRL	Injection site pain/ Left arm injection site pain	1	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/N
16-55/ C4591001 1149 11491146	GENRL	Injection site pain/ Pain at injection site#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491150	GENRL	Chills/ Chills#	4	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
		Fatigue/ Fatigue#	4	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
		Injection site pain/ Arm Soreness at injection site#	4	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
		Pyrexia/ Fever#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
		MUSC Myalgia/ Generalized muscle aches#	4	11FEB2021	2/3	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1149 11491155	GENRL	Injection site pain/ IM pain at injection site#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
16-55/ C4591001 1149 11491157	GASTR	Abdominal discomfort/ Upset stomach	2	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
		Diarrhoea/ Diarrhea	2	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
		GENRL Injection site pain/ Sore left arm at injection site#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/Y
	GENRL	Fatigue/ Fatigue#	4	26JAN2021	1/4	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1149 11491158	GENRL	Fatigue/ General Fatigue#	3	03FEB2021	2/6	1	Yes		NA	R (08FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491165	GENRL	Injection site pain/ left arm pain at injection site with movement	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1149 11491175	GENRL	Injection site pain/ Tenderness at injection site (left arm)#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1149 11491176	GENRL	Injection site pain/ Left arm pain at injection site	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C4591001 1149 11491178	GENRL	Fatigue/ Fatigue#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
		Injection site pain/ Sore at injection site#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1149 11491180	GENRL	Injection site pain/ left arm pain at injection site.	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	NERV	Headache/ headache	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C4591001 1149 11491181	GENRL	Injection site pain/ Left arm pain at injection site with touch	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491186	GENRL	Chills/ Chills#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
		Fatigue/ Fatigue#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ left arm injection site pain with touch	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
	MUSC	Musculoskeletal chest pain/ muscle chest pain	2	23SEP2020	1/3	1	No	O	NA	R (25SEP2020)	N/N
	GENRL	Chills/ chills	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ fever	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1149 11491188	NERV	Headache/ headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Pyrexia/ Fever (101.9)#	4	06FEB2021	2/1	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1149 11491191	GENRL	Injection site pain/ Left arm injection site pain with touch	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1149 11491202	MUSC	Arthralgia/ Joint pain	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1149 11491203	GENRL	Pain in extremity/ Left arm pain	1	05SEP2020	2/4	1	Yes		NA/TC	R (08SEP2020)	N/N	
		Chills/ chills	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N	
	GENRL	Pain/ body aches	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N	
		Pain/ Body aches	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N	
16-55/ C4591001 1149 11491204	MUSC	Pyrexia/ Fever/chills Myalgia/ Myalgia#	2	25SEP2020	1/3	1	Yes		NA/TC	R (27SEP2020)	N/N	
16-55/ C4591001 1149 11491204	MUSC	Myalgia/ Myalgia#	3	09FEB2021	1/3	1	Yes		NA/TC	R (11FEB2021)	N/N	
16-55/ C4591001 1149 11491207	GENRL	Injection site pain/ Arm Soreness at injection site#	3	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N	
16-55/ C4591001 1149 11491208	GENRL	Fatigue/ Fatigue#	4	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N	
	NERV	Headache/ Headache#	4	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1149 11491209	GENRL	Injection site pain/ Pain at injection site with movement	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1149 11491210	GENRL	Injection site pain/ left arm pain at injection site	1	05SEP2020	2/4	1	Yes		NA	R (08SEP2020)	N/N
	NERV	Headache/ headache	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Chills/ chills	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		Fatigue/ fatigue	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		Injection site pain/ Left arm injection site pain with motion	2	26SEP2020	2/4	1	Yes		NA	R (29SEP2020)	N/N
		Pyrexia/ fever	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ headache	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1149 11491211	GENRL	Fatigue/ Tired (general)#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Pain at injection site#	3	02FEB2021	1/4	1	Yes		NA	R (05FEB2021)	N/N
	GASTR	Nausea/ Nausea#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1149 11491218 16-55/ C4591001 1149 11491219	MUSC	Pain in extremity/ Left arm soreness	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
	GENRL	Chills/ Chills	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N	
		Fatigue/ Fatigue	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N	
	NERV	Headache/ Headache	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N	
16-55/ C4591001 1149 11491220	GENRL	Fatigue/ fatigue	1	09SEP2020	2/4	1	Yes		NA	R (12SEP2020)	N/N	
		Injection site pain/ left arm pain at injection site	1	09SEP2020	2/4	1	Yes		NA	R (12SEP2020)	N/N	
16-55/ C4591001 1149 11491221	GENRL	Injection site pain/ injection site pain	1	10SEP2020	1/3	1	Yes		NA/TC	R (12SEP2020)	N/N	
	NERV	Headache/ Headache	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N	
	GASTR	Paraesthesia oral/ Buccal paresthesia	1	13SEP2020	4/27	1	Yes		NA	R (09OCT2020)	N/N	
	MUSC	Musculoskeletal chest pain/ Chest pain (muscular not cardiac)	1	14SEP2020	5/3	3	Yes		NA	R (16SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491227	GASTR	Gingival pain/ Gingival pain	1	22SEP2020	13/4	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	MUSC	Injection site pain/ Left arm injection site pain with motion	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1149 11491234	MUSC	Myalgia/ myalgia	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Left arm injection pain	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1149 11491238	GENRL	Pyrexia/ Low Fever (99.6 F)	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ Left arm injection site pain with motion	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Pyrexia/ Low Grade Fever (99.6 F)	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Feeling hot/ Hot ears	1	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N
	RESP	Injection site pain/ left arm pain at injection site	1	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N
	RESP	Pharyngeal swelling/ Swelling in throat (no shortness of breath)	1	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491247	GENRL	Injection site pain/ Pain at injection site, left arm#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1149 11491254	GASTR	Nausea/ Nausea	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ pain in left arm at injection site	1	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1149 11491256	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1149 11491258	GENRL	Injection site erythema/ Injection site erythema	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/Y
		Injection site pain/ Pain at injection site	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001 1149 11491270	GENRL	Injection site pain/ Left arm pain at injection site	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491271	NERV	Headache/ headache	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ left arm pain at injection site related to motion	1	28SEP2020	8/8	1	Yes		NA	R (05OCT2020)	N/N
16-55/ C4591001 1149 11491273	GENRL	Pyrexia/ fever	2	14OCT2020	3/2	1	Yes		NA	R (15OCT2020)	N/N
	NERV	Headache/ headache	2	14OCT2020	3/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1149 11491274	GENRL	Fatigue/ fatigue	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Left arm injection site pain with touch and movement	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1149 11491275	MUSC	Arthralgia/ Generalized Joint pain	2	13OCT2020	1/2	3	Yes		NA	R (14OCT2020)	N/N
	GENRL	Myalgia/ Myalgia	2	13OCT2020	1/2	3	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1149 11491275	GENRL	Injection site pain/ Right arm injection site pain with touch	1	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Right arm injection site pain with movement and touch	2	13OCT2020	1/2	2	Yes		NA	R (14OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491281	GENRL	Injection site pain/ Left arm injection site pain with touch	1	23SEP2020	2/4	1	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ Fever	1	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1149 11491285	MUSC	Flank pain/ left flank pain	1	23SEP2020	1/5	1	Yes		NA	R (27SEP2020)	N/N
		Pain in extremity/ Left arm pain	1	23SEP2020	1/5	1	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1149 11491286	GENRL	Nodule/ hypopigmented nodule lesion right dorsal 2nd metacarpal	1	30SEP2020	8/7	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1149 11491289	GENRL	Injection site pain/ Left arm pain at injection site	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Chills/ chills	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1149 11491294	GENRL	Injection site pain/ left arm injection site pain with touch	1	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491305	GENRL	Injection site pain/ left arm injection site pain with movement	1	24SEP2020	1/22	1	Yes		NA	R (15OCT2020)	N/Y
16-55/ C4591001 1149 11491308	GENRL	Pyrexia/ Fever#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1149 11491310	GENRL	Chills/ chills	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
		Pyrexia/ fever	2	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
	NERV	Headache/ headache	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1149 11491311	GENRL	Injection site pain/ left arm injection site pain	1	24SEP2020	1/4	1	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1149 11491314	GENRL	Injection site pain/ left arm injection site pain	1	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ headache	1	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001	GENRL	Chills/ chills	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1149 11491315		Fatigue/ fatigue	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N	
		Pyrexia/ fever	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N	
16-55/ C4591001 1149 11491316	GENRL	Pyrexia/ Fever	1	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N	
	GENRL	Injection site pain/ right arm pain at injection site	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N	
		Pyrexia/ fever	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N	
16-55/ C4591001 1149 11491328	GENRL	Injection site pain/ Left arm injection site pain with touch	1	19OCT2020	1/3	1	Yes		NA	R (21OCT2020)	N/N	
16-55/ C4591001 1149 11491329	GENRL	Injection site pain/ mild pain in left arm (injection site)	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N	
16-55/ C4591001 1149 11491335†	GENRL	Injection site pain/ mild pain at site of injection (right arm)	1	27OCT2020	2/2	1	Yes		NA/TC	R (28OCT2020)	N/N	
16-55/ C4591001 1149 11491340	NERV	Headache/ Headache*		27OCT2020	1/3	1	Yes		NA	R (29OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501001	GENRL	Fatigue/ Fatigue	1	29OCT2020	3/1	1	Yes		NA	R (29OCT2020)	N/N
	MUSC	Myalgia/ General Muscle Pain	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N
	GASTR	Pancreatitis/ Worsening Pancreatitis	1	21AUG2020	5/34	3	No	O	NA	R (23SEP2020)	Y/N
16-55/ C4591001 1150 11501003	GENRL	Injection site pain/ Pain at injection site	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1150 11501004	RESP	Cough/ cough	1	05SEP2020	20/5	1	No	O	NA	R (09SEP2020)	N/N
16-55/ C4591001 1150 11501005		Nasal congestion/ nasal congestion	1	05SEP2020	20/5	1	No	O	NA	R (09SEP2020)	N/N
		Oropharyngeal pain/ sore throat	1	05SEP2020	20/5	1	No	O	NA	R (09SEP2020)	N/N
		Rhinorrhoea/ runny nose	1	05SEP2020	20/5	1	No	O	NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ arm soreness (injection site, left arm)	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Chills/ Chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1150 11501006	GENRL	Pyrexia/ Fever (100.1)	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
		Pain/ Body Aches	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	
16-55/ C4591001 1150 11501007	GASTR	Pyrexia/ Fever (100.0 F)	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	
		Diarrhoea/ Diarrhea	2	15SEP2020	8/1	1	No	O	NA	R (15SEP2020)	N/N	
16-55/ C4591001 1150 11501008	GENRL	Pain/ Body Aches#	3	16FEB2021	1/4	1	Yes		NA	R (19FEB2021)	N/N	
	NERV	Headache/ Headache#	3	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N	
16-55/ C4591001 1150 11501009	GENRL	Injection site pain/ Pain at injection site#	4	24FEB2021	2/6	1	Yes		NA	R (01MAR2021)	N/N	
	GASTR	Diarrhoea/ Diarrhea	1	25AUG2020	8/1	1	Yes		NA	R (25AUG2020)	N/N	
	RESP	Oropharyngeal pain/ Sore Throat	1	03SEP2020	17/1	1	No	O	NA	R (03SEP2020)	N/N	
	GENRL	Chills/ Chills#	3	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501010	GASTR	Injection site pain/ Pain at injection site#	3	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
		Diarrhoea/ Diarrhea#	3	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
		Pyrexia/ Fever#	3	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Pain at injection site#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1150 11501011	GENRL	Injection site pain/ Arm soreness (injection site,left)	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Pain/ Body Aches	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ Fever (101.5 F)	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1150 11501013	GENRL	Injection site pain/ Arm soreness (injection site, left arm)	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501014	GENRL	Injection site pain/ Burning sensation at injection site (left arm)	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/Y
	GENRL	Injection site pain/ Injection Site Pain#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1150 11501015	GENRL	Injection site pain/ Pain at injection site	2	12SEP2020	3/3	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001 1150 11501016	GENRL	Injection site pain/ Injection Site Soreness	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ Headache	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1150 11501017	GENRL	Injection site pain/ Pain at injection site	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1150 11501018	GENRL	Injection site pain/ Arm soreness (injection site)	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Pain/ Body Aches#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501019	GENRL	Pyrexia/ Fever (101.6)#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
		Fatigue/ fatigue	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
		Myalgia/ muscle aches	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
		Chills/ Chills	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		Pain/ Body Aches	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1150 11501020	GENRL	Pyrexia/ Fever	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		Eczema/ Eczema	2	DEC2020	83/C	2	No	O	NA	RG	N/N
		Fatigue/ fatigue	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N
		Fatigue/ Fatigue	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
		Fatigue/ Fatigue#	3	02FEB2021	2/3	2	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site#	3	02FEB2021	2/3	2	Yes		NA	R (04FEB2021)	N/N
		Fatigue/ Fatigue#	4	22FEB2021	1/2	2	Yes		NA	R (23FEB2021)	N/N
		Fatigue/ fatigue	1	19AUG2020	1/2	1	Yes		NA	R (20AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1150 11501021	GENRL	Injection site pain/ Pain at injection site#	3	20JAN2021	1/4	2	Yes		NA	R (23JAN2021)	N/N
	NERV	Headache/ Headache#	3	23JAN2021	4/1	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001	RENAL	Nephrolithiasis/ Kidney Stones	2	02DEC2020	86/7	3	No	O	NA/TC	R (08DEC2020)	Y/N
1150 11501022	GENRL	Fatigue/ Fatigue#	3	19JAN2021	1/2	2	Yes		NA	R (20JAN2021)	N/N
		Injection site pain/ Pain at injection site#	3	19JAN2021	1/2	2	Yes		NA	R (20JAN2021)	N/N
	MUSC	Myalgia/ Muscle Pain#	3	19JAN2021	1/2	2	Yes		NA	R (20JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	09FEB2021	2/4	2	Yes		NA	R (12FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	09FEB2021	2/2	2	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ Headache#	4	09FEB2021	2/4	2	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Tiredness	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N
1150 11501024		Injection site pain/ Arm soreness (Injection site left arm)	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Chills/ Chills	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501025	MUSC	Fatigue/ Tiredness	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ Fever (101.5)	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		Myalgia/ Muscle Aches	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		Headache/ Headache	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		Chills/ Chills	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1150 11501026	MUSC	Myalgia/ Muscle Aches	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
		GENRL	Fatigue/ Fatigue#	3	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)
16-55/ C4591001 1150 11501027	GENRL	Injection site pain/ Pain at injection site#	3	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	22FEB2021	1/1	2	Yes		NA	R (22FEB2021)	N/N
		Fatigue/ Fatigue#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
		Injection site pain/ Arm soreness (left injection site)	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Chills/ Chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501028	GENRL	Injection site pain/ Pain at injection site	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Fatigue/ Fatigue#	3	03FEB2021	2/3	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1150 11501029	GENRL	Injection site pain/ Injection Site Pain#	3	03FEB2021	2/3	1	Yes		NA	R (05FEB2021)	N/N
		Injection site pain/ Arm soreness in injection site	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N
16-55/ C4591001 1150 11501032	NERV	Headache/ Headache	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/N
16-55/ C4591001 1150 11501033	GENRL	Fatigue/ fatigue	1	25AUG2020	2/5	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501034	GENRL	Injection site pain/ Injection Site Pain#	4	25FEB2021	2/3	1	Yes		NA	R (27FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	23FEB2021	2/3	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1150 11501036	NERV	Headache/ Headache#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1150 11501037	GENRL	Injection site pain/ Arm soreness (injection L site arm)	1	24AUG2020	1/2	2	Yes		NA	R (25AUG2020)	N/N
16-55/ C4591001 1150 11501038	GASTR	Nausea/ Nausea	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	BLOOD	Lymphadenopathy/ Swollen lymph nodes under left armpit	2	18SEP2020	5/75	1	No	O	NA	R (01DEC2020)	N/N
	GASTR	Nausea/ Nausea#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501039	GENRL	Injection site pain/ Injection Site Pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
		Nausea/ Nausea#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Chills/ Chills#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Pain/ Body Aches#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1150 11501040	GENRL	Injection site pain/ Pain at injection site	1	25AUG2020	1/2	2	Yes		NA	R (26AUG2020)	N/N
	GENRL	Pain/ Body Aches	2	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1150 11501040	GENRL	Injection site pain/ pain at injection site	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/N
	CARD	Supraventricular tachycardia/ Worsening Supraventricular Tachycardia	1	02SEP2020	9/C	2	Yes		NA	RG	N/N
	GENRL	Chills/ Chills	2	14SEP2020	1/3	2	Yes		NA	R (16SEP2020)	N/N
	GENRL	Pain/ Body Aches	2	14SEP2020	1/3	2	Yes		NA	R (16SEP2020)	N/N
NERV	Headache/ Headache	2	14SEP2020	1/3	2	Yes		NA	R (16SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1150 11501041	GENRL	Pyrexia/ fever (101.0)	1	11SEP2020	18/1	1	No	O	NA	R (11SEP2020)	N/N	
16-55/ C4591001 1150 11501043	INJ&P	Concussion/ concussion	1	05SEP2020	12/6	1	No	O	NA	R (10SEP2020)	N/N	
		Fall/ Fall from stairs at home	1	05SEP2020	12/1	1	No	O	NA/TCN	R (05SEP2020)	N/N	
		Ligament sprain/ ankle sprain (left)	1	05SEP2020	12/4	1	No	O	NA	R (08SEP2020)	N/N	
	GENRL	Pain/ Body Aches	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001 1150 11501044	GENRL	Injection site pain/ pain at injection site	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/N	
	GENRL	Chills/ Chills	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	
		Injection site pain/ Pain at injection site (right arm)	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	
	MUSC	Myalgia/ Muscle Aches	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	
	SKIN	Hyperhidrosis/ Sweats	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001 1150 11501045	GENRL	Injection site pain/ Pain at injection site#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site erythema/ Redness at injection site#	3	03FEB2021	2/6	2	Yes		NA	R (08FEB2021)	N/N
	NERV	Headache/ Headache#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	22FEB2021	1/2	2	Yes		NA	R (23FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	22FEB2021	1/2	2	Yes		NA	R (23FEB2021)	N/N
		Pain/ Generalized Body Aches#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
	NERV	Headache/ Headache#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1150 11501046	GENRL	Injection site pain/ pain at injection site	1	26AUG2020	2/3	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1150 11501047	GENRL	Injection site pain/ Injection Site Pain#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Chills/ Chills#	4	02FEB2021	2/3	1	Yes		NA	R (04FEB2021)	N/N
		Pain/ Body Aches#	4	02FEB2021	2/3	1	Yes		NA	R (04FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1150 11501048	GENRL	Injection site pain/ pain at injection site	1	26AUG2020	2/3	2	Yes		NA	R (28AUG2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/Y	
	GENRL	Chills/ Chills	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	
		Pyrexia/ Fever	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001 1150 11501049	GENRL	Injection site pain/ Injection Site Pain#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N	
	GENRL	Chills/ Chills#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N	
	MUSC	Myalgia/ Muscle Aches#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N	
16-55/ C4591001 1150 11501050	GENRL	Chills/ Chills	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
		Injection site pain/ Pain at injection Site	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
	RESP	Oropharyngeal pain/ Sore Throat	2	01OCT2020	16/3	1	No	O	NA	R (03OCT2020)	N/N	
16-55/ C4591001 1150 11501051	GENRL	Injection site pain/ pain at injection site	1	26AUG2020	1/2	2	Yes		NA	R (27AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Nausea/ Nausea	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	METAB	Decreased appetite/ Loss of Appetite	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Tremor/ Body Shakes	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	PSYCH	Insomnia/ Insomnia	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	SKIN	Night sweats/ Night Sweats	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	2	20SEP2020	5/1	2	Yes		NA	R (20SEP2020)	N/N
	PSYCH	Depression/ Depression	2	NOV2020	47/C	2	No	O	NA	RG	N/N
16-55/ C4591001 1150 11501052	GENRL	Injection site pain/ Pain at injection site#	3	04FEB2021	1/2	2	Yes		NA	R (05FEB2021)	N/N
	PSYCH	Restlessness/ Restlessness#	3	04FEB2021	1/1	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Chills/ Chills#	4	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
		Fatigue/ Fatigue#	4	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
		Pain/ Generalized Body Aches#	4	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
	NERV	Headache/ Headache#	4	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501053	GENRL	Injection site pain/ Arm soreness (left arm) injection site	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Arm soreness (Left arm, injection site)	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1150 11501054	GENRL	Injection site pain/ Pain at injection site#	3	01MAR2021	1/2	2	Yes		NA	R (02MAR2021)	N/N
16-55/ C4591001 1150 11501056	GENRL	Fatigue/ Fatigue	2	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1150 11501057	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
		Pain/ Body Aches#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501058	GASTR	Pain/ Body Aches#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
		Nausea/ nausea	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ fatigue	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
		Injection site pain/ arm pain: injection site, left arm	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
		Fatigue/ Fatigue	2	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Arm Pain (Injection Site)	2	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1150 11501059	GENRL	Pain/ Body Aches	2	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ pain at injection site	1	27AUG2020	2/4	1	Yes		NA	R (30AUG2020)	N/N
	NERV	Headache/ Headache	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1150 11501060	NERV	Headache/ Headache	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
		GENRL	Injection site pain/ arm soreness (injection site), Left arm	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501061	GASTR	Nausea/ Nausea	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		Vomiting/ Vomiting	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Chills/ Chills#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
		Myalgia/ Muscle Pain#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Pain/ Body Aches	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501064	GENRL	Injection site pain/ arm soreness (left arm); injection site	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1150 11501065	GENRL	Injection site pain/ Pain at injection site#	3	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	01FEB2021	1/2	2	Yes		NA	R (02FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	01FEB2021	1/3	2	Yes		NA	R (03FEB2021)	N/N
		Pain/ Body Aches#	4	01FEB2021	1/2	2	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1150 11501067	GENRL	Injection site pain/ pain at injection site	1	28AUG2020	2/3	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	GASTR	Abdominal pain/ Abdominal Pain	2	19SEP2020	3/3	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Chills/ Chills	2	19SEP2020	3/3	1	Yes		NA	R (21SEP2020)	N/N
		Fatigue/ Fatigue	2	19SEP2020	3/3	1	Yes		NA	R (21SEP2020)	N/N
	NERV	Headache/ Headache	2	19SEP2020	3/3	1	Yes		NA	R (21SEP2020)	N/N
	RESP	Nasal congestion/ Congested Nose	2	19SEP2020	3/3	1	Yes		NA	R (21SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501068	NERV	Oropharyngeal pain/ Sore Throat	2	19SEP2020	3/3	1	Yes		NA	R (21SEP2020)	N/N
		Headache/ Headache	2	05OCT2020	19/2	1	No	O	NA	R (06OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/3	1	Yes		NA	R (07FEB2021)	N/N
	GENRL	Chills/ chills	1	28AUG2020	2/1	2	Yes		NA	R (28AUG2020)	N/N
	INFE	Injection site pain/ Pain at injection site	1	28AUG2020	2/2	2	Yes		NA	R (29AUG2020)	N/N
		Pain/ Body aches	1	28AUG2020	2/1	2	Yes		NA	R (28AUG2020)	N/N
		Ear infection/ Right ear infection	1	14SEP2020	19/18	2	No	O	NA/TC	R (01OCT2020)	N/N
GENRL	Injection site pain/ Pain at injection site	2	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N	
GENRL	Fatigue/ Fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	
16-55/ C4591001 1150 11501069	GENRL	Injection site pain/ arm soreness (left arm, injection site)	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
GENRL	Injection site pain/ Pain at injection site	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N	
NERV	Headache/ Headache	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N	
INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	2	11NOV2020	55/C		No	O	NA	RG	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501070	GENRL	Injection site pain/ Pain at injection site#	3	25FEB2021	1/2	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Chills/ Chills#	3	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N
		Fatigue/ Fatigue#	3	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N
	NERV	Headache/ Headache#	3	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1150 11501071	GENRL	Injection site pain/ Injection Site Pain#	3	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	3	19FEB2021	2/3	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1150 11501073	GENRL	Injection site pain/ Pain at injection site	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
	NERV	Pyrexia/ low grade fever (99.9)	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
		Headache/ headache	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Chills/ Chills	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
		Pain/ Body Aches	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
	Pyrexia/ Fever	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501074	GENRL	Injection site pain/ Pain at injection site#	3	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1150 11501075	GENRL	Injection site pain/ pain at injection site	1	31AUG2020	1/3	2	Yes		NA	R (02SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ Pain at Injection Site	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Burning sensation at injection site	2	30SEP2020	9/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1150 11501077	GASTR	Diarrhoea/ diarrhea	1	15SEP2020	15/2	1	No	O	NA	R (16SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1150 11501078	GASTR	Nausea/ nausea	1	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
	GENRL	Chills/ chills	1	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501079		Injection site pain/ pain at injection site	1	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
	NERV	Migraine/ migraine	1	01SEP2020	1/2	3	Yes		NA	R (02SEP2020)	N/N
	GENRL	Chills/ Chills	2	24SEP2020	1/3	2	Yes		NA	R (26SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	24SEP2020	1/3	2	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	1/3	2	Yes		NA	R (26SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	03SEP2020	3/2	1	Yes		NA	R (04SEP2020)	N/N
	NERV	Dizziness/ dizziness	1	03SEP2020	3/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	15FEB2021	1/3	2	Yes		NA	R (17FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	16FEB2021	2/2	2	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1150 11501080		Pain/ Body Aches#	3	16FEB2021	2/2	2	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	3	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	25FEB2021	1/2	1	Yes		NA	R (26FEB2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501081	NERV	Headache/ Headache#	3	26FEB2021	2/1	2	Yes		NA	R (26FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1150 11501082	GENRL	Pain/ Body Aches	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C4591001 1150 11501083	GENRL	Pyrexia/ Low grade fever	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
		Fatigue/ Fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Pain/ Body Aches	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Headache/ Headache	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1150 11501083	GENRL	Injection site pain/ Pain at injection Site*		01SEP2020	1/4	2	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1150 11501083	GENRL	Fatigue/ Fatigue	1	02SEP2020	2/3	2	Yes		NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1150 11501084	GENRL	Chills/ Chills	1	19SEP2020	19/5	1	No	O	NA	R (23SEP2020)	N/N	
	NERV	Headache/ Headache	1	19SEP2020	19/5	1	No	O	NA	R (23SEP2020)	N/N	
	RESP	Cough/ Cough	1	19SEP2020	19/5	1	No	O	NA	R (23SEP2020)	N/N	
		Oropharyngeal pain/ Sore Throat	1	19SEP2020	19/5	2	No	O	NA	R (23SEP2020)	N/N	
	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	04OCT2020	4/139		No	O	NA	R (19FEB2021)	N/N	
	PREG	Abortion spontaneous/ Spontaneous Miscarriage	2	19FEB2021	142/1	2	No	O	NA	R (19FEB2021)	Y/N	
16-55/ C4591001 1150 11501085	GENRL	Chills/ chills	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
		Fatigue/ fatigue	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
		Injection site pain/ arm soreness (left) injection site	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
	NERV	Headache/ headache	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
		Pain/ Body Aches	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
	NERV	Headache/ Headache	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501087	GENRL	Injection site pain/ Arm soreness (Right arm, injection site)	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Chills/ Chills	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		Pain/ Body Aches	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ Fever	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1150 11501088	GENRL	Fatigue/ fatigue	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		Injection site pain/ left arm pain (injection site)	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	PSYCH	Insomnia/ trouble sleeping	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C4591001 1150 11501089	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	GASTR	Nausea/ nausea	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	PSYCH	Irritability/ irritable mood	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GASTR	Abdominal pain upper/ Stomach Pain	2	24SEP2020	2/22	1	Yes		NA	R (15OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501090	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	3	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C4591001 1150 11501091	GENRL	Injection site pain/ Pain at injection site	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	04FEB2021	2/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1150 11501092	GENRL	Injection site pain/ arm soreness (L arm, injection site)	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1150 11501093	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	RESP	Oropharyngeal pain/ Sore Throat	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	BLOOD	Lymphadenopathy/ Swollen lymph nodes (left armpit)#	3	03FEB2021	2/3	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Chills/ Chills#	3	03FEB2021	2/3	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site pain#	3	03FEB2021	2/3	1	Yes		NA	R (05FEB2021)	N/N
	GENRL										

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501094	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1150 11501096	MUSC	Neck pain/ Cervical neck pain	2	NOV2020	40/C	1	No	O	NA	RG	N/N
	GENRL	Injection site pain/ pain at injection site	1	04SEP2020	2/4	2	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1150 11501097	GENRL	Injection site pain/ Pain at injection Site	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Chills/ Chills#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1150 11501098		Injection site pain/ Injection Site Pain#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Fatigue/ fatigue	1	03SEP2020	1/3	3	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	1	04SEP2020	2/2	3	Yes		NA	R (05SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/4	3	Yes		NA	R (27SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1150 11501099	GENRL	Fatigue/ Fatigue#	3	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1150 11501100	GENRL	Injection site pain/ pain at injection site	1	03SEP2020	1/3	2	Yes		NA	R (05SEP2020)	N/N
	GENRL	Chills/ Chills	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
		Pain/ Body Aches	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1150 11501101	GENRL	Injection site pain/ Pain at injection site	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	PSYCH	Insomnia/ Trouble Sleeping	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501102	GENRL	Injection site pain/ Injection Site Pain#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N
	GENRL	Chills/ Chills#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
		Fatigue/ Fatigue#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1150 11501103	GENRL	Injection site pain/ Pain at injection site#	3	21JAN2021	1/2	2	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1150 11501104	GENRL	Injection site pain/ left injection site arm soreness	1	09SEP2020	2/1	3	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1150 11501106	GENRL	Injection site pain/ Arm soreness (Left arm/injection site)	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Chills/ Chills	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1150 11501107	GENRL	Fatigue/ Fatigue#	3	27JAN2021	1/3	2	Yes		NA	R (29JAN2021)	N/N
		Injection site pain/ Pain at injection site#	3	27JAN2021	1/3	2	Yes		NA	R (29JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501110	NERV	Headache/ Headache#	3	27JAN2021	1/3	2	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	17FEB2021	1/3	2	Yes		NA	R (19FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	17FEB2021	1/3	2	Yes		NA	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	17FEB2021	1/3	2	Yes		NA	R (19FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	18FEB2021	2/2	2	Yes		NA	R (19FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	2	03OCT2020	3/2	1	Yes		NA	R (04OCT2020)	N/N
		Pain/ Body Aches	2	03OCT2020	3/2	1	Yes		NA	R (04OCT2020)	N/N
	NERV	Sciatica/ Sciatica Nerve Pain	2	08OCT2020	8/13	1	No	O	NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ Injection site Pain#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1150 11501111		Pyrexia/ Fever (101.9)#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	12SEP2020	2/2	2	Yes		NA	R (13SEP2020)	N/N
	NERV	Dizziness/ Lightheaded	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501112	GENRL	Injection site pain/ Pain at injection site	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	17FEB2021	1/4	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1150 11501113	GENRL	Injection site pain/ Pain at injection site	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1150 11501114	GENRL	Fatigue/ Fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1150 11501115		Injection site pain/ Pain at injection site	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001		Injection site pain/ Injection site pain	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
		Pyrexia/ Fever (101.0)	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001	GASTR	Nausea/ Nausea#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1150 11501116	GENRL	Fatigue/ Fatigue#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
16-55/ C4591001 1150 11501117	GENRL	Fatigue/ Fatigue	1	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N	
	GENRL	Chills/ Chills#	3	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N	
		Injection site pain/ Injection Site Pain#	3	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N	
16-55/ C4591001 1150 11501122	GENRL	Injection site pain/ Pain at injection site	1	16OCT2020	2/4	2	Yes		NA	R (19OCT2020)	N/N	
16-55/ C4591001 1150 11501137	GENRL	Injection site pain/ Burning Sensation of Injection Site	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/Y	
	GENRL	Injection site erythema/ Redness at injection site#	3	09FEB2021	1/3	2	Yes		NA	R (11FEB2021)	N/N	
		Injection site pain/ Pain at injection site#	3	09FEB2021	1/3	2	Yes		NA	R (11FEB2021)	N/N	
16-55/ C4591001 1150 11501139	GENRL	Injection site pain/ Pain at injection site	1	27OCT2020	1/3	2	Yes		NA	R (29OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501140	GENRL	Injection site pain/ Pain at injection site	1	28OCT2020	2/3	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1150 11501141	GENRL	Fatigue/ Fatigue#	3	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
		Injection site pain/ Pain at injection site#	3	15FEB2021	1/3	2	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1150 11501144	GENRL	Injection site pain/ Pain at injection site	1	29OCT2020	1/2	2	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1150 11501148	GENRL	Injection site pain/ Pain at injection site#	3	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
		Pain/ Generalized Body Aches#	3	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
	NERV	Dizziness/ Dizziness#	3	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1150 11501149	GENRL	Injection site pain/ Pain at injection site#	3	16FEB2021	1/3	2	Yes		NA	R (18FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1150 11501151	NERV	Pain/ Generalized Body Aches#	3	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N	
		Headache/ Headache#	3	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N	
		Injection site pain/ Pain at injection site#	3	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	3	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	3	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N	
	PSYCH	Depression/ Worsening Depression- no prior hospitalizations for depression#	3	02MAR2021	7/C	4	No	O	NA	RG	Y/N	
	GENRL	Injection site pain/ Pain at injection site#	3	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	3	18FEB2021	1/3	2	Yes		NA	R (20FEB2021)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	3	18FEB2021	1/3	2	Yes		NA	R (20FEB2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain#	3	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1150 11501169	GENRL	Injection site pain/ Injection Site Pain#	3	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N	
1150 11501170	NERV	Headache/ headache, intermittent	1	13AUG2020	2/21	2	No	O	NA/TC	R (02SEP2020)	N/N	
1150 11521010	INJ&P	Procedural pain/ post-surgical pain left shoulder	2	21SEP2020	20/22	2	No	O	NA/TC	R (12OCT2020)	N/N	
1150 11521012	GENRL	Fatigue/ Fatigue	1	16AUG2020	5/93	1	Yes		NA	R (16NOV2020)	N/N	
1150 11521014	RESP	Throat irritation/ Scratchy Throat	2	28SEP2020	27/2	1	No	O	NA	R (29SEP2020)	N/N	
1150 11521022	MUSC	Arthralgia/ bilateral hip joint pain	2	19NOV2020	79/5	1	No	O	NA/TC	R (23NOV2020)	N/N	
1150 11521024	INJ&P	Upper limb fracture/ broken right arm#	2	15JAN2021	136/C	2	No	O	NA/TC/TCN	N	N/N	
1150 11521024	NERV	Migraine/ intermittent migraine	2	03SEP2020	2/3	2	No	O	NA/TC	R (05SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1152 11521029 16-55/ C4591001	SKIN	Rash/ body rash	2	03SEP2020	3/C	2	Yes		NA/TC	N	N/N	
1152 11521046 16-55/ C4591001	GASTR	Nausea/ Nausea	2	13FEB2021	166/C	2	No	O	NA/TC	RG	N/N	
1152 11521053	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	15FEB2021	168/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1152 11521063	MUSC	Exostosis/ Bilateral heel spur pain#	2	09FEB2021	162/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1152 11521076	RESP	Exostosis/ Bilateral heel spurs# Nasal polyps/ Nasal polyps	2	09FEB2021 03DEC2020	162/C 92/C	1 2	No No	O O	NA/TC NA/TC	N RG	N/N N/N	
16-55/ C4591001 1152 11521077	GASTR	Toothache/ tooth pain	1	27AUG2020	15/1	2	No	O	NA/TC/TCN	R (27AUG2020)	N/N	
16-55/ C4591001 1152 11521081	INJ&P	Chest injury/ Bruised Ribs	2	22FEB2021	174/C	1	No	O	NA/TC	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Contusion/ Bruised knee	2	22FEB2021	174/C	1	No	O	NA/TC	N	N/N
		Fall/ Fall	2	22FEB2021	174/1	1	No	O	NA	R (22FEB2021)	N/N
		Tooth fracture/ Cracked tooth (molar 14)	2	22FEB2021	174/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C4591001 1152 11521085	GENRL	Death/ UNDETERMINED CAUSE OF DEATH	1	26AUG2020	8/1	4	No	O	P/W	F (26AUG2020)	Y/N
16-55/ C4591001 1152 11521110	GENRL	Pyrexia/ Fever (101.2 f)	1	19AUG2020	1/2	2	Yes		NA/TC	R (20AUG2020)	N/N
	MUSC	Myalgia/ Myalgias	1	19AUG2020	1/2	1	Yes		NA/TC	R (20AUG2020)	N/N
	GENRL	Chills/ chills	2	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N
	MUSC	Myalgia/ myalgia	2	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1152 11521121	GASTR	Oesophagitis/ esophagitis	2	17DEC2020	99/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1152 11521137	GENRL	Injection site pain/ Injection Site Pain	2	16DEC2020	97/5	2	No	O	NA/TC	R (20DEC2020)	N/N
16-55/ C4591001	INFEC	Urinary tract infection/ Urinary Tract Infection	1	14SEP2020	25/7	1	No	O	NA/TC	R (20SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1152 11521138	INJ&P	Contusion/ Antecubital bruise of the right arm	2	08OCT2020	29/15	1	No	O	NA	R (22OCT2020)	N/N
1152 11521147	PSYCH	Depression/ worsening depression	2	28SEP2020	18/18	2	No	O	NA/TC	R (15OCT2020)	N/N
1152 11521149	PSYCH	Anxiety/ worsened anxiety	2	16NOV2020	67/26	1	No	O	NA/TC	R (11DEC2020)	N/N
1152 11521150	GASTR	Nausea/ nausea	2	22SEP2020	9/3	2	No	O	NA/TC	R (24SEP2020)	N/N
1152 11521165	MUSC	Myalgia/ myalgias#	4	18FEB2021	2/3	2	Yes		NA/TC	R (20FEB2021)	N/N
1152 11521167	GASTR	Nausea/ Nausea#	3	08MAR2021	1/2	2	Yes		NA/TC	R (09MAR2021)	N/N
1152 11521180	GENRL	Chills/ Chills#	3	08MAR2021	1/2	2	Yes		NA/TC	R (09MAR2021)	N/N
		Fatigue/ Fatigue#	3	08MAR2021	1/3	2	Yes		NA	R (10MAR2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521182	NERV	Injection site pain/ Injection site pain#	3	08MAR2021	1/2	2	Yes		NA/TC	R (09MAR2021)	N/N
		Headache/ Headache#	3	08MAR2021	1/2	2	Yes		NA/TC	R (09MAR2021)	N/N
16-55/ C4591001 1152 11521182	GENRL	Injury associated with device/ needle stick injury (finger)	1	26AUG2020	3/1	1	No	O	NA/TC	R (26AUG2020)	N/N
16-55/ C4591001 1152 11521183	INFEC	Genital herpes/ genital herpes diagnosed	1	04SEP2020	12/7	2	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1152 11521188	NERV	Headache/ Headache#	3	25JAN2021	4/25	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1152 11521192	GENRL	Injection site pain/ INJECTION SITE PAIN*		25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	17DEC2020	95/1	1	Yes		NA	R (17DEC2020)	N/N
	NERV	Headache/ HEADACHE	2	08JAN2021	117/1	1	Yes		NA/TC	R (08JAN2021)	N/N
16-55/ C4591001 1152 11521206	GENRL	Chills/ chills	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1152 11521209	RESP	Injection site pain/ injection site pain	2	14SEP2020	1/8	1	Yes		NA	R (21SEP2020)	N/N	
		Throat irritation/ irritated throat	1	02SEP2020	8/6	1	No	O	NA	R (07SEP2020)	N/N	
16-55/ C4591001 1152 11521220	GENRL	Injection site pain/ Pain at Injection Site#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N	
	NERV	Headache/ Headache#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N	
16-55/ C4591001 1152 11521222	BLOOD	Lymphadenopathy/ swollen lymph nodes (neck-both sides)#	3	10MAR2021	2/C	1	Yes		NA/TC	N	N/N	
	GENRL	Fatigue/ fatigue#	3	10MAR2021	2/C	1	Yes		NA/TC	N	N/N	
	MUSC	Injection site pain/ injection site pain.#	3	10MAR2021	2/C	1	Yes		NA/TC	N	N/N	
16-55/ C4591001 1152 11521227	GENRL	Myalgia/ myalgia#	3	10MAR2021	2/C	1	Yes		NA/TC	N	N/N	
		Injury associated with device/ needle stick injury, right foot	2	27SEP2020	11/1	2	No	O	NA/TC	R (27SEP2020)	N/N	
16-55/ C4591001 1152 11521240	GASTR	Diarrhoea/ Diaherrea#	4	11JAN2021	1/1	1	Yes		NA	R (11JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521256	GENRL	Fatigue/ Fatigue#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	GENRL	Pyrexia/ Fever	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C4591001 1152 11521263	GENRL	Chills/ Chills	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C4591001 1152 11521271	PSYCH	Anxiety/ anxiety	2	01NOV2020	42/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1152 11521276	MUSC	Myalgia/ Myalgia	1	05SEP2020	6/6	2	Yes		NA/TC	R (10SEP2020)	N/N
	NERV	Neuropathy peripheral/ neuropathy	1	05SEP2020	6/6	2	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1152 11521282	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	02DEC2020	71/C	2	No	O	NA/TC	N	N/N
	GENRL	Chills/ Chills	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521284	MUSC	Pyrexia/ Fever	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
		Myalgia/ Myalgia	2	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Chills/ Chills	1	31AUG2020	1/3	2	Yes		NA/TC	R (02SEP2020)	N/N
16-55/ C4591001 1152 11521298	MUSC	Pyrexia/ Fever	1	31AUG2020	1/3	1	Yes		NA/TC	R (02SEP2020)	N/N
	PSYCH	Myalgia/ Myalgia	1	31AUG2020	1/3	2	Yes		NA/TC	R (02SEP2020)	N/N
16-55/ C4591001 1152 11521308		Depression/ Worsening depression	2	DEC2020	70/C	2	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ injection site pain	1	04SEP2020	2/4	3	Yes		NA/TC	R (07SEP2020)	N/N
16-55/ C4591001 1152 11521316	GENRL	Fatigue/ fatigue	1	08SEP2020	6/5	2	No	O	NA	R (12SEP2020)	N/N
	MUSC	Myalgia/ myalgia	1	08SEP2020	6/4	2	No	O	NA	R (11SEP2020)	N/N
	GENRL	Pain/ Body aches	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
	INFEC	Viral infection/ Viral infection#	2	23FEB2021	155/C	2	No	O	NA/TC	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	NERV	Facial paralysis/ Bell's palsy - L side#	2	23FEB2021	155/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1152 11521318	PSYCH	Insomnia/ worsening insomnia	1	03SEP2020	1/8	2	Yes		NA/TC	R (10SEP2020)	N/N	
16-55/ C4591001 1152 11521327	NERV	Migraine/ Worsening Migraine	2	30OCT2020	37/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1152 11521329	GENRL	Chills/ Chills	2	23SEP2020	2/1	2	Yes		NA/TC	R (23SEP2020)	N/N	
		Injection site pain/ Injection Site Pain	2	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N	
		Pyrexia/ Fever	2	23SEP2020	2/1	2	Yes		NA/TC	R (23SEP2020)	N/N	
16-55/ C4591001 1152 11521332	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
		Pyrexia/ Fever	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
	VASC	Hypertension/ Hypertension#	2	01MAR2021	161/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001	GENRL	Chills/ Chills	2	23SEP2020	2/1	2	Yes		NA/TC	R (23SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1152 11521335		Pain/ Body Aches	2	23SEP2020	2/1	2	Yes		NA/TC	R (23SEP2020)	N/N	
16-55/ C4591001 1152 11521338	GENRL	Chills/ Chills	2	23SEP2020	2/3	1	Yes		NA/TC	R (25SEP2020)	N/N	
		Pyrexia/ Fever	2	23SEP2020	2/3	1	Yes		NA/TC	R (25SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N	
16-55/ C4591001 1152 11521347	GENRL	Fatigue/ Fatigue	1	04SEP2020	2/1	1	Yes		NA	R (04SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia	1	04SEP2020	2/1	1	Yes		NA	R (04SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
	GENRL	Chills/ Chills	2	18DEC2020	88/1	2	Yes		NA	R (18DEC2020)	N/N	
		Fatigue/ Fatigue	2	18DEC2020	88/3	2	Yes		NA	R (20DEC2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	19DEC2020	89/2	2	Yes		NA/TC	R (20DEC2020)	N/N	
	RESP	Nasal congestion/ Nasal congestion	2	19DEC2020	89/2	2	Yes		NA	R (20DEC2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	08JAN2021	109/2	2	No	O	NA/TC	R (09JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521354	PSYCH	Anxiety/ Body anxiety	2	08JAN2021	109/2	2	No	O	NA	R (09JAN2021)	N/N
	MUSC	Musculoskeletal stiffness/ Neck stiffness#	2	18FEB2021	148/C	1	No	O	NA	N	N/N
16-55/ C4591001 1152 11521355	GENRL	Chills/ Chills#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1152 11521365	SKIN	Pruritus/ itchy scalp	2	05OCT2020	8/25	2	Yes		NA/TC/TCN	R (29OCT2020)	N/N
16-55/ C4591001 1152 11521371	GENRL	Rash/ rash back of neck	2	05OCT2020	8/25	2	Yes		NA/TC	R (29OCT2020)	N/N
		Rash/ rash bilateral arms	2	05OCT2020	8/25	2	Yes		NA/TC	R (29OCT2020)	N/N
		Chills/ Chills	2	29SEP2020	2/2	2	Yes		NA/TC	R (30SEP2020)	N/N
		Pain/ Body Aches	2	29SEP2020	2/2	2	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1152 11521373	GENRL	Injection site pain/ Injection Site Pain	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1152 11521374	MUSC	Myalgia/ Myalgia	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N	
	NERV	Headache/ Headache	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N	
	GENRL	Chills/ Chills#	4	07JAN2021	2/1	1	Yes		NA/TC	R (07JAN2021)	N/N	
			Pyrexia/ Fever#	4	07JAN2021	2/1	1	Yes		NA/TC	R (07JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	07JAN2021	2/3	1	Yes		NA/TC	R (09JAN2021)	N/N	
	NERV	Headache/ Headaches#	4	07JAN2021	2/1	1	Yes		NA/TC	R (07JAN2021)	N/N	
16-55/ C4591001 1152 11521377	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/N	
16-55/ C4591001 1152 11521382		Pyrexia/ Fever	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	2	28SEP2020	1/4	1	Yes		NA/TC	R (01OCT2020)	N/N	
		Pyrexia/ Fever	2	28SEP2020	1/1	2	Yes		NA/TC	R (28SEP2020)	N/N	
	GENRL	Chest pain/ Chest Pain	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N	
	GENRL	Pyrexia/ Fever (102.5 F)	2	29SEP2020	2/7	3	Yes		NA	R (05OCT2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521384	NERV	Headache/ Headache	2	29SEP2020	2/4	2	Yes		NA	R (02OCT2020)	N/N
	GENRL	Chills/ Chills	2	28SEP2020	1/2	2	Yes		NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 1152 11521401		Pyrexia/ Fever	2	28SEP2020	1/2	2	Yes		NA/TC	R (29SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1152 11521404	GENRL	Pyrexia/ Fever	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Injection site erythema/ Injection Site Redness	2	30SEP2020	3/7	1	Yes		NA	R (06OCT2020)	N/N
	INJ&P	Foot fracture/ Fractured left second toe	2	29DEC2020	93/C	3	No	O	NA/TCN	RG	N/N
16-55/ C4591001 1152 11521412	GASTR	Nausea/ Nausea#	4	04FEB2021	1/3	1	Yes		NA/TC	R (06FEB2021)	N/N
	GENRL	Chills/ Chills#	4	04FEB2021	1/3	1	Yes		NA/TC	R (06FEB2021)	N/N
		Fatigue/ Fatigue#	4	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N
		Pain/ Body Aches#	4	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521416	NERV	Headache/ Headaches#	4	05FEB2021	2/2	2	Yes		NA/TC	R (06FEB2021)	N/N
	GENRL	Pyrexia/ Fever	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1152 11521424	MUSC	Myalgia/ Myalgia	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1152 11521430	GENRL	Chills/ Chills#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1152 11521434	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/2	2	Yes		NA	R (11FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	10FEB2021	2/2	2	Yes		NA/TC	R (11FEB2021)	N/N
	NERV	Hypogeusia/ Diminished sense of taste#	4	10FEB2021	2/1	2	Yes		NA	R (10FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ Fever	2	29SEP2020	1/2	2	Yes		NA/TC	R (30SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521435	MUSC	Myalgia/ Myalgia	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
	NERV	Headache/ Headache	2	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ injection Site Pain	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ FEVER	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	RESP	Upper respiratory tract congestion/ Head Congestion	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	16-55/ C4591001 1152 11521436	GASTR	Proctalgia/ Rectal Pain	2	03NOV2020	36/12	2	No	O	NA/TC	R (14NOV2020)
16-55/ C4591001 1152 11521437	INJ&P	Limb injury/ injured right arm	1	27SEP2020	19/4	1	No	O	NA	R (30SEP2020)	N/N
16-55/ C4591001 1152 11521449	GASTR	Diarrhoea/ Diarrhea	1	16SEP2020	1/1	2	Yes		NA	R (16SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	09OCT2020	1/1	2	Yes		NA	R (09OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521450	GENRL	Fatigue/ Fatigue#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
		Pain/ Body Aches#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	PSYCH	Anxiety/ Anxiety#	4	10FEB2021	2/1	1	No	O	NA	R (10FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	2	09OCT2020	1/3	2	Yes		NA/TC	R (11OCT2020)	N/N
	GENRL	Pain/ Body Aches	2	10OCT2020	2/2	2	Yes		NA/TC	R (11OCT2020)	N/N
	NERV	Headache/ Headache	2	10OCT2020	2/3	2	Yes		NA/TC	R (12OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	12OCT2020	4/1	2	Yes		NA	R (12OCT2020)	N/N
	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	26DEC2020	79/C	3	No	O	NA	N	N/N
	INJ&P	Muscle strain/ Muscle Strain (right chest)#	3	04FEB2021	9/5	1	No	O	NA	R (08FEB2021)	N/N
	16-55/ C4591001 1152 11521464	GENRL	Injection site pain/ Injection Site Pain	1	19SEP2020	2/4	1	Yes		NA	R (22SEP2020)
NERV	Headache/ Headache	1	19SEP2020	2/4	1	Yes		NA	R (22SEP2020)	N/N	
RESP	Upper respiratory tract congestion/ Head Congestion	1	19SEP2020	2/4	1	Yes		NA	R (22SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Fatigue/ Fatigue	2	08OCT2020	2/4	2	Yes		NA	R (11OCT2020)	N/N	
		Pyrexia/ Fever	2	08OCT2020	2/4	2	Yes		NA	R (11OCT2020)	N/N	
	NERV	Headache/ Headache	2	08OCT2020	2/4	2	Yes		NA	R (11OCT2020)	N/N	
16-55/ C4591001 1152 11521467	GASTR	Diarrhoea/ diarrhea	2	16OCT2020	5/6	3	Yes		NA	R (21OCT2020)	N/N	
16-55/ C4591001 1152 11521474	CARD	Palpitations/ Heart Palpitations	1	11OCT2020	18/21	2	No	O	NA	R (31OCT2020)	N/N	
16-55/ C4591001 1152 11521480	NERV	Headache/ Headache	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N	
16-55/ C4591001 1152 11521482	GASTR	Dyspepsia/ worsened heartburn	2	10NOV2020	26/22	2	No	O	NA/TC	R (01DEC2020)	N/N	
16-55/ C4591001 1152 11521490	GENRL	Fatigue/ Fatigue	1	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	1	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N	
	NERV	Headache/ Headache	1	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Fatigue/ Fatigue	2	21OCT2020	1/3	2	Yes		NA/TC	R (23OCT2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	2	22OCT2020	2/1	2	Yes		NA/TC	R (22OCT2020)	N/N	
		Pain/ Body Aches	2	22OCT2020	2/2	2	Yes		NA/TC	R (23OCT2020)	N/N	
		Pyrexia/ Fever	2	22OCT2020	2/2	2	Yes		NA/TC	R (23OCT2020)	N/N	
	NERV	Headache/ Headache	2	22OCT2020	2/2	2	Yes		NA/TC	R (23OCT2020)	N/N	
	GASTR	Abdominal pain upper/ Stomach Cramps	2	23OCT2020	3/1	1	Yes		NA	R (23OCT2020)	N/N	
		Diarrhoea/ Diarrhea	2	23OCT2020	3/1	1	Yes		NA	R (23OCT2020)	N/N	
16-55/ C4591001 1152 11521492	GENRL	Pyrexia/ Fever	2	27OCT2020	1/2	1	Yes		NA/TC	R (28OCT2020)	N/N	
	NERV	Headache/ Headache	2	27OCT2020	1/2	1	Yes		NA/TC	R (28OCT2020)	N/N	
16-55/ C4591001 1152 11521504	GENRL	Chills/ Chills#	4	11JAN2021	1/4	1	Yes		NA/TC	R (14JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	11JAN2021	1/4	1	Yes		NA/TC	R (14JAN2021)	N/N	
	NERV	Headache/ Headaches#	4	14JAN2021	4/29	2	Yes		NA/TC	R (11FEB2021)	N/N	
	VASC	Hypertension/ Hypertension#	4	18JAN2021	8/C	1	No	O	NA/TC	N	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521511	GENRL	Injection site pain/ Injection Site Pain	1	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
	NERV	Headache/ Light Headaches	1	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	29OCT2020	2/1	1	Yes		NA/TC	R (29OCT2020)	N/N
		Pyrexia/ Fever	2	29OCT2020	2/1	1	Yes		NA/TC	R (29OCT2020)	N/N
	NERV	Dizziness/ Light Headed	2	29OCT2020	2/1	1	Yes		NA/TC	R (29OCT2020)	N/N
16-55/ C4591001 1152 11521512	NERV	Headache/ Headache#	4	05JAN2021	1/3	2	Yes		NA/TCN	R (07JAN2021)	N/N
	EYE	Eye pain/ Eye Ache#	4	06JAN2021	2/2	2	Yes		NA/TCN	R (07JAN2021)	N/N
	GENRL	Chills/ Chills#	4	06JAN2021	2/3	2	Yes		NA/TCN	R (08JAN2021)	N/N
		Pyrexia/ Fever#	4	06JAN2021	2/2	2	Yes		NA/TCN	R (07JAN2021)	N/N
16-55/ C4591001 1152 11521517	GENRL	Chills/ Chills	1	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Chills/ Chills	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
		Fatigue/ Fatigue	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521522	MUSC	Injection site pain/ Injection Site Pain	2	04NOV2020	1/3	2	Yes		NA/TC	R (06NOV2020)	N/N
		Pyrexia/ Fever 101.7F	2	04NOV2020	1/3	2	Yes		NA/TC	R (06NOV2020)	N/N
		Myalgia/ Myalgia	2	04NOV2020	1/3	2	Yes		NA/TC	R (06NOV2020)	N/N
	NERV	Paraesthesia/ tingling left fingers	1	15OCT2020	1/1	1	Yes		NA	R (15OCT2020)	N/Y
	NERV	Headache/ intermittent headache	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
	NERV	Headache/ Headache	2	04NOV2020	1/2	2	Yes		NA/TC	R (05NOV2020)	N/N
	GENRL	Pain/ Body Aches	2	05NOV2020	2/1	2	Yes		NA/TC	R (05NOV2020)	N/N
	16-55/ C4591001 1152 11521534	INFEC	Skin infection/ skin infection right axilla	1	01NOV2020	17/30	1	No	O	NA/TC	R (30NOV2020)
	GENRL	Chills/ Chills	2	04NOV2020	1/2	1	Yes		NA	R (05NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521549	GASTR	Nausea/ Nausea	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
		Pain/ Body Aches	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N
	VASC	Flushing/ generalized flushing	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N
16-55/ C4591001 1152 11521551	GENRL	Pyrexia/ Fever (101.9 F)	1	21OCT2020	1/4	2	Yes		NA	R (24OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
	BLOOD	Lymphadenopathy/ Swollen Lymph Nodes (Left Jaw)#	4	22JAN2021	15/C	2	No	O	NA/TC	N	N/N
		Lymphadenopathy/ Swollen Lymph Nodes (Left Neck)#	4	22JAN2021	15/C	2	No	O	NA/TC	N	N/N
	EAR	Ear pain/ Left Ear Pain#	4	22JAN2021	15/C	2	No	O	NA/TC	N	N/N
	16-55/ C4591001 1152 11521557	GENRL	Chills/ Chills#	4	05JAN2021	1/4	2	Yes		NA/TCN	R (08JAN2021)
		Fatigue/ Fatigue#	4	05JAN2021	1/4	2	Yes		NA	R (08JAN2021)	N/N
		Feeling abnormal/ Brain Fog#	4	05JAN2021	1/1	2	Yes		NA	R (05JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521560	MUSC	Arthralgia/ generalized joint soreness#	4	05JAN2021	1/5	2	Yes		NA/TCN	R (09JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1152 11521591	MUSC	Myalgia/ Myalgia	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
	NERV	Headache/ Headache#	3	12MAR2021	2/1	2	Yes		NA/TC	R (12MAR2021)	N/N
16-55/ C4591001 1152 11521643	ENDO	Autoimmune thyroiditis/ Hashimoto's disease	2	12FEB2021	47/C	2	No	O	NA	N	N/N
16-55/ C4591001 1156 11561002	GENRL	Injection site pain/ INJECTION SITE PAIN	1	19AUG2020	1/4	1	Yes		NA	R (22AUG2020)	N/N
		Injection site pain/ INJECTION-SITE SORENESS	1	19AUG2020	1/4	1	Yes		NA	R (22AUG2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	1	24AUG2020	6/1	1	Yes		NA	R (24AUG2020)	N/N
	GENRL	Pyrexia/ FEVER	1	24AUG2020	6/1	1	Yes		NA	R (24AUG2020)	N/N
	RESP	Cough/ COUGH	1	24AUG2020	6/1	1	No	O	NA	R (24AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1156 11561006	RESP	Pulmonary embolism/ PULMONARY EMBOLISM	1	31AUG2020	12/3	3	No	O	NA/TC	R (02SEP2020)	N/N	
	VASC	Deep vein thrombosis/ DEEP VEIN THROMBOSIS	1	31AUG2020	12/10	3	No	O	NA/TC	R (09SEP2020)	Y/N	
	MUSC	Musculoskeletal stiffness/ right shoulder stiffness	1	05SEP2020	17/3	1	No	O	NA/TCN	R (07SEP2020)	N/N	
16-55/ C4591001 1156 11561007	PREG	Abortion spontaneous incomplete/ INCOMPLETE SPONTANEOUS ABORTION	2	04OCT2020	25/4	3	No	O	NA/TCN	R (07OCT2020)	Y/N	
	RESP	Haemoptysis/ HEMOPTYSIS	2	04OCT2020	25/1	2	No	O	NA	R (04OCT2020)	N/N	
16-55/ C4591001 1156 11561008	GENRL	Chills/ Chills	1	27AUG2020	8/2	1	Yes		NA	R (28AUG2020)	N/N	
	MUSC	Myalgia/ muscle aches	1	27AUG2020	8/2	1	Yes		NA	R (28AUG2020)	N/N	
16-55/ C4591001 1156 11561009	GENRL	Injection site pain/ Injection Site Pain (left deltoid)	1	03SEP2020	15/6	1	Yes		NA	R (08SEP2020)	N/N	
16-55/ C4591001 1156 11561015	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY*		21AUG2020	1/C		No	O	P	UNK	N/N	
16-55/ C4591001	REPRO	Dysfunctional uterine bleeding/ DYSFUNCTIONAL UTERINE BLEEDING	1	10SEP2020	18/22	2	No	O	NA/TC	R (01OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1156 11561018	INFEC	Urinary tract infection/ ACUTE URINARY TRACT INFECTION	2	30SEP2020	16/7	1	No	O	NA/TC	R (06OCT2020)	N/N	
16-55/ C4591001 1156 11561048	GENRL	Pyrexia/ fever	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N	
16-55/ C4591001 1156 11561054	MUSC	Arthralgia/ arthralgia	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N	
16-55/ C4591001 1156 11561054	RESP	Dyspnoea/ Shortness of breath	1	04SEP2020	8/2	1	No	O	NA	R (05SEP2020)	N/N	
16-55/ C4591001 1156 11561057	MUSC	Arthralgia/ arthralgia	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001 1156 11561057	GENRL	Pyrexia/ fever	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N	
16-55/ C4591001 1156 11561073	MUSC	Arthralgia/ arthralgia	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N	
16-55/ C4591001 1156 11561073	MUSC	Myalgia/ MYALGIA#	3	19JAN2021	5/2	1	Yes		NA/TC	R (20JAN2021)	N/N	
16-55/ C4591001 1156 11561076	RESP	Oropharyngeal pain/ sore throat	1	03SEP2020	3/2	1	Yes		NA/TCN	R (04SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Pyrexia/ fever	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N	
	MUSC	Myalgia/ myalgia	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N	
16-55/ C4591001 1156 11561086	INFEC	Conjunctivitis bacterial/ BACTERIAL CONJUNCTIVITIS	2	03OCT2020	11/12	1	No	O	NA/TC	R (14OCT2020)	N/N	
16-55/ C4591001 1156 11561089	GENRL	Pyrexia/ fever	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N	
16-55/ C4591001 1156 11561090	GENRL	Injection site pain/ Injection Site Pain (Left Shoulder)	1	04SEP2020	2/5	1	Yes		NA	R (08SEP2020)	N/N	
	MUSC	Back pain/ Back Pain	2	08OCT2020	7/6	1	No	O	NA/TCN	R (13OCT2020)	N/N	
	RENAL	Urethral discharge/ Urethral Discharge	2	08OCT2020	7/10	1	No	O	NA/TC	R (17OCT2020)	N/N	
16-55/ C4591001 1156 11561111	INFEC	Otitis externa/ external otitis	1	11SEP2020	4/6	1	No	O	NA/TC	R (16SEP2020)	N/N	
16-55/ C4591001 1156 11561113	REPRO	Vaginal discharge/ Vaginal discharge	2	29SEP2020	2/22	1	No	O	NA/TC	R (20OCT2020)	N/N	
	INFEC	Vaginal infection/ ACUTE VAGINITIS	2	20OCT2020	23/7	1	No	O	NA/TC	R (26OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	METAB	Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2	20OCT2020	23/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1156 11561121	GASTR	Diarrhoea/ diarrhea	1	10SEP2020	2/9	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Arthralgia/ left shoulder pain	1	10SEP2020	2/5	1	Yes		NA	R (14SEP2020)	N/N
	RESP	Oropharyngeal pain/ sore throat	1	10SEP2020	2/5	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001 1156 11561124	INJ&P	Overdose/ MULTIPLE DRUG OVERDOSE	2	02NOV2020	32/1	4	No	O	NA/W	F (02NOV2020)	Y/N
	RESP	Respiratory arrest/ RESPIRATORY ARREST	2	02NOV2020	32/1	4	No	O	NA/W	F (02NOV2020)	Y/N
16-55/ C4591001 1156 11561131	BLOOD	Lymphadenopathy/ CERVICAL LYMPHADENOPATHY#	3	26FEB2021	2/C	1	Yes		NA	RG	N/N
	SKIN	Rash/ FACIAL RASH#	3	26FEB2021	2/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1156 11561159	GASTR	Diarrhoea/ diarrhea	1	27SEP2020	7/2	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C4591001 1156 11561166	SKIN	Dermal cyst/ sebaceous cyst	1	06OCT2020	14/C	1	No	O	NA	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1156 11561172	GASTR	Vomiting/ VOMITING	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N	
	GASTR	Gastritis/ GASTRITIS	1	28SEP2020	4/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1156 11561175	NEOPL	Acrochordon/ ACROCHORDON	1	28SEP2020	4/67	1	No	O	NA	R (03DEC2020)	N/N	
	GASTR	Aphthous ulcer/ APHTHOUS ULCERS	2	07DEC2020	53/12	2	No	O	NA/TC	R (18DEC2020)	N/N	
16-55/ C4591001 1156 11561194	INFEC	Tinea versicolour/ PITYRIASIS VERICOLOR	2	04NOV2020	15/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1156 11561230	GENRL	Fatigue/ FATIGUE	1	12OCT2020	1/6	1	Yes		NA	R (17OCT2020)	N/N	
16-55/ C4591001 1156 11561231	GENRL	Chills/ CHILLS	1	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N	
	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	2	05NOV2020	2/5	2	Yes		NA	R (09NOV2020)	N/N	
16-55/ C4591001 1156 11561252	INFEC	Otitis externa/ OTITIS EXTERNA OF LEFT EAR	2	29NOV2020	26/9	1	No	O	NA/TC	R (07DEC2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1156 11561294	GENRL	Injection site pain/ PAIN IN SITE OF INJECTION	1	03NOV2020	1/4	2	Yes		NA/TC	R (06NOV2020)	N/N
	MUSC	Myalgia/ MYALGIA	1	03NOV2020	1/4	2	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1156 11561296	INFEC	Bacterial vulvovaginitis/ BACTERIAL VAGINITIS	2	08DEC2020	15/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1156 11561300	GENRL	Pyrexia/ FEVER	1	18NOV2020	2/2	3	Yes		NA	R (19NOV2020)	N/N
16-55/ C4591001 1156 11561329	NERV	Headache/ HEADACHE	2	07JAN2021	2/42	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1157 11571054	GENRL	Chills/ Chills#	3	21JAN2021	3/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1157 11571083	SKIN	Rash vesicular/ Vesicular Rash Below the lower lip#	3	08JAN2021	18/32	1	No	O	NA	R (08FEB2021)	N/N
16-55/ C4591001 1157 11571113	MUSC	Myalgia/ Myalgia	1	02SEP2020	2/6	1	Yes		NA	R (07SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1157 11571114 16-55/ C4591001 1157 11571115 16-55/ C4591001 1157 11571125 16-55/ C4591001 1157 11571126 16-55/ C4591001 1157 11571130 16-55/ C4591001 1157 11571132	GENRL	Chills/ Chills	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
	GASTR	Nausea/ Nausea	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Pain/ Body Aches	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	MUSC	Myalgia/ General Muscle Aches	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	IMMUN	Allergy to arthropod bite/ Allergic reaction to mosquito bite	2	01OCT2020	9/10	2	No	O	NA/TC	R (10OCT2020)	N/N
	NERV	Headache/ Headache	1	16SEP2020	16/5	1	No	O	NA	R (20SEP2020)	N/N
	GENRL	Injection site erythema/ Redness at injection site	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1157 11571141	INFEC	Injection site swelling/ Swelling at injection site	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
		Sinusitis/ Sinusitis	2	03OCT2020	12/13	2	No	O	NA/TC	R (15OCT2020)	N/N	
	GENRL	Injection site erythema/ Redness at injection site	2	27OCT2020	1/8	1	Yes		NA	R (03NOV2020)	N/N	
		Injection site induration/ Induration at injection site	2	27OCT2020	1/8	1	Yes		NA	R (03NOV2020)	N/N	
		Chills/ Chills	2	28OCT2020	2/5	1	Yes		NA/TC	R (01NOV2020)	N/N	
		Myalgia/ Myalgia	2	28OCT2020	2/5	1	Yes		NA/TC	R (01NOV2020)	N/N	
	NERV	Headache/ Headache	2	28OCT2020	2/5	1	Yes		NA/TC	R (01NOV2020)	N/N	
	16-55/ C4591001 1157 11571156	GENRL	Injection site pain/ Pain at study vaccine injection site ( Right arm)#	4	02MAR2021	1/5	1	Yes		NA	R (06MAR2021)	N/N
		GENRL	Chills/ Chills#	4	03MAR2021	2/2	1	Yes		NA	R (04MAR2021)	N/N
			Fatigue/ Fatigue#	4	03MAR2021	2/2	1	Yes		NA	R (04MAR2021)	N/N
Pyrexia/ Fever#			4	03MAR2021	2/2	1	Yes		NA/TC	R (04MAR2021)	N/N	
NERV	Headache/ Headache#	4	03MAR2021	2/3	1	Yes		NA	R (05MAR2021)	N/N		
16-55/ C4591001	EAR	Excessive cerumen production/ Excess cerumen, lt EAC	1	16OCT2020	77/C	1	No	O	NA	N	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1161 11611011	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	2	17JAN2021	60/C	1	No	O	NA	UNK	N/N
16-55/ C4591001 1161 11611016	BLOOD	Lymphadenopathy/ 1+right distal cervical lymph node enlarged	1	08NOV2020	98/C	1	No	O	NA	N	N/N
16-55/ C4591001 1161 11611020	GASTR	Nausea/ nausea#	3	21JAN2021	2/3	1	Yes		NA	R (23JAN2021)	N/N
1161 11611027		Vomiting/ vomiting#	3	21JAN2021	2/3	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Chills/ chills#	3	21JAN2021	2/3	1	Yes		NA	R (23JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	3	21JAN2021	2/6	2	Yes		NA/TC	R (26JAN2021)	N/N
	NERV	Dizziness/ dizziness#	3	21JAN2021	2/3	1	Yes		NA	R (23JAN2021)	N/N
		Headache/ headache#	3	21JAN2021	2/4	2	Yes		NA/TC	R (24JAN2021)	N/N
16-55/ C4591001 1161 11611034	NERV	Neuropathy peripheral/ Bilateral Peripheral Neuropathy	2	01DEC2020	8/C	1	No	O	NA	N	N/N
		Restless legs syndrome/ Restless Leg Syndrome	2	01DEC2020	8/C	1	No	O	NA/TC	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1162 11621019	INFEC	Sinusitis/ sinus infection	2	06OCT2020	42/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1162 11621025	GASTR	Gastroesophageal reflux disease/ Esophageal pain/Acid Reflux	1	13AUG2020	10/2	1	No	O	NA	R (14AUG2020)	N/N	
16-55/ C4591001 1162 11621103	NERV	Headache/ Headache	2	05SEP2020	2/3	1	No	O	NA	R (07SEP2020)	N/N	
16-55/ C4591001 1162 11621121	RESP	Nasal congestion/ Nasal Congestion	2	02OCT2020	31/2	1	No	O	NA	R (03OCT2020)	N/N	
16-55/ C4591001 1162 11621128	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	SEP2020	1/C		No	O	NA	UNK	N/N	
16-55/ C4591001 1162 11621137	NERV	Tension headache/ Stress induced Headache	2	14SEP2020	6/2	1	No	O	NA	R (15SEP2020)	N/N	
16-55/ C4591001 1162 11621142	GENRL	Pyrexia/ Fever	1	20AUG2020	4/2	1	Yes		NA	R (21AUG2020)	N/N	
16-55/ C4591001 1162 11621151	NERV	Headache/ Headache	2	14OCT2020	35/1	1	No	O	NA	R (14OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1162 11621158	GENRL	Fatigue/ Fatigue	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
		Injection site pain/ Left shoulder soreness (injection site pain)	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
		Pyrexia/ Slight increased fever	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
	EAR	Vertigo/ Intermittent Vertigo	2	27SEP2020	19/26	1	No	O	NA	R (22OCT2020)	N/N	
16-55/ C4591001 1162 11621166	GASTR	Diarrhoea/ Diarrhea	2	11OCT2020	26/2	1	No	O	NA	R (12OCT2020)	N/N	
16-55/ C4591001 1162 11621205	GENRL	Fatigue/ Fatigue	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N	
	NERV	Headache/ Headache	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N	
16-55/ C4591001 1162 11621216	RENAL	Nephrolithiasis/ Kidney Stones	2	25NOV2020	69/2	1	No	O	NA/TC	R (26NOV2020)	N/N	
	INFEC	Urinary tract infection/ urinary tract infection	2	29NOV2020	73/11	1	No	O	NA/TC	R (09DEC2020)	N/N	
16-55/ C4591001 1162 11621255	INFEC	Urinary tract infection/ Urinary tract infection	2	04DEC2020	73/C	1	No	O	NA/TC	RG	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1162 11621279	NERV	Migraine/ Migraine	2	12OCT2020	19/17	1	No	O	NA/TC	R (28OCT2020)	N/N	
16-55/ C4591001 1162 11621283	INFEC	Pharyngitis streptococcal/ Strep Throat	2	12OCT2020	18/11	1	No	O	NA/TC/TCN	R (22OCT2020)	N/N	
16-55/ C4591001 1162 11621324	GENRL	Fatigue/ Fatigue	1	14SEP2020	5/2	1	No	O	NA	R (15SEP2020)	N/N	
	RESP	Oropharyngeal pain/ Sore throat	1	14SEP2020	5/2	1	No	O	NA	R (15SEP2020)	N/N	
16-55/ C4591001 1162 11621392	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/Y	
	RESP	Oropharyngeal pain/ Sore throat	1	18SEP2020	2/2	1	No	O	NA	R (19SEP2020)	N/N	
16-55/ C4591001 1162 11621401	MUSC	Pain in extremity/ Arm soreness	1	17SEP2020	1/C	1	Yes		NA/TC/TCN	N	N/N	
16-55/ C4591001 1162 11621416	GENRL	Chills/ Chills	1	02OCT2020	12/1	1	No	O	NA	R (02OCT2020)	N/N	
16-55/ C4591001	NERV	Hypoaesthesia/ Leg Numbness	1	05OCT2020	6/2	1	No	O	NA	R (06OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1162 11621464 16-55/ C4591001	NERV	Headache/ headache	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
1162 11621583 16-55/ C4591001	GENRL	Injection site pain/ Left Deltoid injection Site pain#	4	09MAR2021	2/2	1	Yes		NA	R (10MAR2021)	N/N
1163 11631039 16-55/ C4591001	INFEC	Urinary tract infection/ UTI	1	22AUG2020	17/7	2	No	O	NA/TC	R (28AUG2020)	N/N
1163 11631040 16-55/ C4591001	IMMUN	Drug hypersensitivity/ Allergic Reaction to study investigational product	1	08AUG2020	2/18	2	Yes		P/TC	R (25AUG2020)	N/N
1163 11631059	SKIN	Dermatitis allergic/ Allergic Reaction upper body rash	1	08AUG2020	2/18	2	Yes		NA/TC	R (25AUG2020)	N/N
16-55/ C4591001	PSYCH	Depression/ DEPRESSION	1	01SEP2020	23/C	2	No	O	NA/TC	N	N/N
1163 11631069 16-55/ C4591001	GENRL	Pyrexia/ FEVER	2	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
1163 11631077	NERV	Headache/ HEADACHE	2	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1166 11661003	GENRL	Injection site pain/ Injection site soreness	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
		Pyrexia/ Low grade fever	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1166 11661009	GENRL	Chills/ CHILLS	2	11SEP2020	2/3	1	Yes		NA/TC	R (13SEP2020)	N/N
		Pyrexia/ FEVER	2	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
	MUSC	Muscle fatigue/ MUSCLE FATIGUE	2	11SEP2020	2/3	1	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1166 11661028	GENRL	Pyrexia/ Fever#	3	01MAR2021	1/3	1	Yes		NA	R (03MAR2021)	N/N
16-55/ C4591001 1166 11661030	VASC	Hot flush/ Exacerbation of hot flashes	2	02OCT2020	22/C	2	No	O	NA/TC	N	N/N
	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	27OCT2020	47/20	1	No	O	NA/TC	R (15NOV2020)	N/N
	INFEC	Urinary tract infection/ URINARY TRACT INFECTION#	3	28DEC2020	8/12	1	No	O	NA/TC	R (08JAN2021)	N/N
16-55/ C4591001 1166 11661036	NERV	Dysgeusia/ Metallic taste	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1166 11661046 16-55/ C4591001 1166 11661047 16-55/ C4591001 1166 11661063 16-55/ C4591001 1166 11661068 16-55/ C4591001 1166 11661072 16-55/ C4591001 1166 11661076 16-55/ C4591001 1166 11661076	PSYCH	Insomnia/ Insomnia	1	21AUG2020	2/9	2	Yes		NA	R (29AUG2020)	N/N
	GENRL	Pyrexia/ Fever	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
	NERV	Dizziness/ Dizziness	1	31AUG2020	1/1	1	Yes		P	R (31AUG2020)	N/N
	GENRL	Pyrexia/ Fever	2	25SEP2020	1/31	1	Yes		NA	R (25OCT2020)	N/N
	INJ&P	Joint injury/ Left knee injury	2	21JAN2021	120/C	2	No	O	NA	RG	N/N
	GENRL	Pyrexia/ fever#	3	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N
	GENRL	Pyrexia/ FEVER#	4	12JAN2021	2/2	1	Yes		NA/TC	R (13JAN2021)	N/N
	INJ&P	Contusion/ LEFT UPPER CHEST BRUISING.	1	25SEP2020	11/32	1	No	O	NA/TC	R (26OCT2020)	N/N
		Road traffic accident/ Motor vehicle accident (MVA)	1	25SEP2020	11/1	1	No	O	NA	R (25SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Skin abrasion/ SUPERFICIAL ABRAISIONS, dorsal wrist, right.	1	25SEP2020	11/15	1	No	O	NA	R (09OCT2020)	N/N
		Skin abrasion/ SUPERFICIAL ABRAISIONS, dorsal wrists, left	1	25SEP2020	11/15	1	No	O	NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1166 11661078	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	2	18DEC2020	75/C		No	O	NA	UNK	N/N
16-55/ C4591001 1166 11661087	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/1	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1166 11661091	GENRL	Fatigue/ FATIGUE	2	05NOV2020	2/2	1	No	O	NA	R (06NOV2020)	N/N
16-55/ C4591001 1166 11661097	GENRL	Injection site pain/ INJECTION SITE PAIN (POST- INJECTION; EXACT START TIME UNKNOWN)	1	23OCT2020	1/2	2	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1166 11661106	MUSC	Muscle fatigue/ BILATERAL LEG MUSCLE FATIGUE	1	16NOV2020	19/2	1	No	O	NA	R (17NOV2020)	N/N
16-55/ C4591001 1166 11661109	GENRL	Injection site pain/ INJECTION SITE PAIN	2	20NOV2020	2/2	1	Yes		NA	R (21NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1167 11671009	HEPAT	Cholecystitis acute/ Acute Cholecystitis	1	21AUG2020	5/2	3	No	O	NA/TC/TCN	R (22AUG2020)	Y/N	
		Cholelithiasis/ Cholelithiasis	1	21AUG2020	5/2	2	No	O	NA/TCN	RS (22AUG2020)	N/N	
	HEPAT	Hepatitis acute/ Acute hepatitis#	4	25FEB2021	53/C	2	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1167 11671021	INJ&P	Muscle strain/ Back Strain	2	14OCT2020	36/23	1	No	O	NA/TC	R (05NOV2020)	N/N	
16-55/ C4591001 1167 11671036	GENRL	Pyrexia/ fever#	4	19FEB2021	1/2	2	Yes		NA/TC	R (20FEB2021)	N/N	
16-55/ C4591001 1167 11671051	INFEC	Herpes zoster oticus/ Ramsey-Hunt Syndrome	2	05DEC2020	82/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1167 11671065	NERV	Headache/ Headache#	4	06JAN2021	3/1	2	Yes		NA/TC	R (06JAN2021)	N/N	
16-55/ C4591001 1167 11671073	MUSC	Back pain/ Lumbago	2	NOV2020	46/C	2	No	O	NA/TC	RG	N/N	
	INV	Antinuclear antibody positive/ Positive ANA#	4	11JAN2021	5/C	2	No	O	NA	N	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		C-reactive protein increased/ Elevated C Reactive Protein#	4	11JAN2021	5/C	1	No	O	NA	N	N/N
16-55/ C4591001 1167 11671120	INFEC	Cellulitis/ Cellulitis nose	2	27SEP2020	6/21	2	No	O	NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 1167 11671130	METAB	Type 2 diabetes mellitus/ Worsening Type 2 diabetes	1	09SEP2020	7/94	2	No	O	NA/TC	R (11DEC2020)	N/N
	VASC	Hypertension/ Hypertension with microalbumin	1	09SEP2020	7/C	1	No	O	NA/TC	RG	N/N
	GASTR	Nausea/ Nausea	1	22SEP2020	20/1	1	No	CD	NA	R (22SEP2020)	N/N
	GENRL	Chest pain/ Chest pain	1	22SEP2020	20/1	2	No	CD	NA	R (22SEP2020)	N/N
16-55/ C4591001 1167 11671134	GENRL	Pain/ body aches#	4	08FEB2021	1/2	2	Yes		NA/TC	R (09FEB2021)	N/N
		Pyrexia/ fever#	4	08FEB2021	1/2	2	Yes		NA/TC	R (09FEB2021)	N/N
	NERV	Headache/ headache#	4	09FEB2021	2/2	2	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1167 11671175	NERV	Cerebrovascular accident/ Cerebrovascular accident	2	21OCT2020	23/C	3	No	O	NA/TC	RG	Y/N
16-55/ C4591001	GASTR	Nausea/ nausea, not COVID related	1	15AUG2020	3/1	1	No	O	NA	R (15AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1168 11681016 16-55/ C4591001 1168 11681024	SKIN	Urticaria/ HIVES(NECK)	2	22SEP2020	19/5	1	No	CD	NA	R (26SEP2020)	N/N
	GENRL	Peripheral swelling/ swelling in bilateral upper extremities#	3	12JAN2021	8/C	2	No	O	NA	RG	N/N
	MUSC	Arthralgia/ mild bilateral hand joint pain#	3	12JAN2021	8/33	2	No	O	NA/TC/TCN	RS (13FEB2021)	N/N
	MUSC	Arthralgia/ worsening bilateral hand joint pain#	4	14FEB2021	20/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1168 11681054	GENRL	Chills/ chills	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	SKIN	Cold sweat/ cold sweat	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1168 11681073	SKIN	Rash/ upper body rash	2	13SEP2020	3/2	1	Yes		NA/TC	R (14SEP2020)	N/N
	SKIN	Rash/ intermittent upper body rash	2	18SEP2020	8/25	1	Yes		NA	R (12OCT2020)	N/N
16-55/ C4591001 1168 11681105	GENRL	Fatigue/ FATIGUE	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	1	28AUG2020	1/8	1	Yes		NA	R (04SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1168 11681109	MUSC	Myalgia/ MUSCLE ACHES	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Pain in extremity/ Intermittent pain in both feet	1	06SEP2020	10/6	1	No	O	NA	R (11SEP2020)	N/N
	GENRL	Peripheral swelling/ Intermittent Swelling in the L hand	1	09SEP2020	13/3	1	No	O	NA	R (11SEP2020)	N/N
	GENRL	Pyrexia/ Fever	1	03SEP2020	3/2	2	Yes		NA/TC	R (04SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
	GASTR	Nausea/ nausea	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Pyrexia/ low grade fever	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	MUSC	Back pain/ low back pain	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
NERV	Headache/ headache	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1168 11681162	GENRL	Fatigue/ FATIGUE	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1168 11681176	MUSC	Myalgia/ Myalgia	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1168 11681195	GENRL	Chills/ chills	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Pyrexia/ low grade fever	2	14OCT2020	2/3	1	Yes		NA/TC	R (16OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	14OCT2020	2/6	1	Yes		NA/TC	R (19OCT2020)	N/N
16-55/ C4591001 1168 11681198	INFEC	Sinusitis/ SINUS INFECTION	1	27SEP2020	5/8	1	No	O	NA/TC	R (04OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1168 11681207	INFEC	Hordeolum/ Sty left eye	2	14NOV2020	30/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1168 11681210	GENRL	Chills/ chills	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1168 11681213	GENRL	Pain/ body aches	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ fever	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		Chills/ chills	2	15OCT2020	1/3	2	Yes		NA	R (17OCT2020)	N/N
		Pain/ body aches	2	15OCT2020	1/3	2	Yes		NA	R (17OCT2020)	N/N
	NERV	Pyrexia/ fever	2	15OCT2020	1/3	2	Yes		NA	R (17OCT2020)	N/N
		Headache/ headache	2	16OCT2020	2/2	2	Yes		NA	R (17OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1168 11681215	GENRL	Injection site pain/ injection site soreness	1	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Fatigue/ fatigue	1	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ muscle ache	1	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1168 11681217	GENRL	Injection site erythema/ redness at injection site	2	27OCT2020	2/8	1	Yes		NA	R (03NOV2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1168 11681219	MUSC	Injection site pruritus/ itching at the injection site	2	27OCT2020	2/8	1	Yes		NA	R (03NOV2020)	N/N	
		Injection site swelling/ swelling at the injection site	2	27OCT2020	2/8	1	Yes		NA	R (03NOV2020)	N/N	
		Axillary mass/ Lump in L armpit	2	30OCT2020	2/6	1	Yes		NA	R (04NOV2020)	N/N	
16-55/ C4591001 1168 11681231	GENRL	Pain in extremity/ pain in L upper arm	2	30OCT2020	2/4	1	Yes		NA	R (02NOV2020)	N/N	
		Injection site pain/ INJECTION SITE PAIN	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N	
16-55/ C4591001 1169 11691001	GENRL	Injection site pain/ Pain at Injection Site	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/Y	
	NERV	Headache/ Headache	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/Y	
	GENRL	Injection site induration/ Red induration at injection site	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Soreness at injection site	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N	
		Injection site warmth/ Warmth at injection site	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N	
		Headache/ Headache	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N	
		Malaise/ General Malaise	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1169 11691002	RESP	Oropharyngeal pain/ Sore Throat	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	INFEC	Skin infection/ Skin Infection Right Wrist	2	16DEC2020	85/9	1	No	O	NA/TCN	R (24DEC2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
1169 11691007	GENRL	Injection site pain/ Injection Site Pain#	3	06JAN2021	1/2	1	Yes		NA/TC	R (07JAN2021)	N/N
	NERV	Headache/ Headache#	3	06JAN2021	1/2	1	Yes		NA/TC	R (07JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	27JAN2021	1/3	1	Yes		NA/TC	R (29JAN2021)	N/N
		Injection site pain/ Injection site Pain#	4	27JAN2021	1/3	1	Yes		NA/TC	R (29JAN2021)	N/N
	NERV	Headache/ Headache#	4	27JAN2021	1/3	1	Yes		NA/TC	R (29JAN2021)	N/N
16-55/ C4591001	BLOOD	Lymphadenopathy/ Swollen Right Axillary lymph node	1	03SEP2020	1/40	1	Yes		NA	R (12OCT2020)	N/Y
1169 11691010	GENRL	Injection site pain/ Injection Site pain	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/Y
16-55/ C4591001	MUSC	Arthralgia/ Painful Left Knee	1	08SEP2020	6/4	1	No	O	NA/TC	R (11SEP2020)	N/N
1169 11691011											

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1169 11691012	GENRL	Joint swelling/ swelling Left knee	1	08SEP2020	6/4	1	No	O	NA	R (11SEP2020)	N/N
		Injection site pain/ Soreness at injection site	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12OCT2020	21/3	1	No	O	NA	R (14OCT2020)	N/N
	GENRL	Injection site pain/ Arm pain at Injection Site	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Sensation of foreign body/ Globus Sensation of the throat	1	06SEP2020	3/19	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Arm pain at Injection Site	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	16-55/ C4591001 1169 11691017	GENRL	Injection site pain/ Mild Soreness at Injection Site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)
16-55/ C4591001 1169 11691018	GENRL	Injection site pain/ Mild Injection Site pain#	3	08JAN2021	4/2	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Injection site pain/ arm pain at injection site#	3	08JAN2021	1/3	1	Yes		NA/TC	R (10JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	29JAN2021	1/2	1	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	29JAN2021	1/2	1	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Pain/ Generalized Body Aches#	4	29JAN2021	1/2	1	Yes		NA/TC	R (30JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1169 11691019	MUSC	Pain in extremity/ Left Arm pain	2	30SEP2020	1/2	2	Yes		NA/TCN	R (01OCT2020)	N/N
	GENRL	Chills/ Chills	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1169 11691020	GENRL	Injection site pain/ Tenderness at injection site	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site swelling/ Swelling at injection site	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Fatigue/ Fatigue	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
		Injection site pain/ Soreness at Injection Site	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
	NERV	Mental impairment/ Mental Fogginess	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	03OCT2020	3/1	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1169 11691021	GENRL	Fatigue/ Fatigue#	3	30JAN2021	2/3	1	Yes		NA/TC	R (01FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site pain#	3	30JAN2021	2/3	1	Yes		NA/TC	R (01FEB2021)	N/N
		Injection site pain/ Injection Site pain#	4	18FEB2021	1/3	1	Yes		NA/TC	R (20FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1169 11691022	GENRL	Injection site pain/ Mild Injection Site Pain#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
	GENRL	Injection site pain/ Mild injection site pain#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1169 11691023	GENRL	Injection site pain/ Pain at injection site	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Moderate Pain at Injection Site	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
		Injection site swelling/ Mild swelling at Injection site	2	29SEP2020	1/3	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1169 11691024	GENRL	Injection site pain/ Pain at injection site	1	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
		Injection site swelling/ 2 cm swelling at injection site	1	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
		Injection site erythema/ Redness at Injection Site	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
		Injection site pain/ Moderate pain at injection Site	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
		Injection site swelling/ Swelling at Injection Site	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	04JAN2021	1/1	2	Yes		NA	R (04JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1169 11691025	NERV	Somnolence/ Drowsiness#	3	04JAN2021	1/1	2	Yes		NA	R (04JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	25JAN2021	1/3	2	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Chills/ Chills#	4	26JAN2021	2/2	2	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1169 11691026	GASTR	Diarrhoea/ Diarrhea	1	13SEP2020	5/2	1	No	O	NA	R (14SEP2020)	N/N
	GENRL	Injection site pain/ arm soreness at injection site#	3	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
	INJ&P	Foot fracture/ Fractured left foot#	3	18JAN2021	14/C	2	No	O	NA/TCN	N	N/N
16-55/ C4591001 1169 11691027	MUSC	Arthralgia/ Generalized joint aches#	4	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1169 11691029	GENRL	Fatigue/ Fatigue	1	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ Pain at Injection Site	1	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ Tenderness at Injection Site	1	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	1	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1169 11691030	GENRL	Fatigue/ Fatigue	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
		Injection site pain/ Pain at Injection Site	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
		Injection site pain/ Tenderness at Injection site	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
	MUSC	Pain in extremity/ pain in left arm	1	10SEP2020	1/4	1	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Injection site pain/ Moderate Pain at Injection Site	2	01OCT2020	1/4	2	Yes		NA/TC	R (04OCT2020)	N/N
	GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Fatigue/ Fatigue	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ Mild pain at Injection Site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		NERV	Headache/ Headache	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)
16-55/ C4591001 1169 11691033	GENRL	Injection site bruising/ Bruise at Injection Site	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/N
		Injection site pain/ Soreness at Injection Site	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1169 11691036	GENRL	Fatigue/ Fatigue#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N	
		Injection site erythema/ Redness at injection site#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N	
		Injection site pain/ Injection Site Pain#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N	
		Injection site pain/ Tenderness at injection site	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N	
16-55/ C4591001 1169 11691038	GENRL	Injection site pain/ Soreness at Injection site	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain#	3	07JAN2021	1/3	2	Yes		NA/TC	R (09JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	3	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N	
	INFEC	Rhinitis/ Rhinitis#	3	08JAN2021	2/2	2	No	O	NA/TC	R (09JAN2021)	N/N	
	METAB	Decreased appetite/ Decreased Appetite#	3	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N	
	NERV	Headache/ Headache#	3	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N	
	GASTR	Nausea/ Nausea#	4	28JAN2021	1/3	2	Yes		NA/TC	R (30JAN2021)	N/N	
		Vomiting/ Vomiting#	4	28JAN2021	1/3	2	Yes		NA/TC	R (30JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	28JAN2021	1/3	2	Yes		NA/TC	R (30JAN2021)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1169 11691040	NERV	Headache/ Headache#	4	28JAN2021	1/3	2	Yes		NA/TC	R (30JAN2021)	N/N	
	GASTR	Nausea/ Nausea	2	03OCT2020	2/2	2	Yes		NA/TC	R (04OCT2020)	N/N	
	GENRL	Pain/ Body Aches	2	03OCT2020	2/2	2	Yes		NA/TC	R (04OCT2020)	N/N	
16-55/ C4591001 1169 11691041	MUSC	Arthralgia/ Joint Aches	2	03OCT2020	2/2	2	Yes		NA/TC	R (04OCT2020)	N/N	
	GENRL	Injection site pain/ Injection Site Soreness	1	11SEP2020	1/3	1	Yes		NA/TC	R (13SEP2020)	N/N	
	GENRL	Malaise/ General malaise	1	12SEP2020	2/3	1	Yes		NA/TC	R (14SEP2020)	N/N	
16-55/ C4591001 1169 11691043	GENRL	Fatigue/ fatigue	2	03OCT2020	2/3	1	Yes		NA/TC	R (05OCT2020)	N/N	
		Injection site pain/ injection site soreness	2	03OCT2020	2/3	1	Yes		NA/TC	R (05OCT2020)	N/N	
		Malaise/ malaise	2	03OCT2020	2/3	1	Yes		NA/TC	R (05OCT2020)	N/N	
	GENRL	Chills/ Chills	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N	
		Pyrexia/ Fever of 100.7	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1169 11691044	GENRL	Chills/ Chills#	3	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
		Injection site pain/ Mild injection site pain#	3	08JAN2021	1/3	2	Yes		NA/TC	R (10JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Aches#	3	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
		Myalgia/ Muscle Aches#	3	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1169 11691046	GENRL	Injection site pain/ Injection Site Soreness#	2	05JAN2021	92/3	2	Yes		NA	R (07JAN2021)	N/N
		Pain/ Generalized Body Aches#	2	05JAN2021	92/3	2	Yes		NA	R (07JAN2021)	N/N
	BLOOD	Lymph node pain/ Tender Supraclavicular Lymph Node#	3	07JAN2021	3/5	1	Yes		NA	R (11JAN2021)	N/N
	GENRL	Chills/ Chills#	4	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
		Pain/ Generalized body aches#	4	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
16-55/ C4591001 1169 11691047	GENRL	Injection site pain/ Pain at injection site	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ Tenderness at injection site	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1169 11691049	GENRL	Injection site pain/ Pain at Injection Site	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N	
	NERV	Headache/ Headache	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N	
	GENRL	Injection site pain/ Painful Right Arm Injection Site	1	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/N	
			Pyrexia/ Fever	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
	NERV		Headache/ Headache	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL		Chills/ Chills	2	06OCT2020	2/2	2	Yes		NA/TC	R (07OCT2020)	N/N
			Injection site pain/ Injection Site Pain	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1169 11691053		Pyrexia/ Fever	2	06OCT2020	2/2	2	Yes		NA/TC	R (07OCT2020)	N/N	
	MUSC	Myalgia/ Generalized Muscle Aches#	4	26JAN2021	2/2	2	Yes		NA/TC	R (27JAN2021)	N/N	
16-55/ C4591001 1169 11691055	BLOOD	Lymphadenopathy/ Enlarged Left Axillary and subclavicular lymph nodes#	3	06JAN2021	1/4	1	Yes		NA	R (09JAN2021)	N/N	
	NERV	Headache/ Mild Headache#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection Site	2	08OCT2020	1/4	2	Yes		NA/TC	R (11OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1169 11691056		Pyrexia/ Fever of 99.9	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
	SKIN	Onycholysis/ Toenail Onycholysis x3	2	14DEC2020	68/33	2	No	O	NA	R (15JAN2021)	N/N
	BLOOD	Lymphadenopathy/ Enlarged Bilateral Inguinal Lymph Nodes	2	16DEC2020	70/22	2	No	O	NA	R (06JAN2021)	N/N
	GENRL	Peripheral swelling/ Bilateral Lower extremity swelling	2	16DEC2020	70/63	2	No	O	NA/TC	R (16FEB2021)	N/N
	CARD	Tachycardia/ Tachycardia#	2	31DEC2020	85/C	2	No	O	NA/TC	N	N/N
	NERV	Tremor/ Tremors#	2	31DEC2020	85/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1169 11691057	GENRL	Chills/ Chills	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
		Fatigue/ Fatigue	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
		Pain/ Generalized Body Aches	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
		Pyrexia/ Fever	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001	GENRL	Chills/ chills#	3	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1169 11691058		Injection site pain/ pain at injection site#	3	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N	
		Pyrexia/ fever 100.2 F#	3	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N	
	NERV	Headache/ headache#	3	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N	
	NERV	Headache/ Headache#	4	29JAN2021	2/1	1	Yes		NA	R (29JAN2021)	N/N	
16-55/ C4591001 1169 11691059	MUSC	Pain in extremity/ Left Arm Pain	1	18SEP2020	2/6	1	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 1169 11691062	GASTR	Nausea/ Nausea	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N	
	GENRL	Chills/ Chills	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N	
		Pain/ Generalized Body Aches	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N	
	MUSC	Pain in extremity/ Sore Left Arm	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N	
16-55/ C4591001 1169 11691063	INJ&P	Fall/ Fall	2	21DEC2020	77/1	2	No	O	NA	R (21DEC2020)	N/N	
		Ligament sprain/ Right ankle sprain	2	21DEC2020	77/68	2	No	O	NA/TCN	R (26FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1169 11691065	GENRL	Injection site pain/ Injection Site Pain#	3	07JAN2021	2/3	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain	1	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Joint range of motion decreased/ mild range of motion deficit left arm	1	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1169 11691067	GENRL	Injection site pain/ mild pain at injection site	2	09OCT2020	1/3	1	Yes		NA/TC/TCN	R (11OCT2020)	N/N
	MUSC	Joint range of motion decreased/ Limited range of motion in left arm	2	09OCT2020	1/3	1	Yes		NA/TC/TCN	R (11OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	INFEC	Urinary tract infection/ Urinary Tract Infection	2	15OCT2020	7/13	2	No	O	NA/TC	R (27OCT2020)	N/N
	SKIN	Pruritus/ Pruritis	2	29OCT2020	21/13	2	No	O	NA/TC	R (10NOV2020)	N/N
16-55/ C4591001 1169 11691072		Urticaria/ Hives- Entire Body	2	29OCT2020	21/13	2	No	O	NA/TC	R (10NOV2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ Tenderness at injection site	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Chills/ Chills	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1169 11691073†	MUSC	Myalgia/ Myalgia	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N	
	GASTR	Diarrhoea/ Diarrhea	1	08OCT2020	8/1	1	No	O	NA	R (08OCT2020)	N/N	
	GENRL	Injection site pain/ Injection Site Soreness#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N	
	GENRL	Chills/ Chills#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N	
	GENRL	Injection site pain/ Injection Site Pain#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N	
	GENRL	Pyrexia/ Fever#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N	
	MUSC	Arthralgia/ Generalized Joint Pain#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N	
	MUSC	Myalgia/ Generalized Muscle Pain#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N	
16-55/ C4591001 1170 11701003	GENRL	Fatigue/ Fatigue	2	26SEP2020	27/2	1	Yes		NA	R (27SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701006	NERV	Pain/ Body Aches	2	26SEP2020	27/2	1	Yes		NA	R (27SEP2020)	N/N
		Headache/ Headache	2	26SEP2020	27/2	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	19AUG2020	8/1	1	Yes		NA	R (19AUG2020)	N/N
16-55/ C4591001 1170 11701013	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	NOV2020	55/C		No	O	NA/W		N/N
16-55/ C4591001 1170 11701015	GENRL	Injection site pain/ Injection Site Pain#	3	07JAN2021	1/4	1	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1170 11701016	GENRL	Chills/ Chills#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
		Fatigue/ Fatigue#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Injection site pain/ Injection at pain site#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
		Myalgia/ General Muscle pain#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
GENRL	Chills/ chills#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Pyrexia/ fever#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1170 11701018	GENRL	Injection site pain/ Pain at Injection Site#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
16-55/ C4591001 1170 11701020	GENRL	Injection site pain/ Injection Site Pain	1	18AUG2020	2/4	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1170 11701021	GENRL	Injection site pain/ Pain at Injection Site	1	18AUG2020	2/5	1	Yes		NA	R (22AUG2020)	N/N
	NERV	Headache/ Headache	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Injection site swelling/ Injection Site Swelling	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site swelling/ Injection Site Swelling#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001	GENRL	Pain/ Exercise Induced Body Soreness	1	06SEP2020	21/2	1	No	O	NA/TC	R (07SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701022	NERV	Headache/ Headache	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1170 11701024	GENRL	Fatigue/ fatigue	1	23AUG2020	7/2	2	Yes		NA	R (24AUG2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	15DEC2020	1/3	1	Yes		NA	R (17DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	4	05JAN2021	2/1	1	Yes		NA	R (05JAN2021)	N/N
	NERV	Headache/ Headache#	4	05JAN2021	2/1	1	Yes		NA	R (05JAN2021)	N/N
16-55/ C4591001 1170 11701029	GENRL	Injection site erythema/ Injection Site Redness	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N
		Injection site pain/ Injection Site Pain	1	18AUG2020	1/4	1	Yes		NA	R (21AUG2020)	N/N
	NERV	Headache/ Headache	1	18AUG2020	1/2	1	Yes		NA/TC	R (19AUG2020)	N/N
	GENRL	Pyrexia/ Fever	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701031	GENRL	Pyrexia/ Fever	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Chest pain/ Chest Pain	2	10SEP2020	2/2	1	No	O	NA/TC	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
16-55/ C4591001 1170 11701034	NERV	Headache/ headache#	4	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	2	12SEP2020	4/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1170 11701035	MUSC	Pyrexia/ Fever	2	12SEP2020	4/2	1	Yes		NA	R (13SEP2020)	N/N
		Myalgia/ Myalgias	2	12SEP2020	4/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Chills/ Chills#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Injection site pain/ Injection Site Pain#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
		Pyrexia/ Fever#	4	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/N
		Myalgia/ Generalized Muscle Pain#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701036	GENRL	Vomiting/ Vomiting#	4	13JAN2021	2/1	1	Yes		NA	R (13JAN2021)	N/N
		Fatigue/ Fatigue#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
		Malaise/ Malaise#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	2	09SEP2020	1/4	1	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1170 11701040	GENRL	Chills/ Chills#	3	30DEC2020	1/1	1	Yes		NA	R (30DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701041	MUSC	Fatigue/ Fatigue#	3	30DEC2020	1/1	1	Yes		NA	R (30DEC2020)	N/N
		Injection site pain/ Pain at Injection site#	3	30DEC2020	1/1	1	Yes		NA	R (30DEC2020)	N/N
		Pyrexia/ Fever#	3	30DEC2020	1/1	1	Yes		NA	R (30DEC2020)	N/N
		Myalgia/ General Muscle Pain#	3	30DEC2020	1/1	1	Yes		NA	R (30DEC2020)	N/N
	NERV	Headache/ Headache#	3	30DEC2020	1/1	1	Yes		NA	R (30DEC2020)	N/N
	GENRL	Asthenia/ Generalized Weakness#	4	21JAN2021	1/C	1	No	O	NA	RG	N/N
	MUSC	Fatigue/ Fatigue#	4	21JAN2021	1/8	1	Yes		NA	R (28JAN2021)	N/N
		Pyrexia/ Fever#	4	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
		Arthralgia/ Generalized Joint Pain#	4	21JAN2021	1/C	1	Yes		NA	RG	N/N
		Myalgia/ Generalized Muscle Pain#	4	21JAN2021	1/4	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	20AUG2020	2/3	1	Yes		NA	R (22AUG2020)	N/N
GENRL	Chills/ Chills	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N	
	Injection site erythema/ Redness at injection site	2	11SEP2020	2/6	2	Yes		NA	R (16SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701042	MUSC	Injection site pain/ Pain at injection site	2	11SEP2020	2/6	1	Yes		NA	R (16SEP2020)	N/N	
		Myalgia/ Muscle pain	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N	
		Arthralgia/ Sacroiliac joint pain	2	14SEP2020	5/C	1	No	O	NA	RG	N/N	
		Back pain/ Lower Back Pain	2	14SEP2020	5/C	1	No	O	NA	RG	N/N	
		Muscular weakness/ Bilateral Lower Extremity Weakness	2	14SEP2020	5/C	1	No	O	NA	RG	N/N	
		Myalgia/ Bilateral Lower Extremity Myalgia	2	14SEP2020	5/C	1	No	O	NA	RG	N/N	
	GENRL	Fatigue/ Fatigue	1	20AUG2020	1/	1	Yes		NA	R	N/N	
	NERV	Headache/ Headache	1	20AUG2020	1/	2	Yes		NA	R	N/N	
	GASTR	Diarrhoea/ Diarrhea#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N	
		Injection site pain/ Injection Site Pain#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N	
		Injection site swelling/ Injection Site Swelling#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N	
	MUSC	Pyrexia/ Fever#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N	
	Myalgia/ Generalized Muscle Pain#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N		

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701043	NERV	Headache/ Headache#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N
	GENRL	Chills/ Chills#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
		Fatigue/ Fatigue#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	05FEB2021	1/30	1	Yes		NA	R (06MAR2021)	N/N
		Pyrexia/ fever#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	MUSC	Myalgia/ General Muscle Pain#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	NERV	Headache/ headache#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ Headache	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	16-55/ C4591001 1170 11701044	GENRL	Injection site pain/ Injection Site Pain	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)
GENRL	Fatigue/ Fatigue	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N	
GENRL	Injection site pain/ Injection Site Pain	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N	
GENRL	Fatigue/ Fatigue	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701045	SKIN	Rash pruritic/ Itchy Pink Rash (bilateral forearms, upper back, top of head at forehead and scalp)	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	21AUG2020	2/3	1	Yes		NA	R (23AUG2020)	N/N
		Injection site erythema/ Redness at injection site	1	21AUG2020	2/3	1	Yes		NA	R (23AUG2020)	N/N
		Injection site swelling/ Swelling at injection site	1	21AUG2020	2/3	1	Yes		NA	R (23AUG2020)	N/N
16-55/ C4591001 1170 11701047		Pyrexia/ Fever	1	21AUG2020	2/3	1	Yes		NA	R (23AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		Pyrexia/ Fever	2	12SEP2020	2/2	2	Yes		NA/TC	R (13SEP2020)	N/N
MUSC	Myalgia/ Myalgias	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N	
NERV	Headache/ Headache	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701049	GENRL	Chills/ Chills	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
		Fatigue/ Fatigue	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
		Pyrexia/ Fever	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ Headache	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1170 11701052	GENRL	Injection site pain/ Injection Site Soreness#	3	17DEC2020	2/1	2	Yes		NA	R (17DEC2020)	N/N
	NERV	Headache/ headache#	3	17DEC2020	2/1	1	Yes		NA	R (17DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
		Injection site erythema/ Injection Site Redness#	4	06JAN2021	2/1	1	Yes		NA	R (06JAN2021)	N/N
		Pyrexia/ Fever#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
	NERV	Headache/ Headache#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain#	3	15JAN2021	2/3	1	Yes		NA	R (17JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701054	GENRL	Injection site erythema/ Injection Site Redness#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1170 11701055	GENRL	Injection site pain/ Injection Site Pain	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1170 11701057	GENRL	Injection site pain/ Injection Site Pain	1	21AUG2020	1/3	2	Yes		NA/TC	R (23AUG2020)	N/N
		Pyrexia/ Fever	1	21AUG2020	1/2	2	Yes		NA	R (22AUG2020)	N/N
16-55/ C4591001 1170 11701059	GENRL	Fatigue/ Fatigue#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Pyrexia/ Fever#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1170 11701060	GENRL	Injection site pain/ Injection Site Pain#	3	07JAN2021	1/3	2	Yes		NA	R (09JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701063	GENRL	Injection site pain/ Pain at injection site#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Injection site swelling/ Swelling at injection site#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ Pain at Injection Site	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1170 11701064	GENRL	Chills/ Chills	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	16DEC2020	1/3	1	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1170 11701065	GENRL	Fatigue/ Fatigue	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1170 11701069	GENRL	Myalgia/ Myalgias	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
		Chills/ Chills	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N
		Fatigue/ Fatigue	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701072	MUSC	Injection site pain/ Injection Site Pain	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N
		Pyrexia/ Fever	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N
		Myalgia/ Muscle Pain	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
	MUSC	Myalgia/ Generalize Muscle Pain#	3	19DEC2020	2/1	1	Yes		NA	R (19DEC2020)	N/N
	NERV	Headache/ Headache#	3	19DEC2020	2/1	1	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1170 11701073	GENRL	Injection site pain/ Injection Site Pain	1	26AUG2020	2/4	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1170 11701074	GENRL	Injection site pain/ Injection Site Pain	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Pyrexia/ Fever#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Chills/ Chills#	3	13JAN2021	2/1	1	Yes		NA	R (13JAN2021)	N/N
		Fatigue/ Fatigue#	3	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	3	13JAN2021	2/1	1	Yes		NA	R (13JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701075	GENRL	Chills/ Chills#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
		Fatigue/ Fatigue#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ Fever#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
		Fatigue/ Fatigue	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Injection site pain/ Injection Site Soreness	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
		Pyrexia/ Fever	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N
		Headache/ Headache	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N
		Fatigue/ Fatigue	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1170 11701079	GENRL	Injection site pain/ Injection Site Pain	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		Myalgia/ Muscle Pain	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
	MUSC	Fatigue/ Fatigue	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1170 11701085		Injection site pain/ Injection Site Pain	1	26AUG2020	1/3	2	Yes		NA	R (28AUG2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N	
		Injection site pain/ Pain at Injection Site	2	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N	
		Pyrexia/ Fever	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N	
	MUSC	Myalgia/ Muscle Pain	2	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N	
	NERV	Headache/ Headache	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001 1170 11701086	GENRL	Chills/ Chills#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N	
		Injection site pain/ Pain at injection site#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N	
16-55/ C4591001 1170 11701087	GENRL	Injection site erythema/ Injection Site Redness	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
		Injection site pain/ Injection Site Pain	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001 1170 11701089	GENRL	Pyrexia/ Fever	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701091	GENRL	Chills/ Chills	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Fatigue/ Fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Injection site erythema/ Injection Site Redness	2	17SEP2020	2/8	1	Yes		NA	R (24SEP2020)	N/N
		Injection site swelling/ Injection Site Swelling	2	17SEP2020	2/8	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1170 11701092	GENRL	Injection site pain/ Injection Site Pain#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1170 11701093	GENRL	Injection site pain/ Pain at Injection Site	1	26AUG2020	1/2	1	Yes		NA/TC	R (27AUG2020)	N/N
	MUSC	Injection site swelling/ Swelling at Injection Site	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
		Myalgia/ Generalized Muscle Pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701094	GENRL	Injection site pain/ Pain at Injection Site	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
		Injection site swelling/ Injection Site Swelling	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
		MUSC	Myalgia/ Generalized Muscle Pain	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		NERV	Headache/ Headache	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		Chills/ Chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	
16-55/ C4591001 1170 11701095	GENRL	Injection site pain/ Pain at Injection Site	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	
		Chills/ Chills#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N	
	MUSC	Fatigue/ Fatigue#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N	
		Injection site pain/ Injection Site Pain#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N	
		Pyrexia/ Fever#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N	
		Arthralgia/ Generalized Joint Pain#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N	
		Myalgia/ Generalized Muscle Pain#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N	
NERV	Headache/ Headache#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N		



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701096	GENRL	Chills/ chills#	4	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N	
	NERV	Headache/ Headache#	4	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N	
	MUSC	Myalgia/ Myalgias	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N	
	NERV	Headache/ Headache	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N	
	GENRL	Pyrexia/ Fever	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N	
16-55/ C4591001 1170 11701097	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	1/4	1	Yes		NA	R (21DEC2020)	N/N	
16-55/ C4591001 1170 11701098	GENRL	Chills/ Chills#	4	06JAN2021	1/2	1	Yes		NA/TC	R (07JAN2021)	N/N	
	MUSC	Myalgia/ General Muscle Pain#	4	06JAN2021	1/2	1	Yes		NA/TC	R (07JAN2021)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	4	07JAN2021	2/4	2	Yes		NA/TC	R (10JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N	
	MUSC	Myalgia/ Generalized Muscle Pain#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine Subject	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701099	GENRL	Injection site pain/ Pain at Injection Site	1	27AUG2020	1/3	1	Yes	NA		R (29AUG2020)	N/N
1170 11701101	GENRL	Injection site pain/ Pain at Injection Site	2	17SEP2020	1/3	1	Yes	NA		R (19SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/2	1	Yes	NA		R (19SEP2020)	N/N
	NERV	Headache/ Headache	2	18SEP2020	2/2	1	Yes	NA		R (19SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/1	1	Yes	NA		R (18SEP2020)	N/N
1170 11701102	NERV	Headache/ Headache	2	18SEP2020	2/1	1	Yes	NA		R (18SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	18JAN2021	1/3	1	Yes	NA		R (20JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	08FEB2021	1/3	1	Yes	NA		R (10FEB2021)	N/N
	GENRL	Chills/ Chills#	4	09FEB2021	2/2	1	Yes	NA		R (10FEB2021)	N/N
		Fatigue/ Fatigue#	4	09FEB2021	2/2	1	Yes	NA		R (10FEB2021)	N/N
	MUSC	Myalgia/ General Muscle Pain#	4	09FEB2021	2/2	1	Yes	NA		R (10FEB2021)	N/N
16-55/ C4591001	GASTR	Nausea/ Nausea	2	15SEP2020	1/2	1	Yes	NA/TC		R (16SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1170 11701103	GENRL	Chills/ Chills	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N	
		Malaise/ Malaise	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N	
		Pyrexia/ Fever	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N	
	MUSC	Myalgia/ Myalgias	2	16SEP2020	2/2	1	Yes		NA/TC	R (17SEP2020)	N/N	
	NERV	Headache/ Headache	2	16SEP2020	2/2	1	Yes		NA/TC	R (17SEP2020)	N/N	
16-55/ C4591001 1170 11701104	GENRL	Injection site pain/ Pain at Injection Site	1	27AUG2020	1/1	1	Yes		NA	R (27AUG2020)	N/N	
	MUSC	Myalgia/ Generalized Muscle Pain#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N	
16-55/ C4591001 1170 11701105	GENRL	Injection site pain/ Pain at Injection Site	1	28AUG2020	2/4	1	Yes		NA	R (31AUG2020)	N/N	
	GENRL	Chills/ Chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	
		Fatigue/ Fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	
		Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	
	MUSC	Arthralgia/ Generalized Joint Pain	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701106	NERV	Myalgia/ Myalgias	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Headache/ Headache	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ Pain at Injection Site	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ Fever	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Myalgia/ Generalized Muscle Pain	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1170 11701107	NERV	Headache/ Headache	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Chills/ Chills#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Chills/ Chills#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701108	NERV	Malaise/ Malaise#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		Pain/ Body Aches#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		Headache/ Headache	1	01SEP2020	6/2	1	Yes		NA	R (02SEP2020)	N/N
		Pyrexia/ Fever#	3	05JAN2021	2/1	1	Yes		NA	R (05JAN2021)	N/N
16-55/ C4591001 1170 11701111	GENRL	Fatigue/ Fatigue#	4	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	27AUG2020	1/3	2	Yes		NA	R (29AUG2020)	N/N
	GENRL	Pyrexia/ Fever	1	28AUG2020	2/2	2	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1170 11701112	GENRL	Injection site pain/ Injection Site Pain	2	18SEP2020	1/2	2	Yes		NA/TC	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
	IMMUN	Drug hypersensitivity/ Allergic Reaction to Lisinopril	1	15SEP2020	19/2	3	No	O	NA/TC	R (16SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site swelling/ Injection Site Swelling	2	17OCT2020	2/3	1	Yes		NA	R (19OCT2020)	N/N
	GENRL	Chills/ Chills#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701115	MUSC	Myalgia/ Generalized Muscle Pain#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1170 11701116	GENRL	Fatigue/ Fatigue	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1170 11701117	MUSC	Myalgia/ Muscle Pain Generalized	1	28AUG2020	1/2	1	Yes		NA/TC	R (29AUG2020)	N/N
16-55/ C4591001 1170 11701117	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
16-55/ C4591001 1170 11701119	GENRL	Injection site pain/ Injection Site Pain#	4	06JAN2021	1/4	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Chills/ Chills#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
		Fatigue/ Fatigue#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
	NERV	Headache/ Headache#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1170 11701119	GENRL	Injection site pain/ Injection Site Pain#	3	28DEC2020	1/2	1	Yes		NA	R (29DEC2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at Injection Site	1	28AUG2020	1/2	2	Yes		NA/TC	R (29AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701120	MUSC	Myalgia/ Generalized Muscle Pain	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site erythema/ Injection Site Redness	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		Injection site swelling/ Injection Site Swelling	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001	NERV	Headache/ Headache	2	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N
1170 11701121	GENRL	Injection site pain/ Injection Site Pain#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
	NERV	Headache/ Headache#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
	INJ&P	Fall/ Fall#	4	22JAN2021	3/1	2	No	O	NA	R (22JAN2021)	N/N
		Lower limb fracture/ Right Lower Extremity Fracture#	4	22JAN2021	3/C	3	No	O	NA/TCN	RG	Y/N
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	1/2	2	Yes		NA	R (29AUG2020)	N/N
1170 11701122											

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701123	NERV	Headache/ Headache	1	28AUG2020	1/2	2	Yes		NA	R (29AUG2020)	N/N
	GENRL	Chills/ Chills	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Injection site pain/ Injection Pain Site	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Pyrexia/ Fever	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ Headache	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Chills/ Chills	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Fatigue/ Fatigue	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ Fever	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
METAB	Decreased appetite/ Poor Appetite	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N	
MUSC	Myalgia/ Myalgias	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
NERV	Hypoaesthesia/ Numbness In Toes	2	21SEP2020	6/2	1	Yes		NA	R (22SEP2020)	N/N	
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701125	GENRL	Chills/ Chills	1	28AUG2020	1/1	1	Yes	NA	NA	R (28AUG2020)	N/N
16-55/ C4591001 1170 11701126	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	1/8	1	Yes	NA	NA	R (04SEP2020)	N/N
	GENRL	Chills/ Chills	2	17SEP2020	1/2	1	Yes	NA	NA	R (18SEP2020)	N/N
		Fatigue/ Fatigue	2	17SEP2020	1/2	1	Yes	NA	NA	R (18SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	17SEP2020	1/8	1	Yes	NA	NA	R (24SEP2020)	N/N
16-55/ C4591001 1170 11701127	GENRL	Fatigue/ Fatigue#	3	18DEC2020	1/2	1	Yes	NA	NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	18DEC2020	1/2	1	Yes	NA	NA	R (19DEC2020)	N/N
	GENRL	Chills/ Chills#	4	07JAN2021	2/1	1	Yes	NA	NA	R (07JAN2021)	N/N
		Fatigue/ Fatigue#	4	07JAN2021	2/1	1	Yes	NA	NA	R (07JAN2021)	N/N
16-55/ C4591001 1170 11701128	GENRL	Fatigue/ Fatigue	2	18SEP2020	1/3	1	Yes	NA	NA	R (20SEP2020)	N/N
	GENRL	Chills/ Chills	2	19SEP2020	2/2	1	Yes	NA	NA	R (20SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701129	MUSC	Pyrexia/ Fever	2	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N
		Myalgia/ Myalgias	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ Injection Pain Site	2	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1170 11701131	GENRL	Chills/ Chills	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
16-55/ C4591001 1170 11701136	GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
		Chills/ Chills	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1170 11701137	GENRL	Fatigue/ Fatigue#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
		Injection site swelling/ Injection Site Swelling#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1170 11701137	GENRL	Injection site pain/ Injection Site Pain#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701138	GENRL	Fatigue/ Fatigue#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
	BLOOD	Lymph node pain/ Right Axillary Lymph Node Tenderness#	4	08JAN2021	3/2	1	Yes		NA/TC	R (09JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	1	31AUG2020	1/3	2	Yes		NA	R (02SEP2020)	N/N
		Injection site erythema/ Injection Site Redness	1	31AUG2020	1/8	1	Yes		NA	R (07SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	31AUG2020	1/4	2	Yes		NA/TC	R (03SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	1	01SEP2020	2/1	2	Yes		NA	R (01SEP2020)	N/N
	NERV	Headache/ Headache	1	02SEP2020	3/6	2	Yes		NA	R (07SEP2020)	N/N
	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		Fatigue/ Fatigue	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	NERV	Headache/ Headache	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701139		Injection site pain/ pain at injection site#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	GASTR	Nausea/ nausea#	3	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	GENRL	Chills/ Chills#	3	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	MUSC	Myalgia/ General Muscle Pain#	3	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	NERV	Headache/ Headache#	3	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1170 11701143	GENRL	Fatigue/ Fatigue	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
	NERV	Headache/ Headache	1	01SEP2020	2/2	2	Yes		NA/TC	R (02SEP2020)	N/N
	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Injection site erythema/ Injection Site Redness	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701144	GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
	GASTR	Gingival pain/ Gum Tingling Pain	1	04SEP2020	5/1	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	INFEC	Sinusitis/ Sinus Infection	2	02OCT2020	12/8	2	No	O	NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1170 11701145	GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Pain/ Body Aches	2	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Pain in extremity/ Arm Pain	2	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1170 11701146	GENRL	Injection site pain/ Pain at injection site	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701149	GENRL	Fatigue/ Fatigue#	3	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N	
		Injection site pain/ Injection Site Pain#	3	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N	
		Pyrexia/ Fever#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N	
	NERV	Headache/ Headache#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	
		Injection site pain/ injection at pain site#	4	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N	
	NERV	Headache/ headaches#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	
16-55/ C4591001 1170 11701150	GENRL	Fatigue/ Fatigue#	3	18DEC2020	1/4	1	Yes		NA	R (21DEC2020)	N/N	
		Injection site pain/ Injection Site Pain#	3	18DEC2020	1/4	1	Yes		NA	R (21DEC2020)	N/N	
	MUSC	Arthralgia/ Generalized Joint Pain#	3	18DEC2020	1/4	1	Yes		NA	R (21DEC2020)	N/N	
	GENRL	Chills/ Chills#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N	
		Pyrexia/ Fever#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N	
	NERV	Headache/ Headache#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701151	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Chills/ Chills	2	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
		Fatigue/ Fatigue	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1170 11701152	GENRL	Fatigue/ Fatigue#	3	23DEC2020	2/3	1	Yes		NA	R (25DEC2020)	N/N
	NERV	Headache/ headache#	3	23DEC2020	2/3	1	Yes		NA	R (25DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	18JAN2021	7/4	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1170 11701153	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1170 11701154	GENRL	Injection site pain/ pain at injection site#	3	29JAN2021	2/1	1	Yes		NA	R (29JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701156	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1170 11701158	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/1	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1170 11701159	GENRL	Fatigue/ Fatigue	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1170 11701163	EYE	Blepharitis/ Blepharitis of the left eye	1	15SEP2020	15/70	1	No	O	NA/TC	R (23NOV2020)	N/N
	GENRL	Chills/ Chills#	3	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
		Injection site pain/ Injection Site Soreness#	3	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
		Pyrexia/ Fever#	3	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701165	GENRL	Chills/ Chills#	4	01FEB2021	1/2	1	Yes	NA	NA	R (02FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	01FEB2021	1/5	1	Yes	NA	NA	R (05FEB2021)	N/N
		Pyrexia/ Fever#	4	01FEB2021	1/2	1	Yes	NA	NA	R (02FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	02FEB2021	2/1	1	Yes	NA	NA	R (02FEB2021)	N/N
	MUSC	Myalgia/ General Muscle Pain#	4	02FEB2021	2/1	1	Yes	NA	NA	R (02FEB2021)	N/N
	NERV	Headache/ Headache#	4	02FEB2021	2/1	1	Yes	NA	NA	R (02FEB2021)	N/N
	GENRL	Injection site pruritus/ Injection Site Itching#	4	06FEB2021	6/2	1	Yes	NA	NA	R (07FEB2021)	N/N
		Chills/ Chills	1	01SEP2020	1/2	1	Yes	NA	NA	R (02SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes	NA	NA	R (03SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	24SEP2020	1/5	1	Yes	NA	NA	R (28SEP2020)	N/N
	Arthralgia/ Joint Pain	2	24SEP2020	1/2	1	Yes	NA	NA	R (25SEP2020)	N/N	
	Myalgia/ Muscle Pain	2	24SEP2020	1/2	1	Yes	NA	NA	R (25SEP2020)	N/N	
16-55/ C4591001 1170 11701166	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes	NA	NA	R (03SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701167	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Chills/ Chills	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
		Fatigue/ Fatigue	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
		Pyrexia/ Fever	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Chills/ Chills	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1170 11701174	GENRL	Fatigue/ Fatigue	1	03SEP2020	2/4	1	Yes		NA/TC	R (06SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	03SEP2020	2/4	1	Yes		NA	R (06SEP2020)	N/N
		Injection site pain/ Injection Site Soreness	1	03SEP2020	2/4	2	Yes		NA/TC	R (06SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Arthralgia/ General Joint Pain	1	03SEP2020	2/4	1	Yes		NA	R (06SEP2020)	N/N	
		Myalgia/ Myalgias	1	03SEP2020	2/4	1	Yes		NA/TC	R (06SEP2020)	N/N	
	NERV	Headache/ Headache	1	03SEP2020	2/4	1	Yes		NA/TC	R (06SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/44	2	Yes		NA/TC	R (06NOV2020)	N/N	
		Injection site pain/ Injection Site Pain	2	24SEP2020	2/25	2	Yes		NA/TC	R (18OCT2020)	N/N	
	MUSC	Myalgia/ Myalgias	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N	
	NERV	Headache/ Headache	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N	
	EYE	Vision blurred/ Blurry Vision	2	30SEP2020	8/38	1	No	O	NA/TC	R (06NOV2020)	N/N	
	NERV	Headache/ Headache	2	30SEP2020	8/38	1	No	O	NA/TC	R (06NOV2020)	N/N	
	VASC	Hypertension/ High Blood Pressure	2	30SEP2020	8/38	1	No	O	NA/TC	R (06NOV2020)	N/N	
16-55/ C4591001 1170 11701178	GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1170 11701179	GASTR	Diarrhoea/ Diarrhea	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		Injection site erythema/ Injection Site Redness	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		Malaise/ Malaise	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	NERV	Headache/ Headache	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Chills/ Chills#	4	09FEB2021	1/1	1	Yes		NA	R (09FEB2021)	N/N
		Fatigue/ Fatigue#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1170 11701180	GENRL	Injection site pain/ Pain at injection site#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Chills/ Chills#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
		Fatigue/ Fatigue#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1170 11701181	GENRL	Injection site pain/ Pain at injection site#	3	28DEC2020	1/2	1	Yes		NA	R (29DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701182	GENRL	Chills/ chills#	4	19JAN2021	2/1	1	Yes		NA	R (19JAN2021)	N/N	
		Fatigue/ fatigue#	4	19JAN2021	2/1	1	Yes		NA	R (19JAN2021)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N	
	NERV	Headache/ Headache	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N	
		Pyrexia/ Fever	2	23SEP2020	1/3	2	Yes		NA/TC	R (25SEP2020)	N/N	
	MUSC	Myalgia/ General Muscle Pain	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N	
	NERV	Headache/ Headache	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N	
	16-55/ C4591001 1170 11701183	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	16-55/ C4591001 1170 11701187	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	Fatigue/ Fatigue	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N		
	Injection site pain/ Injection Site Pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N		

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701190	GENRL	Malaise/ Malaise	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		Fatigue/ Fatigue	1	03SEP2020	1/2	2	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1170 11701191	NERV	Headache/ Headache	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1170 11701192	MUSC	Myalgia/ General Muscle Soreness#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1170 11701192	GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1170 11701193	GENRL	Chills/ Chills	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Malaise/ Malaise	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701195	MUSC	Injection site pain/ Injection Site Pain	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N	
		Myalgia/ General Muscle Pain	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N	
		Chills/ Chills#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N	
	MUSC	Fatigue/ Fatigue#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N	
		Pyrexia/ Fever#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N	
		Myalgia/ Myalgias#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N	
16-55/ C4591001 1170 11701196	GENRL	Fatigue/ Fatigue#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N	
16-55/ C4591001 1170 11701199	NERV	Headache/ Headache#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
	MUSC	Myalgia/ Generalized Muscle Pain	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701203	GENRL	Fatigue/ Fatigue#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1170 11701204	GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1170 11701205	GENRL	Chills/ Chills	1	05SEP2020	3/1	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1170 11701206	GENRL	Chills/ Chills	2	21SEP2020	1/4	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1170 11701207	GENRL	Injection site pain/ Injection Site Pain	1	04SEP2020	1/1	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1170 11701208	GENRL	Injection site pain/ Pain at injection site#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1170 11701207	GENRL	Injection site erythema/ Injection site Redness	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1170 11701207	GENRL	Injection site pain/ Pain at injection Site	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1170 11701208	GENRL	Injection site pain/ Pain at injection site#	3	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701209	GENRL	Injection site pain/ Injection Site Pain	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1170 11701210	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1170 11701211	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Injection site swelling/ Injection Site Swelling	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Pyrexia/ Fever	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1170 11701213	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/6	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	2	29SEP2020	1/5	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1170 11701215	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Fatigue/ Fatigue	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	
16-55/ C4591001 1170 11701221	NERV	Headache/ Headache	2	01OCT2020	3/2	1	Yes		NA	R (02OCT2020)	N/N	
16-55/ C4591001 1170 11701222	NERV	Dysgeusia/ Metallic Taste	1	22SEP2020	15/8	1	No	O	NA	R (29SEP2020)	N/N	
	NERV	Headache/ Headache	1	25SEP2020	18/1	1	No	O	NA	R (25SEP2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/4	1	Yes		NA	R (11FEB2021)	N/N	
16-55/ C4591001 1170 11701223	GENRL	Injection site pain/ Injection Site Pain#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N	
16-55/ C4591001 1170 11701225	GENRL	Pyrexia/ Fever	2	02OCT2020	4/2	1	Yes		NA	R (03OCT2020)	N/N	
16-55/ C4591001 1170 11701226	GENRL	Fatigue/ Fatigue	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
	NERV	Headache/ Headache	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701227	GENRL	Injection site pain/ Injection Site Pain	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1170 11701228	MUSC	Injection site swelling/ Injection Site Swelling	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1170 11701228	GENRL	Injection site pain/ Injection Pain	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1170 11701229	GENRL	Injection site pain/ Injection Site Pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1170 11701229	GASTR	Diarrhoea/ Diarrhea	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Chills/ Chills	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701230		Fatigue/ Fatigue	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1170 11701232	GENRL	Chills/ Chills	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		Fatigue/ Fatigue	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1170 11701233	NERV	Headache/ Headache	1	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1170 11701234	GENRL	Injection site pain/ Injection Site Pain	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	11/4	1	Yes		NA	R (25FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701235	NERV	Headache/ Headache	1	12SEP2020	4/8	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	28DEC2020	1/2	1	Yes		NA	R (29DEC2020)	N/N
	NERV	Headache/ Headache#	3	28DEC2020	1/3	1	Yes		NA	R (30DEC2020)	N/N
	GENRL	Chills/ Chills#	4	19JAN2021	2/3	1	Yes		NA	R (21JAN2021)	N/N
		Injection site pain/ Pain at injection site#	4	19JAN2021	2/3	1	Yes		NA	R (21JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	4	19JAN2021	2/3	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1170 11701236	GENRL	Injection site pain/ Pain at injection site	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1170 11701237	GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		Fatigue/ Fatigue	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ Pain at Injection Site	2	30SEP2020	1/2	3	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001	NERV	Headache/ Headache	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701241	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1170 11701243	GENRL	Injection site pain/ Injection Site Pain#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Chills/ Chills#	3	11FEB2021	22/2	1	Yes		NA	R (12FEB2021)	N/N
		Fatigue/ Fatigue#	3	11FEB2021	22/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1170 11701244	GENRL	Injection site pain/ Injection Site Pain	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Myalgia/ Generalized Muscle Pain	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Chills/ Chills	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		Fatigue/ Fatigue	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		Injection site pain/ Pain at injection site	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701245	GENRL	Fatigue/ Fatigue	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Chills/ Chills	2	02OCT2020	1/1	1	Yes		NA	R (02OCT2020)	N/N
		Injection site erythema/ Redness at injection site	2	02OCT2020	1/4	1	Yes		NA	R (05OCT2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	02OCT2020	1/1	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1170 11701249	GENRL	Chills/ Chills#	3	01FEB2021	1/1	1	Yes		NA	R (01FEB2021)	N/N
		Fatigue/ Fatigue#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1170 11701250	GENRL	Chills/ Chills#	4	04FEB2021	2/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1170 11701252	GENRL	Injection site pain/ Injection Site Pain	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701253	GENRL	Fatigue/ Fatigue#	4	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1170 11701256	GENRL	Injection site pain/ Pain at injection site#	3	15DEC2020	1/2	1	Yes		NA	R (16DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	4	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N
		Myalgia/ Myalgias#	4	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N
16-55/ C4591001 1170 11701257	GENRL	Fatigue/ Fatigue	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
		Injection site pain/ Pain at injection site	2	30SEP2020	1/37	2	Yes		NA	R (05NOV2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
		Myalgia/ Muscle Pain	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701258	GENRL	Injection site pain/ Pain at injection site	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1170 11701259	GENRL	Injection site pain/ Injection Site Pain#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1170 11701260	GENRL	Injection site pain/ Injection Site Pain#	3	21JAN2021	1/4	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1170 11701261	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ Headache	1	11SEP2020	2/4	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	NERV	Headache/ Headache	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1170 11701262	GENRL	Injection site pain/ Pain at injection site#	4	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1170 11701263	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701264	GENRL	Fatigue/ Fatigue	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	13JAN2021	1/1	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1170 11701268		Injection site pain/ Injection Site Pain#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		Myalgia/ Generalized Muscle Pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Chills/ Chills	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Fatigue/ Fatigue	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Injection site pain/ Pain at Injection Site	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Myalgia/ Muscle Pain	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701269	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/2	1	Yes	NA	R	(11SEP2020)	N/N
		Chills/ Chills	2	01OCT2020	1/2	1	Yes	NA/TC	R	(02OCT2020)	N/N
		Injection site erythema/ Redness at Injection Site	2	01OCT2020	1/2	1	Yes	NA	R	(02OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	01OCT2020	1/2	1	Yes	NA/TC	R	(02OCT2020)	N/N
		Pyrexia/ Fever	2	01OCT2020	1/2	1	Yes	NA/TC	R	(02OCT2020)	N/N
	NERV	Headache/ Headache	2	01OCT2020	1/2	1	Yes	NA/TC	R	(02OCT2020)	N/N
16-55/ C4591001 1170 11701271	GENRL	Fatigue/ Fatigue#	3	13JAN2021	2/2	1	Yes	NA	R	(14JAN2021)	N/N
16-55/ C4591001 1170 11701274	GASTR	Nausea/ Nausea#	4	07JAN2021	1/2	1	Yes	NA	R	(08JAN2021)	N/N
	GENRL	Vomiting/ Vomiting#	4	07JAN2021	1/2	1	Yes	NA	R	(08JAN2021)	N/N
		Chills/ Chills#	4	07JAN2021	1/2	1	Yes	NA	R	(08JAN2021)	N/N
		Fatigue/ Fatigue#	4	07JAN2021	1/8	1	Yes	NA	R	(14JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	07JAN2021	1/3	1	Yes	NA	R	(09JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701279	MUSC	Pyrexia/ Fever#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
		Myalgia/ Myalgias#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
		Headache/ Headache#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
	GASTR	Abdominal pain/ Abdominal Cramps#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N	
		Diarrhoea/ Diarrhea#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N	
GENRL		Injection site pain/ Injection Site Pain	1	10SEP2020	1/4	1	Yes		NA	R (13SEP2020)	N/N	
16-55/ C4591001 1170 11701280	GENRL	Pyrexia/ Fever	1	11SEP2020	2/3	1	Yes		NA/TC	R (13SEP2020)	N/N	
	GENRL	Chills/ Chills#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N	
		Injection site erythema/ Injection Site Redness#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N	
	NERV	Injection site pain/ Injection Site Pain#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N	
		Pyrexia/ Fever#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N	
		Headache/ Headache#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N	
	GENRL		Fatigue/ Fatigue#	3	30DEC2020	2/2	1	Yes		NA	R (31DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701281	GENRL	Injection site pain/ Injection Site Soreness#	3	30DEC2020	2/2	1	Yes		NA	R (31DEC2020)	N/N
		Fatigue/ Fatigue#	4	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Sore (Left Arm)	1	11SEP2020	2/3	2	Yes		NA	R (13SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	12SEP2020	3/4	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	12SEP2020	3/4	1	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ Headache	1	12SEP2020	3/4	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1170 11701283	GENRL	Injection site erythema/ Injection Site Redness	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
		Chills/ Chills#	3	28DEC2020	1/3	1	Yes		NA	R (30DEC2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	3	28DEC2020	1/3	1	Yes		NA	R (30DEC2020)	N/N
	NERV	Myalgia/ Muscle pain#	3	28DEC2020	1/3	1	Yes		NA	R (30DEC2020)	N/N
Headache/ Headache#		3	28DEC2020	1/3	1	Yes		NA	R (30DEC2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/4	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1170 11701285	NERV	Headache/ Headache	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N	
16-55/ C4591001 1170 11701286	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N	
16-55/ C4591001 1170 11701287	GENRL	Injection site pain/ Injection Site Pain#	4	14JAN2021	1/3	1	Yes		NA	R (16JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N	
16-55/ C4591001 1170 11701289	NERV	Headache/ Headache	1	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N	
	GENRL	Chills/ Chills#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N	
		Fatigue/ Fatigue#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N	
16-55/ C4591001 1170 11701290	GENRL	Injection site pain/ Pain at injection site	2	05OCT2020	1/1	1	Yes		NA	R (05OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701291	GENRL	Chills/ Chills	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
		Fatigue/ Fatigue	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
	NERV	Headache/ Headache	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ Headache	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		Injection site pain/ Left Arm Injection Site Pain	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		Pain/ Body Aches	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1170 11701293	GENRL	Fatigue/ Fatigue	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001	NERV	Headache/ Headache#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701297	NERV	Headache/ Headache#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1170 11701298	GENRL	Injection site pain/ Injection Site Pain#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1170 11701300	GENRL	Injection site pain/ Injection Site Pain	1	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1170 11701303	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain Generalized	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ Headache	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		Injection site pain/ Pain at Injection site	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
	NERV	Headache/ Headache	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701304	GENRL	Injection site pain/ Pain at Injection Site	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1170 11701306	GENRL	Injection site pain/ Pain at injection site#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	22DEC2020	2/1	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	13JAN2021	2/2	2	Yes		NA/TC	R (14JAN2021)	N/N
	MUSC	Muscular weakness/ Left arm weakness#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1170 11701307	GENRL	Injection site pain/ Injection Site Pain	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	26SEP2020	16/3	1	Yes		NA	R (28SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
	MUSC	Myalgia/ General Muscle Pain	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		Pain in extremity/ Left Arm Pain	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1170 11701308	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1170 11701310	GENRL	Injection site pain/ Injection Site Pain	1	15SEP2020	2/4	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1170 11701312	NERV	Headache/ Headache	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1170 11701313	GENRL	Injection site pain/ Injection Site Pain	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
		Injection site swelling/ Injection Site Swelling	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Chills/ Chills	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701314	GENRL	Fatigue/ Fatigue	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N	
		Chills/ Chills	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N	
		Injection site pain/ Pain at Injection Site	2	05OCT2020	1/4	1	Yes		NA	R (08OCT2020)	N/N	
		Pyrexia/ Fever	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N	
	NERV	Headache/ Headache	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N	
16-55/ C4591001 1170 11701316	GENRL	Chills/ Chills#	4	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N	
	NERV	Headache/ Headache#	4	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N	
	GASTR	Nausea/ Nausea	1	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N	
	MUSC	Pyrexia/ Fever	1	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N	
		Myalgia/ Myalgias	1	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701317	GENRL	Chills/ Chills	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N	
		Pyrexia/ Fever	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N	
	MUSC	Myalgia/ Muscle Pain	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N	
		GASTR	Dysphagia/ Difficulty Swallowing	1	15SEP2020	1/5	1	Yes		NA	R (19SEP2020)	N/N
	GENRL		Eructation/ Burping	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site#	3	04JAN2021	1/4	1	Yes		NA	R (07JAN2021)	N/N
	GENRL		Pyrexia/ Fever#	3	04JAN2021	1/1	1	Yes		NA	R (04JAN2021)	N/N
		GENRL	Chills/ chills#	4	25JAN2021	1/4	1	Yes		NA	R (28JAN2021)	N/N
	GENRL		Fatigue/ fatigue#	4	25JAN2021	1/4	1	Yes		NA	R (28JAN2021)	N/N
		GENRL	Pyrexia/ fever#	4	25JAN2021	1/4	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1170 11701318	GENRL		Chills/ Chills	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
		Fatigue/ Fatigue	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N	
		Injection site erythema/ Injection Site Redness	1	15SEP2020	1/6	1	Yes		NA	R (20SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Injection site pain/ Pain Injection Site	1	15SEP2020	1/5	1	Yes		NA	R (19SEP2020)	N/N
		Injection site swelling/ Injection Site Swelling	1	15SEP2020	1/6	1	Yes		NA	R (20SEP2020)	N/N
		Pyrexia/ Fever	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
		Myalgia/ Muscle Pain	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ Headache	1	18SEP2020	4/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	2	06OCT2020	1/33	1	Yes		NA	R (07NOV2020)	N/N
		Fatigue/ Fatigue	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Injection site erythema/ Redness at Injection Site	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		Injection site pain/ Pain at Injection Site	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		Injection site swelling/ Swelling at Injection Site	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		Pyrexia/ Fever	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Myalgia/ Muscle Pain	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ Headache	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701319	NERV	Headache/ Headache#	3	17DEC2020	1/1	1	Yes		NA	R (17DEC2020)	N/N	
		Paraesthesia/ Tingling in left and right hand#	3	17DEC2020	1/1	1	Yes		NA	R (17DEC2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	2/2	1	Yes		NA	R (19DEC2020)	N/N	
	INFEC	Ear infection/ Ear Infection#	3	03JAN2021	18/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1170 11701320	GENRL	Injection site pain/ Pain at injection site#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N	
	GASTR	Diarrhoea/ Diarrhea	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	16SEP2020	2/3	1	Yes		NA/TC	R (18SEP2020)	N/N	
	MUSC	Myalgia/ Myalgias	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	
	NERV	Headache/ Headache	1	16SEP2020	2/3	1	Yes		NA/TC	R (18SEP2020)	N/N	
	GENRL	Injection site erythema/ Redness at injection site	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N	
		Pyrexia/ Fever#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N	
	MUSC	Myalgia/ Generalized Muscle Pain#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701321	NERV	Headache/ Headache#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N	
		Injection site pain/ Pain at injection site#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N	
	MUSC	Myalgia/ General Muscle Pain#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N	
		Injection site pain/ Pain at injection site	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N	
	16-55/ C4591001 1170 11701322	GENRL	Chills/ Chills	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		Fatigue/ Fatigue	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N	
		Injection site pain/ Injection Site Pain	1	15SEP2020	1/5	1	Yes		NA	R (19SEP2020)	N/N	
	NERV	Headache/ Headache	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001 1170 11701321	GENRL	Fatigue/ Fatigue	2	06OCT2020	1/4	1	Yes		NA/TC	R (09OCT2020)	N/N	
		Pyrexia/ Fever	2	06OCT2020	1/3	1	Yes		NA/TC	R (08OCT2020)	N/N	
	MUSC	Myalgia/ Myalgias	2	06OCT2020	1/4	1	Yes		NA/TC	R (09OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701323	NERV	Headache/ Headache	2	06OCT2020	1/4	1	Yes		NA/TC	R (09OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	17OCT2020	12/2	1	No	O	NA	R (18OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1170 11701324		Injection site pain/ Pain at injection site#	3	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Chills/ Chills#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
		Pyrexia/ Fever#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1170 11701325†	MUSC	Myalgia/ Myalgias#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
	NERV	Headache/ headache#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Injection site erythema/ Injection Site Redness	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1170 11701334†		Injection site pain/ Injection Site Pain	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701337	GENRL	Injection site pain/ Injection Site Pain	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1170 11701338	GENRL	Chills/ Chills	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
	MUSC	Myalgia/ General Muscle Pain	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
	NERV	Headache/ Headache	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Chills/ Chills#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
		Fatigue/ Fatigue#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
		Injection site pain/ Pain at Injection Site#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	MUSC	Myalgia/ Muscle Pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Chills/ Chills#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Fatigue/ Fatigue#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
	MUSC	Myalgia/ General Muscle Pain#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701340	NERV	Headache/ Headache	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Chills/ Chills	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Fatigue/ Fatigue	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	1	19SEP2020	3/4	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1170 11701341	GENRL	Injection site pain/ Pain at injection site#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N
	EYE	Conjunctival haemorrhage/ subconjunctival hemorrhage of right eye#	3	18DEC2020	3/21	1	No	O	NA	R (07JAN2021)	N/N
16-55/ C4591001 1170 11701342	PSYCH	Attention deficit hyperactivity disorder/ Attention Deficit Hyperactivity Disorder	2	OCT2020	1/C	1	No	O	NA/TC	RG	N/N
	GENRL	Chills/ Chills#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Fatigue/ Fatigue#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ Headache#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701343		Injection site pain/ Injection Site Pain	1	18SEP2020	2/3	1	Yes		NA/TC	R (20SEP2020)	N/N
	GENRL	Injection site erythema/ Injection site redness	2	08OCT2020	1/15	1	Yes		NA/TC	R (22OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Chills/ Chills	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
		Injection site pain/ Injection at Pain Site	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
	GASTR	Vomiting/ vomiting	2	10OCT2020	3/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1170 11701346	GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	2/3	1	Yes		NA	R (25JAN2021)	N/N
16-55/ C4591001 1170 11701348	GENRL	Injection site pain/ Injection Site Pain	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1170 11701352†	GENRL	Chills/ Chills	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701355†	MUSC	Myalgia/ Muscle Pain	1	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	28DEC2020	1/3	1	Yes		NA	R (30DEC2020)	N/N
	GENRL	Chills/ Chills#	4	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
		Fatigue/ Fatigue#	4	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
	NERV	Headache/ Headache#	4	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
16-55/ C4591001 1170 11701358	GENRL	Injection site pain/ Injection Site Pain	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	MUSC	Muscle spasms/ Muscle Spasms	1	07OCT2020	17/34	1	Yes		NA	R (09NOV2020)	N/N
	NERV	Dizziness/ Dizziness	2	16OCT2020	5/5	1	No	O	NA	R (20OCT2020)	N/N
	EYE	Glaucoma/ Glaucoma	2	NOV2020	21/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1170 11701359	GENRL	Fatigue/ Fatigue	1	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1170 11701360	GENRL	Injection site pain/ Injection Site Pain#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701362	GENRL	Injection site pain/ Pain at injection site#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Chills/ Chills	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
	MUSC	Myalgia/ General Muscle Pain	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
	INJ&P	Maternal exposure during breast feeding/ EXPOSURE DURING BREASTFEEDING	1	22SEP2020	1/C	1	No	O	NA	N	N/N
	GASTR	Diarrhoea/ Diarrhea	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Chills/ Chills#	4	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
	NERV	Headache/ Headache#	4	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1170 11701372	MUSC	Myalgia/ Muscle Pain	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache Pain	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Chills/ Chills#	3	16DEC2020	1/1	1	Yes		NA	R (16DEC2020)	N/N
		Fatigue/ Fatigue#	3	16DEC2020	1/1	1	Yes		NA	R (16DEC2020)	N/N
		Injection site pain/ Injection site pain#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N
	GENRL	Chills/ Chills#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
		Injection site swelling/ Injection Site Swelling on Finger#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
		Injection site swelling/ Injection Site Swelling on Hand#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
		Injection site swelling/ Injection Site Swelling on Wrist#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
16-55/ C4591001 1170 11701373	GENRL	Injection site pain/ Injection Site Pain	1	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Chills/ Chills	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
		Fatigue/ Fatigue	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701375	GENRL	Injection site pain/ Injection Site Pain	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Chills/ Chills#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
		Injection site pain/ pain at injection site#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
		Injection site swelling/ Swelling at injection site#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
	MUSC	Myalgia/ Muscle Pain#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
		Injection site pain/ Pain at injection site#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
		Injection site swelling/ Injection site swelling#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
	NERV	Dizziness/ Dizziness#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
		Headache/ headache#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
	GENRL	Chills/ Chills#	4	09JAN2021	2/3	1	Yes		NA	R (11JAN2021)	N/N
		Pyrexia/ Fever#	4	09JAN2021	2/3	1	Yes		NA	R (11JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	09JAN2021	2/3	1	Yes		NA	R (11JAN2021)	N/N
	16-55/ C4591001	GENRL	Chills/ Chills	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1170 11701376		Pyrexia/ Fever	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N	
	VASC	Hypertension/ Hypertension	2	25NOV2020	16/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1170 11701378	GENRL	Chills/ Chills	2	10NOV2020	1/1	1	Yes		NA	R (10NOV2020)	N/N	
	NERV	Headache/ Headache	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N	
16-55/ C4591001 1170 11701379	GENRL	Injection site pain/ Injection Site Pain	2	11NOV2020	1/1	1	Yes		NA	R (11NOV2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain#	3	22JAN2021	1/4	1	Yes		NA	R (25JAN2021)	N/N	
16-55/ C4591001 1170 11701380	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
	MUSC	Myalgia/ General Muscle Pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
	NERV	Headache/ Headache#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
16-55/ C4591001 1170 11701381	GENRL	Fatigue/ Fatigue	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701382	GENRL	Injection site pain/ Pain at injection site.	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
		Fatigue/ Fatigue	2	11NOV2020	2/3	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1170 11701383	GENRL	Injection site pain/ Injection Site Pain#	4	06JAN2021	1/4	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1170 11701383	GENRL	Injection site pain/ Injection Site Pain	1	20OCT2020	1/3	2	Yes		NA/TC	R (22OCT2020)	N/N
		Injection site swelling/ Injection Site Swelling	1	20OCT2020	1/3	2	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1170 11701384	NERV	Dysgeusia/ Metallic Taste in Mouth	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
		Pyrexia/ Fever	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1170 11701384	MUSC	Myalgia/ Myalgias	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
		Chills/ Chills	2	10NOV2020	1/3	2	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1170 11701384	GENRL	Fatigue/ Fatigue	2	10NOV2020	1/8	1	Yes		NA	R (17NOV2020)	N/N
		Pyrexia/ Fever	2	10NOV2020	1/3	2	Yes		NA/TC	R (12NOV2020)	N/N
		Myalgia/ Myalgias	2	10NOV2020	1/3	2	Yes		NA/TC	R (12NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701385†	NERV	Headache/ Headache	2	10NOV2020	1/3	2	Yes		NA/TC	R (12NOV2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Chills/ Chills#	4	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/N
		Fatigue/ Fatigue#	4	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1170 11701387	GENRL	Pyrexia/ Fever#	4	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	22DEC2020	1/3	1	Yes		NA	R (24DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1170 11701388	GENRL	Chills/ Chills#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Chills/ Chills	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701390	MUSC	Injection site pain/ Pain in Injection Site	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N	
		Injection site swelling/ Injection Site Swelling	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N	
		Myalgia/ Generalized Muscle Pain	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N	
	NERV		Dysgeusia/ Strange taste in mouth	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N
	GENRL		Injection site pain/ Injection Site Pain	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N
	GENRL		Chills/ Chills	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N
			Fatigue/ Fatigue	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N
			Pyrexia/ Fever	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N
	MUSC		Myalgia/ General Muscle Pain	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N
	GENRL		Fatigue/ Fatigue	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
			Injection site pain/ Pain at Injection Site	1	20OCT2020	1/4	1	Yes		NA	R (23OCT2020)	N/N
	NERV		Headache/ Headache	1	20OCT2020	1/4	1	Yes		NA	R (23OCT2020)	N/N
	GENRL		Chills/ Chills	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
			Fatigue/ Fatigue	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701391	MUSC	Pyrexia/ Fever	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
		Myalgia/ Myalgias	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
	MUSC	Muscle spasms/ Back Spasm	2	15NOV2020	7/2	2	No	O	NA/TC	R (16NOV2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	15DEC2020	1/2	1	Yes		NA	R (16DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	05JAN2021	2/1	1	Yes		NA	R (05JAN2021)	N/N
16-55/ C4591001 1170 11701392	GENRL	Fatigue/ Fatigue	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	MUSC	Injection site pain/ Injection Site Pain	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
		Pyrexia/ Fever	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1170 11701393	MUSC	Myalgia/ Myalgias	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	NERV	Headache/ Headache	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	CARD	Palpitations/ Palpitations	2	15NOV2020	5/2	1	No	O	NA/TC	R (16NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	15NOV2020	5/2	1	Yes		NA	R (16NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701394†	PSYCH	Anxiety/ Anxiety	2	15NOV2020	5/2	1	No	O	NA	R (16NOV2020)	N/N
	GENRL	Chills/ Chills#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
		Fatigue/ Fatigue#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ Fever#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	MUSC	Myalgia/ Muscle Pain	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	11NOV2020	1/1	1	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1170 11701397	GENRL	Injection site pain/ Pain at injection site#	3	29JAN2021	2/1	1	Yes		NA	R (29JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701398	GENRL	Fatigue/ Fatigue	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
		Injection site pain/ Pain at injection site	1	21OCT2020	1/4	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1170 11701399	GENRL	Injection site pain/ Injection Site Pain#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1170 11701400	GENRL	Injection site pain/ Pain at injection site	1	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
	NERV	Headache/ Headache	1	21OCT2020	1/1	1	Yes		NA	R (21OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	13NOV2020	3/2	1	Yes		NA	R (14NOV2020)	N/N
		Pyrexia/ Fever	2	13NOV2020	3/2	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ Headache	2	13NOV2020	3/2	1	Yes		NA	R (14NOV2020)	N/N
	VASC	Flushing/ Facial Flushing	2	13NOV2020	3/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1170 11701403	GENRL	Chills/ Chills	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
		Injection site pain/ Injection Site Pain	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	1	21OCT2020	1/1	1	Yes		NA	R (21OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
	MUSC	Muscle twitching/ Muscle Twitching	2	11NOV2020	1/2	1	No	O	NA	R (12NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	18JAN2021	1/4	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	3	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	3	19JAN2021	2/1	1	Yes		NA	R (19JAN2021)	N/N
	NERV	Headache/ Headache#	3	19JAN2021	2/1	1	Yes		NA	R (19JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
		Pyrexia/ fever#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
	MUSC	Myalgia/ General Muscle Pain#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ headache#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1170 11701404	GENRL	Chills/ Chills	1	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
		Injection site pain/ Injection Site Pain	1	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	1	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701405	GENRL	Fatigue/ Fatigue	1	22OCT2020	2/3	1	Yes		NA/TC	R (24OCT2020)	N/N
		Injection site erythema/ Injection Site Redness	1	22OCT2020	2/3	1	Yes		NA/TC	R (24OCT2020)	N/N
		Injection site swelling/ Injection Site Swelling	1	22OCT2020	2/3	1	Yes		NA/TC	R (24OCT2020)	N/N
		Pyrexia/ Fever	1	22OCT2020	2/3	1	Yes		NA/TC	R (24OCT2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain	1	22OCT2020	2/3	1	Yes		NA/TC	R (24OCT2020)	N/N
	NERV	Headache/ Headache	1	22OCT2020	2/3	1	Yes		NA/TC	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	23NOV2020	1/4	1	Yes		NA	R (26NOV2020)	N/N
	GENRL	Chills/ Chills	2	24NOV2020	2/2	1	Yes		NA	R (25NOV2020)	N/N
		Fatigue/ Fatigue	2	24NOV2020	2/2	1	Yes		NA	R (25NOV2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	24NOV2020	2/2	1	Yes		NA	R (25NOV2020)	N/N
	NERV	Headache/ Headache	2	24NOV2020	2/2	1	Yes		NA	R (25NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12NOV2020	1/1	1	Yes		NA	R (12NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	12NOV2020	1/1	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701406	GENRL	Fatigue/ Fatigue#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Injection site swelling/ Injection Site Swelling#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1170 11701407	MUSC	Myalgia/ General Muscle Pain#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
		Chills/ Chills	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
	MUSC	Pyrexia/ Fever	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
		Myalgia/ Generalized Muscle Pain	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
		NERV	Headache/ Headache	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)
16-55/ C4591001 1170 11701408†	GENRL	Chills/ Chills	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
		Fatigue/ Fatigue	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701411	MUSC	Pyrexia/ Fever	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
		Arthralgia/ Generalized Joint Pain	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
		Myalgia/ Muscle Pain	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ Headache	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	28DEC2020	1/2	1	Yes		NA	R (29DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	MUSC	Pyrexia/ Fever#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
Myalgia/ General Muscle Pain#		4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N	
NERV		Headache/ Headache#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
GENRL		Injection site pain/ Pain at Injection Site	1	21OCT2020	1/4	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1170 11701413	GENRL	Chills/ Chills	2	11NOV2020	1/1	1	Yes		NA	R (11NOV2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	11NOV2020	1/1	1	Yes		NA	R (11NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701414	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N	
	GASTR	Nausea/ Nausea#	4	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N	
	GENRL		Chills/ Chills#	4	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
			Fatigue/ Fatigue#	4	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
			Pyrexia/ Fever#	4	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	4	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N	
16-55/ C4591001 1170 11701416	GENRL	Fatigue/ Fatigue	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N	
	GENRL		Injection site erythema/ Redness at injection site	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
			Fatigue/ Fatigue	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain	2	11NOV2020	1/1	1	Yes		NA	R (11NOV2020)	N/N	
	GENRL	Chills/ Chills	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N	
	GENRL		Chills/ Chills#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
			Fatigue/ Fatigue#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701418	MUSC	Injection site pain/ Pain at injection site#	3	18JAN2021	1/5	1	Yes		NA	R (22JAN2021)	N/N
		Pyrexia/ Fever#	3	18JAN2021	1/	1	Yes		NA	R	N/N
		Arthralgia/ Generalized Joint Pain#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
		Fatigue/ Fatigue	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1170 11701420	GENRL	Injection site erythema/ Injection Site Redness	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
		Injection site swelling/ Injection Site Swelling	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
		Injection site pain/ Pain at injection site#	3	27JAN2021	1/5	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1170 11701421	GENRL	Fatigue/ Fatigue	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1170 11701422†	GENRL	Injection site pain/ Pain @ injection site	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
		Fatigue/ Fatigue	2	09NOV2020	1/1	1	Yes		NA	R (09NOV2020)	N/N
		Injection site pain/ Pain at injection site	2	09NOV2020	1/1	1	Yes		NA	R (09NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701423	GENRL	Injection site pain/ Injection Site Pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
	NERV	Headache/ Headache#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1170 11701424	GENRL	Injection site pain/ Pain at injection site.	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Chills/ Chills	2	10NOV2020	1/1	1	Yes		NA	R (10NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11NOV2020	2/1	1	Yes		NA	R (11NOV2020)	N/N
	NERV	Headache/ Headache	2	11NOV2020	2/1	1	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1170 11701425	GENRL	Injection site pain/ Pain at Injection#	3	15DEC2020	1/3	1	Yes		NA	R (17DEC2020)	N/N
	GENRL	Chills/ Chills#	4	05JAN2021	2/1	1	Yes		NA	R (05JAN2021)	N/N
		Fatigue/ Fatigue#	4	05JAN2021	2/1	1	Yes		NA	R (05JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	05JAN2021	2/1	2	Yes		NA	R (05JAN2021)	N/N
		Pyrexia/ Fever#	4	05JAN2021	2/1	2	Yes		NA	R (05JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701426	MUSC	Arthralgia/ Generalized Joint Pain#	4	05JAN2021	2/1	1	Yes		NA	R (05JAN2021)	N/N
	NERV	Headache/ Headache#	4	05JAN2021	2/1	2	Yes		NA	R (05JAN2021)	N/N
	GENRL	Chills/ Chills	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
	MUSC	Myalgia/ General Muscle Pain	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
	NERV	Headache/ Headache	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1170 11701428	NERV	Headache/ Headache	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
	GASTR	Nausea/ Nausea	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Chills/ Chills	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
		Fatigue/ Fatigue	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	12NOV2020	2/5	1	Yes		NA	R (16NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701429	MUSC	Pyrexia/ Fever	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
		Arthralgia/ Generalized Joint Pain	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
		Myalgia/ Myalgias	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Injection site pain/ Injection at pain site#	4	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N
	NERV	Headache/ Headache#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Injection site erythema/ Injection Site Redness	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site erythema/ Injection site redness	2	11NOV2020	1/7	1	Yes		NA	R (17NOV2020)	N/N
	GENRL	Injection site pain/ Injection Pain	2	11NOV2020	1/7	2	Yes		NA	R (17NOV2020)	N/N
16-55/ C4591001 1170 11701430	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701431	GENRL	Injection site pain/ Pain at injection site#	3	17DEC2020	1/1	1	Yes		NA	R (17DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1170 11701432	GENRL	Injection site pain/ Pain injection site	2	13NOV2020	1/5	1	Yes		NA/TC	R (17NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	13NOV2020	1/2	1	Yes		NA/TC	R (14NOV2020)	N/N
	NERV	Headache/ Headache	2	13NOV2020	1/2	1	Yes		NA/TC	R (14NOV2020)	N/N
16-55/ C4591001 1170 11701433	GENRL	Fatigue/ Fatigue	2	14NOV2020	2/1	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	14NOV2020	2/1	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1170 11701434	GENRL	Fatigue/ Fatigue	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Chills/ Chills#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
		Fatigue/ fatigue#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701435	NERV	Injection site pain/ Pain at injection site#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
		Pyrexia/ fever#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
		Headache/ Headache#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
	MUSC	Myalgia/ Muscle Pain	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10NOV2020	1/8	2	Yes		NA	R (17NOV2020)	N/N
16-55/ C4591001 1170 11701436	GENRL	Injection site pain/ Pain at injection site	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	12NOV2020	1/1	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1170 11701437	GENRL	Injection site pain/ Injection Site Pain#	3	04JAN2021	1/3	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Injection site erythema/ Injection Site Redness	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
		Injection site swelling/ Injection Site Swelling	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
GENRL	Injection site pain/ Pain at Injection Site	2	13NOV2020	1/1	1	Yes		NA	R (13NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701438	MUSC	Arthralgia/ Joint Pain	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N	
	GENRL	Fatigue/ Fatigue#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
			Injection site erythema/ Injection Site Redness#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Chills/ Chills#	4	28JAN2021	1/1	1	Yes		NA	R (28JAN2021)	N/N	
			Fatigue/ Fatigue#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N	
	GENRL	Injection site pain/ Injection Site Pain#	4	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N	
16-55/ C4591001 1170 11701439	GENRL	Chills/ Chills#	3	16DEC2020	2/2	1	Yes		NA	R (17DEC2020)	N/N	
		Fatigue/ Fatigue#	3	16DEC2020	2/2	1	Yes		NA	R (17DEC2020)	N/N	
	MUSC	Arthralgia/ Generalized Joint Pain#	3	16DEC2020	2/2	1	Yes		NA	R (17DEC2020)	N/N	
		Myalgia/ Myalgias#	3	16DEC2020	2/2	1	Yes		NA	R (17DEC2020)	N/N	
	GENRL	Chills/ Chills#	4	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701440	MUSC	Pyrexia/ Fever#	4	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/N	
		Arthralgia/ Joint Pain#	4	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/N	
		Myalgia/ Myalgias#	4	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	3	17DEC2020	2/1	1	Yes		NA	R (17DEC2020)	N/N	
	MUSC	Injection site pain/ Injection Site Pain#	3	17DEC2020	2/1	1	Yes		NA	R (17DEC2020)	N/N	
		Injection site swelling/ Injection Site Swelling#	3	17DEC2020	2/4	1	Yes		NA	R (20DEC2020)	N/N	
		Myalgia/ Generalized Muscle Pain#	3	17DEC2020	2/1	1	Yes		NA	R (17DEC2020)	N/N	
		NERV	Headache/ headache#	3	17DEC2020	2/1	1	Yes		NA	R (17DEC2020)	N/N
		GENRL	Fatigue/ Fatigue#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
		NERV	Injection site swelling/ Injection Site Swelling#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
Headache/ Headache#			4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N	
16-55/ C4591001 1170 11701442	GENRL	Chills/ Chills	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N	
		Fatigue/ Fatigue	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701443	MUSC	Injection site pain/ Injection Site Pain	2	13NOV2020	2/2	2	Yes		NA	R (14NOV2020)	N/N
		Myalgia/ Myalgias	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	23OCT2020	1/4	1	Yes		NA	R (26OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Injection site pain/ Pain Injection Site	2	12NOV2020	1/4	1	Yes		NA	R (15NOV2020)	N/N
		Myalgia/ Muscle Pain	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1170 11701444	GENRL	Injection site pain/ Pain at injection site	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
	MUSC	Myalgia/ Muscle Pain	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	13NOV2020	1/3	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Chills/ Chills	2	13NOV2020	1/3	1	Yes		NA	R (15NOV2020)	N/N
		Fatigue/ Fatigue	2	13NOV2020	1/3	1	Yes		NA	R (15NOV2020)	N/N
		Injection site pain/ Pain at Injection Site	2	13NOV2020	1/3	1	Yes		NA	R (15NOV2020)	N/N
		Malaise/ Malaise	2	13NOV2020	1/3	1	Yes		NA	R (15NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701445	MUSC	Myalgia/ Myalgias	2	13NOV2020	1/3	1	Yes		NA	R (15NOV2020)	N/N
	NERV	Headache/ Headache	2	13NOV2020	1/3	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	16DEC2020	1/3	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	3	17DEC2020	2/2	1	Yes		NA	R (18DEC2020)	N/N
	MUSC	Myalgia/ Myalgias#	3	17DEC2020	2/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Chills/ Chills#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1170 11701446	MUSC	Pyrexia/ Fever#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Pyrexia/ Fever#	3	18DEC2020	1/1	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Pyrexia/ fever#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701447	GENRL	Fatigue/ Fatigue	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
		Injection site pain/ Pain at Injection Site	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Chills/ Chills	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
		Fatigue/ Fatigue	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1170 11701449	MUSC	Myalgia/ Generalized Muscle Pain	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
		Fatigue/ Fatigue#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1170 11701450	BLOOD	Lymph node pain/ Left Axillary Lymph node Pain	1	12NOV2020	18/2	1	No	O	NA	R (13NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	13NOV2020	1/1	1	Yes		NA	R (13NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	13NOV2020	1/1	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	26OCT2020	1/5	1	Yes		NA	R (30OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701451	GENRL	Injection site swelling/ Injection Site Swelling	1	26OCT2020	1/4	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1170 11701452	GASTR	Nausea/ Nausea	2	13NOV2020	1/3	2	Yes		NA	R (15NOV2020)	N/N
		Vomiting/ Vomiting	2	13NOV2020	1/3	2	Yes		NA	R (15NOV2020)	N/N
	GENRL	Chills/ Chills	2	13NOV2020	1/3	2	Yes		NA	R (15NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	13NOV2020	1/5	2	Yes		NA	R (17NOV2020)	N/N
		Injection site swelling/ Injection Site Swelling	2	13NOV2020	1/5	1	Yes		NA	R (17NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	14NOV2020	2/2	2	Yes		NA	R (15NOV2020)	N/N
		Pyrexia/ Fever	2	14NOV2020	2/2	2	Yes		NA	R (15NOV2020)	N/N
	SKIN	Night sweats/ Night Sweats	2	14NOV2020	2/2	2	Yes		NA	R (15NOV2020)	N/N
16-55/ C4591001 1170 11701453	GENRL	Injection site pain/ Injection Site Pain#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
	REPRO	Sexual dysfunction/ Sexual Dysfunction#	3	20DEC2020	3/5	1	No	O	NA	R (24DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701455	GENRL	Fatigue/ Fatigue#	3	15JAN2021	1/1	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N
	GENRL	Chills/ Chills#	4	04FEB2021	2/3	1	Yes		NA	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	4	04FEB2021	2/34	1	Yes		NA	R (09MAR2021)	N/N
16-55/ C4591001 1170 11701456†	GENRL	Injection site erythema/ Redness at injection site	1	02NOV2020	8/1	1	Yes		NA	R (02NOV2020)	N/N
		Injection site swelling/ Swelling at injection site	1	02NOV2020	8/1	1	Yes		NA	R (02NOV2020)	N/N
16-55/ C4591001 1170 11701457†	GENRL	Chills/ Chills	2	16NOV2020	1/5	1	Yes		NA	R (20NOV2020)	N/N
		Fatigue/ Fatigue	2	16NOV2020	1/7	1	Yes		NA	R (22NOV2020)	N/N
		Injection site pain/ Injection site pain	2	16NOV2020	1/5	1	Yes		NA	R (20NOV2020)	N/N
		Pyrexia/ Fever	2	16NOV2020	1/5	1	Yes		NA	R (20NOV2020)	N/N
	MUSC	Myalgia/ General Muscle pain	2	16NOV2020	1/5	1	Yes		NA	R (20NOV2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain#	3	17DEC2020	1/5	1	Yes		NA	R (21DEC2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701458	GENRL	Chills/ Chills#	3	18DEC2020	2/3	1	Yes		NA	R (20DEC2020)	N/N
		Fatigue/ Fatigue#	3	18DEC2020	2/3	1	Yes		NA/TC	R (20DEC2020)	N/N
	NERV	Headache/ Headache#	3	18DEC2020	2/3	1	Yes		NA	R (20DEC2020)	N/N
	INFEC	Localised infection/ Right Pinky Infection#	3	25DEC2020	9/34	2	No	O	NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1170 11701460	GENRL	Injection site pain/ Pain at Injection Site	2	16NOV2020	1/2	1	Yes		NA	R (17NOV2020)	N/N
16-55/ C4591001 1170 11701461	GENRL	Fatigue/ Fatigue#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
	NERV	Headache/ Headache#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1170 11701463†	GENRL	Chills/ Chills	2	17NOV2020	2/2	2	Yes		NA	R (18NOV2020)	N/N
		Pyrexia/ Fever	2	17NOV2020	2/2	2	Yes		NA	R (18NOV2020)	N/N
	MUSC	Myalgia/ Myalgias	2	17NOV2020	2/3	1	Yes		NA	R (19NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701464	NERV	Headache/ Headache	2	17NOV2020	2/3	1	Yes		NA	R (19NOV2020)	N/N	
	GENRL	Chills/ Chills#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N	
		Fatigue/ Fatigue#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N	
		Injection site pain/ Pain at injection site#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N	
		Pyrexia/ Fever#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N	
	MUSC	Myalgia/ General Muscle Pain#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N	
	NERV	Headache/ Headache#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N	
	GENRL	Pain/ Body Aches#	4	23FEB2021	2/2	2	Yes		NA	R (24FEB2021)	N/N	
16-55/ C4591001 1170 11701465		Pyrexia/ Fever#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N	
	NERV	Headache/ Headache#	4	23FEB2021	2/7	2	Yes		NA	R (01MAR2021)	N/N	
	GENRL	Fatigue/ Fatigue	1	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N	
		Pyrexia/ Fever	1	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701466	GENRL	Pyrexia/ Fever	2	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N
		Injection site pain/ Pain at injection site#	3	26JAN2021	2/4	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Chills/ Chills#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
		Fatigue/ Fatigue#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	22FEB2021	1/2	2	Yes		NA/TC	R (23FEB2021)	N/N
		Injection site pain/ Pain at injection site	1	26OCT2020	1/4	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Chills/ Chills	1	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
	MUSC	Fatigue/ Fatigue	1	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
		Myalgia/ Muscle Pain	1	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Chills/ Chills	2	16NOV2020	1/3	2	Yes		NA/TC	R (18NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	17NOV2020	2/2	2	Yes		NA/TC	R (18NOV2020)	N/N
	MUSC	Injection site pain/ Injection Site Pain	2	17NOV2020	2/2	2	Yes		NA/TC	R (18NOV2020)	N/N
		Pyrexia/ Fever	2	17NOV2020	2/2	2	Yes		NA/TC	R (18NOV2020)	N/N
		Myalgia/ Myalgias	2	17NOV2020	2/2	2	Yes		NA/TC	R (18NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701467	GENRL	Chills/ Chills	2	17NOV2020	2/2	2	Yes		NA/TC	R (18NOV2020)	N/N	
		Fatigue/ Fatigue	2	17NOV2020	2/2	1	Yes		NA/TC	R (18NOV2020)	N/N	
		Pyrexia/ Fever	2	17NOV2020	2/2	2	Yes		NA/TC	R (18NOV2020)	N/N	
	MUSC	Myalgia/ Myalgias	2	17NOV2020	2/2	1	Yes		NA/TC	R (18NOV2020)	N/N	
	NERV	Headache/ Headache	2	17NOV2020	2/2	1	Yes		NA/TC	R (18NOV2020)	N/N	
16-55/ C4591001 1170 11701468	GENRL	Injection site pain/ Pain at injection site#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N	
16-55/ C4591001 1170 11701469	GASTR	Diarrhoea/ Diarrhea	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N	
	GENRL	Chills/ Chills	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N	
		Fatigue/ Fatigue	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N	
		Injection site pain/ Pain Injection Site	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N	
	MUSC	Pyrexia/ Fever	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N	
		Arthralgia/ generalized joint pain	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701470	NERV	Myalgia/ Muscle Pain	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N
		Headache/ Headache	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	GASTR	Nausea/ Nausea#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	MUSC	Myalgia/ General Muscle Pain#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	NERV	Dizziness/ Dizziness#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1170 11701471	GENRL	Headache/ Headache#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
		Injection site pain/ Pain at Injection Site	1	28OCT2020	2/3	1	Yes		NA	R (30OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	18NOV2020	1/3	1	Yes		NA	R (20NOV2020)	N/N
	MUSC	Arthralgia/ generalized joint pain	2	18NOV2020	1/3	1	Yes		NA	R (20NOV2020)	N/N
		Myalgia/ Muscle Pain	2	18NOV2020	1/3	1	Yes		NA	R (20NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701472	NERV	Headache/ Headache	2	18NOV2020	1/5	1	Yes		NA/TC	R (22NOV2020)	N/N
	GENRL	Chills/ Chills	1	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	1	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Chills/ Chills#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1170 11701473		Fatigue/ Fatigue#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	19NOV2020	2/2	2	Yes		NA	R (20NOV2020)	N/N
		Malaise/ Malaise	2	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N
		Pyrexia/ Fever	2	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N
16-55/ C4591001 1170 11701474†	NERV	Headache/ Headache	2	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	17NOV2020	1/1	1	Yes		NA	R (17NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701475	MUSC	Myalgia/ Generalized Muscle Pain#	3	28DEC2020	1/5	1	Yes		NA	R (01JAN2021)	N/N
	NERV	Headache/ Headache#	3	28DEC2020	1/5	1	Yes		NA	R (01JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	29DEC2020	2/2	1	Yes		NA	R (30DEC2020)	N/N
		Injection site pain/ Injection Site Pain#	3	29DEC2020	2/2	1	Yes		NA	R (30DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
		Injection site pain/ Pain at injection site#	4	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
	MUSC	Myalgia/ Muscle Pain#	4	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
	NERV	Headache/ Headache#	4	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Injection site erythema/ Injection Site Redness	1	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
		Injection site pain/ Injection Site Pain	1	27OCT2020	1/2	1	Yes		NA/TC	R (28OCT2020)	N/N
	GENRL	Chills/ Chills	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
		Fatigue/ Fatigue	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
GENRL	Injection site pain/ Injection Site Pain	2	17NOV2020	1/3	2	Yes		NA/TC	R (19NOV2020)	N/N	
	Pyrexia/ Fever	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701476	MUSC	Myalgia/ Myalgias	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N
	NERV	Headache/ Headache	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Chills/ Chills	2	18NOV2020	2/2	2	Yes		NA	R (19NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	18NOV2020	2/2	2	Yes		NA	R (19NOV2020)	N/N
16-55/ C4591001 1170 11701477	GENRL	Injection site pain/ Injection Site Pain	2	18NOV2020	2/2	2	Yes		NA	R (19NOV2020)	N/N
	GENRL	Pyrexia/ Fever	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N
	MUSC	Myalgia/ Myalgias	2	18NOV2020	2/2	2	Yes		NA	R (19NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Injection site erythema/ Injection site redness	2	18NOV2020	1/3	1	Yes		NA	R (20NOV2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	18NOV2020	1/3	1	Yes		NA	R (20NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701478	GENRL	Injection site pain/ Pain at injection site#	4	05FEB2021	2/4	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1170 11701480	GENRL	Fatigue/ Fatigue	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1170 11701482	MUSC	Myalgia/ Muscle Pain	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	28OCT2020	1/4	1	Yes		NA	R (31OCT2020)	N/N
		Malaise/ Malaise	1	28OCT2020	1/4	1	Yes		NA	R (31OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	29OCT2020	2/3	2	Yes		NA	R (31OCT2020)	N/N
	GENRL	Chills/ Chills	1	29OCT2020	2/3	1	Yes		NA	R (31OCT2020)	N/N
		Pyrexia/ Fever	1	29OCT2020	2/2	2	Yes		NA	R (30OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	1	29OCT2020	2/3	2	Yes		NA	R (31OCT2020)	N/N
	NERV	Headache/ Headache	1	29OCT2020	2/3	2	Yes		NA	R (31OCT2020)	N/N
	MUSC	Back pain/ Back Pain	2	22NOV2020	5/2	1	No	O	NA/TC	R (23NOV2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701483		Fatigue/ Fatigue	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
		Injection site pain/ Pain at Injection Site	1	28OCT2020	1/4	1	Yes		NA	R (31OCT2020)	N/N
	NERV	Headache/ Headache	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Chills/ Chills	2	20NOV2020	2/2	2	Yes		NA	R (21NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	20NOV2020	2/2	2	Yes		NA	R (21NOV2020)	N/N
		Malaise/ Malaise	2	20NOV2020	2/2	2	Yes		NA	R (21NOV2020)	N/N
	MUSC	Myalgia/ Myalgias	2	20NOV2020	2/2	2	Yes		NA	R (21NOV2020)	N/N
	NERV	Headache/ Headache	2	20NOV2020	2/2	2	Yes		NA	R (21NOV2020)	N/N
16-55/ C4591001 1170 11701484	GENRL	Injection site erythema/ Redness at injection site#	3	21DEC2020	1/4	1	Yes		NA	R (24DEC2020)	N/N
		Injection site pain/ Pain at injection site#	3	21DEC2020	1/4	1	Yes		NA	R (24DEC2020)	N/N
	GASTR	Nausea/ Nausea#	4	14JAN2021	2/3	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Chills/ Chills#	4	14JAN2021	2/3	1	Yes		NA	R (16JAN2021)	N/N
		Fatigue/ Fatigue#	4	14JAN2021	2/3	1	Yes		NA	R (16JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701485	MUSC	Pyrexia/ Fever#	4	14JAN2021	2/3	1	Yes		NA	R (16JAN2021)	N/N
		Myalgia/ Myalgias#	4	14JAN2021	2/3	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Pyrexia/ Fever	1	29OCT2020	2/3	1	Yes		NA	R (31OCT2020)	N/N
	GENRL	Chills/ Chills	2	24NOV2020	1/4	1	Yes		NA/TC	R (27NOV2020)	N/N
		Injection site pain/ Pain injection site	2	24NOV2020	1/3	1	Yes		NA	R (26NOV2020)	N/N
		Malaise/ Malaise	2	24NOV2020	1/4	1	Yes		NA/TC	R (27NOV2020)	N/N
		Pyrexia/ Fever	2	24NOV2020	1/4	1	Yes		NA/TC	R (27NOV2020)	N/N
MUSC	Myalgia/ Myalgias	2	24NOV2020	1/4	1	Yes		NA/TC	R (27NOV2020)	N/N	
NERV	Headache/ Headache	2	24NOV2020	1/4	1	Yes		NA/TC	R (27NOV2020)	N/N	
16-55/ C4591001 1170 11701486	GENRL	Chills/ Chills#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
		Injection site pain/ Pain at injection site#	3	22DEC2020	1/1	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Chills/ Chills#	4	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701488	GENRL	Fatigue/ Fatigue#	4	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/N	
		Injection site swelling/ Swelling at injection site	1	29OCT2020	1/3	1	Yes		NA	R (31OCT2020)	N/N	
	MUSC	Myalgia/ Muscle Pain	1	30OCT2020	2/2	1	Yes		NA	R (31OCT2020)	N/N	
	GENRL	Chills/ Chills	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N	
		Fatigue/ Fatigue	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N	
	MUSC	Pyrexia/ Fever	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N	
		Arthralgia/ generalized joint pain	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N	
	GENRL	Myalgia/ Muscle pain	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N	
16-55/ C4591001 1170 11701489	GENRL	Injection site pain/ Pain injection Site	2	19NOV2020	3/10	1	Yes		NA	R (28NOV2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain#	3	15JAN2021	1/5	1	Yes		NA	R (19JAN2021)	N/N	
	GENRL	Injection site pain/ pain at injection site#	4	05FEB2021	2/4	1	Yes		NA	R (08FEB2021)	N/N	
		Pyrexia/ fever#	4	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N	
	MUSC	Myalgia/ general muscle pain#	4	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701490	GENRL	Injection site pain/ Pain at Injection Site	1	30OCT2020	2/4	1	Yes		NA	R (02NOV2020)	N/N
	NERV	Headache/ Headache	1	30OCT2020	2/4	1	Yes		NA	R (02NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	19NOV2020	1/3	1	Yes		NA	R (21NOV2020)	N/N
		Injection site pain/ Pain at Injection site	2	19NOV2020	1/3	1	Yes		NA	R (21NOV2020)	N/N
		Pyrexia/ Fever	2	19NOV2020	1/3	1	Yes		NA	R (21NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	19NOV2020	1/2	1	Yes		NA	R (20NOV2020)	N/N
	NERV	Headache/ Headache	2	19NOV2020	1/1	1	Yes		NA	R (19NOV2020)	N/N
16-55/ C4591001 1170 11701491	NERV	Headache/ Headache	1	29OCT2020	1/1	1	Yes		NA	R (29OCT2020)	N/N
	NERV	Headache/ Headache	2	20NOV2020	1/1	1	Yes		NA	R (20NOV2020)	N/N
16-55/ C4591001 1170 11701492	GENRL	Fatigue/ Fatigue	1	30OCT2020	2/17	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	3	31DEC2020	2/1	1	Yes		NA	R (31DEC2020)	N/N
		Fatigue/ Fatigue#	3	31DEC2020	2/1	1	Yes		NA	R (31DEC2020)	N/N
16-55/ C4591001 1170 11701493	GENRL	Injection site pain/ Injection Site Pain	1	29OCT2020	1/4	1	Yes		NA	R (01NOV2020)	N/N
	GENRL	Chills/ Chills	2	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N
		Fatigue/ Fatigue	2	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N
		Injection site pain/ Pain at Injection Site	2	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N
		Pyrexia/ Fever	2	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N
16-55/ C4591001 1170 11701494	NERV	Headache/ Headache	1	30OCT2020	2/2	1	Yes		NA	R (31OCT2020)	N/N
16-55/ C4591001 1170 11701499	GENRL	Fatigue/ Fatigue#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	04JAN2021	1/4	1	Yes		NA	R (07JAN2021)	N/N
		Injection site swelling/ Swelling at injection site#	3	04JAN2021	1/4	1	Yes		NA	R (07JAN2021)	N/N
		Chills/ Chills#	4	26JAN2021	2/4	1	Yes		NA	R (29JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701500	GENRL	Fatigue/ Fatigue#	4	26JAN2021	2/4	1	Yes		NA	R (29JAN2021)	N/N	
		Pyrexia/ Fever#	4	26JAN2021	2/4	1	Yes		NA	R (29JAN2021)	N/N	
		Injection site erythema/ Injection site redness	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N	
		Injection site pain/ injection site pain	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N	
		Injection site swelling/ Injection site swelling	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N	
		Pyrexia/ Fever	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N	
		NERV	Headache/ Headache	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	20NOV2020	1/3	1	Yes		NA	R (22NOV2020)	N/N
			Injection site pain/ Injection Site Pain	2	20NOV2020	1/3	1	Yes		NA	R (22NOV2020)	N/N
			Pyrexia/ Fever	2	20NOV2020	1/3	1	Yes		NA	R (22NOV2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	20NOV2020	1/1	1	Yes		NA	R (20NOV2020)	N/N	
	NERV	Headache/ Headaches	2	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N	
16-55/ C4591001 1170 11701501	GENRL	Injection site pain/ Pain at injection site	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Pyrexia/ Fever	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N
	NERV	Headache/ Headache	1	01NOV2020	3/19	1	Yes		NA	R (19NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	21NOV2020	2/1	1	Yes		NA	R (21NOV2020)	N/N
		Pyrexia/ Fever	2	21NOV2020	2/1	1	Yes		NA	R (21NOV2020)	N/N
	NERV	Headache/ Headache	2	21NOV2020	2/2	1	Yes		NA	R (22NOV2020)	N/N
16-55/ C4591001 1171 11711014	GENRL	Injection site pain/ Arm pain ( at the injection site )	1	02SEP2020	21/3	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1171 11711021	INFEC	Subcutaneous abscess/ Skin abscess (wrist)	2	14SEP2020	5/6	2	No	O	NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1171 11711023	SKIN	Urticaria/ Urticaria on forehead, posterior neck, bilateral posterior hands and bilateral plantar areas#	3	10FEB2021	2/7	2	Yes		P/TC	R (16FEB2021)	N/N
	SKIN	Angioedema/ Angioedema - Forehead#	3	11FEB2021	3/6	1	Yes		P/TC	R (16FEB2021)	N/N
16-55/ C4591001 1171 11711026	MUSC	Neck pain/ Neck Pain	2	30SEP2020	28/17	2	No	O	NA/TC	R (16OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1171 11711027	INJ&P	Muscle strain/ Lower back strain	2	18SEP2020	15/11	2	No	O	NA/TC	R (28SEP2020)	N/N	
16-55/ C4591001 1171 11711033	GENRL	Fatigue/ Fatigue	1	14AUG2020	1/8	1	No	O	NA	R (21AUG2020)	N/N	
16-55/ C4591001 1171 11711034	EAR	Vertigo/ Vertigo (Unknown cause)	2	09OCT2020	36/8	2	No	O	NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001 1171 11711039	RESP	Nasal congestion/ Nasal Congestion	2	10OCT2020	39/6	2	No	O	NA/TC	R (15OCT2020)	N/N	
16-55/ C4591001 1171 11711050	GENRL	Chills/ Chills	2	09SEP2020	2/1	2	Yes		NA/TC	R (09SEP2020)	N/N	
		Injection site pain/ Injection Site Pain [Left Arm Deltoid]	2	09SEP2020	2/1	2	Yes		NA/TC	R (09SEP2020)	N/N	
16-55/ C4591001 1171 11711055	GENRL	Injection site pain/ INJECTION SITE PAIN	1	19AUG2020	2/3	1	Yes		NA	R (21AUG2020)	N/N	
	GENRL	Chills/ Chills	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N	
		Injection site pain/ Injection Site Pain [Left Arm Deltoid]	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1171 11711060	GENRL	Injection site pain/ Soreness around injection site	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1171 11711065	GENRL	Injection site pain/ Soreness around injection site	2	09SEP2020	1/4	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1171 11711067	INV	Heart rate increased/ Elevated pulse rate	1	20AUG2020	3/1	1	Yes		NA	R (20AUG2020)	N/N
16-55/ C4591001 1171 11711069	GENRL	Chills/ Chills	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1171 11711073	GENRL	Injection site pain/ Injection Site Pain	2	15SEP2020	2/4	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1171 11711073	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N
16-55/ C4591001 1171 11711085	GENRL	Pain/ Body Aches (Generalized)	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Headache/ Headache	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1171 11711088 16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
1171 11711091 16-55/ C4591001	GASTR	Diarrhoea/ Diarrhea	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
1171 11711093	MUSC	Arthralgia/ LEFT SHOULDER PAIN	1	31AUG2020	12/12	2	No	O	NA/TC	R (11SEP2020)	N/N
		Neck pain/ WORSENING OF NECK PAIN	1	31AUG2020	12/12	2	No	O	NA/TC	R (11SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	28AUG2020	3/5	1	Yes		NA	R (01SEP2020)	N/N
1171 11711128	NERV	Headache/ Headache	1	29AUG2020	4/4	1	Yes		NA	R (01SEP2020)	N/N
16-55/ C4591001	GASTR	Nausea/ Nausea	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
1171 11711130	GENRL	Chills/ Chills	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
		Injection site pain/ Injection Site Pain [Left Arm Deltoid]	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ Fever	2	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1171 11711137	MUSC	Myalgia/ Myalgia	2	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Soreness around injection site	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
		Pyrexia/ Fever	2	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1171 11711146	MUSC	Myalgia/ Myalgia	2	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1171 11711151	GENRL	Injection site erythema/ Redness to Injection Site	1	31AUG2020	1/6	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1171 11711154		Injection site swelling/ Swelling to Injection Site	1	31AUG2020	1/6	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	02SEP2020	3/4	1	Yes		NA	R (05SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain	1	02SEP2020	3/4	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1171 11711158	GENRL	Injection site erythema/ Erythema to injection site	1	31AUG2020	1/4	1	Yes		NA	R (03SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	31AUG2020	1/4	1	Yes		NA	R (03SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1171 11711175	NERV	Dizziness/ Dizziness	1	31AUG2020	1/4	1	No	O	NA	R (03SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	23SEP2020	1/2	2	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1171 11711191	GENRL	Injection site pain/ Pain around injection site	1	08SEP2020	1/3	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1171 11711200	SKIN	Alopecia/ Hair loss	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Arm Pain (at the injection site)	1	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1171 11711203	GENRL	Pyrexia/ Fever	1	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1171 11711209	GENRL	Injection site pain/ Soreness around injection site	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1171 11711211	GENRL	Injection site pain/ INJECTION SITE PAIN	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ Headache	1	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1171 11711216	NERV	Headache/ Headache	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N	
	CARD	Tachycardia/ Tachycardia	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N	
	GENRL	Chills/ Chills	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N	
		Pyrexia/ Fever	2	30SEP2020	2/1	2	Yes		NA/TC	R (30SEP2020)	N/N	
	GASTR	Diarrhoea/ Diarrhea#	3	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N	
	MUSC	Pain in extremity/ Left Arm Aching#	2	22FEB2021	148/3	2	Yes		NA/TC	R (24FEB2021)	N/N	
	16-55/ C4591001 1171 11711223	NERV	Headache/ Headache	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
	16-55/ C4591001 1171 11711225	MUSC	Pain in extremity/ Pain in Arm [Left]	1	10SEP2020	1/4	2	Yes		NA/TC	R (13SEP2020)	N/N
	16-55/ C4591001 1171 11711236	GENRL	Injection site erythema/ Redness around injection site	1	11SEP2020	1/6	1	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ Injection site pain	1	11SEP2020	1/5	2	Yes		NA	R (15SEP2020)	N/N	
16-55/ C4591001	GENRL	Chills/ Chills#	4	19JAN2021	2/3	1	Yes		NA	R (21JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1171 11711241	NERV	Dizziness/ Dizziness#	4	19JAN2021	2/3	1	Yes		NA	R (21JAN2021)	N/N	
		Headache/ Headache#	4	19JAN2021	2/3	1	Yes		NA/TCN	R (21JAN2021)	N/N	
16-55/ C4591001 1171 11711242	GENRL	Chills/ Chills	1	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N	
		Pyrexia/ Fever	1	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N	
	NERV	Headache/ Headache	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N	
16-55/ C4591001 1171 11711246	GENRL	Injection site erythema/ Erythema at injection site	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N	
		Injection site pain/ Soreness at Injection Site	1	11SEP2020	1/6	2	Yes		NA/TC	R (16SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N	
		Pain/ Body aches	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N	
		Pyrexia/ Fever	2	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N	
		Headache/ Headache	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N	
16-55/ C4591001	MUSC	Myalgia/ Muscle aches, generalized	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1171 11711249 16-55/ C4591001 1171 11711251	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N	
		Pyrexia/ Fever	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N	
	MUSC	Myalgia/ Muscle Ache	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N	
16-55/ C4591001 1171 11711252	GENRL	Chills/ Chills	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N	
		Pyrexia/ Fever	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001 1171 11711260	GENRL	Injection site pain/ Arm pain ( at the injection site )	1	16SEP2020	1/2	1	Yes		NA/TCN	R (17SEP2020)	N/N	
16-55/ C4591001 1171 11711266	GENRL	Injection site pain/ Left Arm pain ( at the injection site )	1	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N	
16-55/ C4591001 1171 11711271	GENRL	Fatigue/ Fatigue	1	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1171 11711274	GENRL	Pain/ Body aches	1	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N	
		Fatigue/ Fatigue	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N	
		Injection site pain/ Soreness around injection site	1	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N	
16-55/ C4591001 1171 11711281	GENRL	Fatigue/ Fatigue	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N	
	NERV	Headache/ Headache	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N	
	GENRL	Injection site pain/ Soreness around injection site	1	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 1171 11711293	GENRL	Injection site pain/ Injection site pain	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N	
	INFEC	Tinea infection/ Ring worm infection	2	05NOV2020	24/15	2	No	O	NA/TC	R (19NOV2020)	N/N	
	GENRL	Injection site pain/ Soreness at Injection Site	2	15OCT2020	1/4	2	Yes		NA/TC	R (18OCT2020)	N/N	
16-55/ C4591001 1171 11711294	GENRL	Pain/ Body aches, generalized	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N	
	NERV	Headache/ Headache	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1174 11741003	NEOPL	Malignant melanoma/ right forearm melanoma	2	01OCT2020	11/8	1	No	O	NA/TCN	R (08OCT2020)	N/N
16-55/ C4591001 1174 11741006	GENRL	Pain/ Generalized Aches and pain#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1174 11741011	CARD	Tachycardia/ Tachycardia	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
		Pyrexia/ Fever	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	NERV	Headache/ Headache	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Nausea/ Nausea	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Pain/ Achiness	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1174 11741015	GASTR	Nausea/ Nausea#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1174 11741020	MUSC	Pain in extremity/ Left arm soreness#	3	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N
	MUSC	Pain in extremity/ Left arm soreness#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1174 11741026	GENRL	Chills/ Chills#	4	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
		Fatigue/ Fatigue#	4	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
		Pain/ Body aches#	4	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
	MUSC	Arthralgia/ Generalized joint pain#	4	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
		Pain in extremity/ Soreness in the right arm#	4	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
16-55/ C4591001 1174 11741027	MUSC	Periarthritis/ Adhesive Capsulitis left shoulder	1	04SEP2020	1/99	1	Yes		NA	R (11DEC2020)	N/N
16-55/ C4591001	MUSC	Pain in extremity/ Left arm soreness#	4	16FEB2021	1/2	1	Yes		NA/TCN	R (17FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1174 11741030	GENRL	Chills/ Chills#	4	17FEB2021	2/1	1	Yes	NA/TCN		R (17FEB2021)	N/N
		Fatigue/ Fatigue#	4	17FEB2021	2/1	1	Yes	NA/TCN		R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	17FEB2021	2/1	1	Yes	NA/TCN		R (17FEB2021)	N/N
16-55/ C4591001 1174 11741031	GENRL	Chills/ Chills	2	26SEP2020	2/2	1	Yes	NA/TCN		R (27SEP2020)	N/N
		Pyrexia/ Fever	2	26SEP2020	2/2	1	Yes	NA/TCN		R (27SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	26SEP2020	2/2	1	Yes	NA/TCN		R (27SEP2020)	N/N
	NERV	Headache/ Headache	2	26SEP2020	2/2	1	Yes	NA/TCN		R (27SEP2020)	N/N
16-55/ C4591001 1174 11741032	GENRL	Chills/ Chills#	4	26FEB2021	1/2	1	Yes	NA/TCN		R (27FEB2021)	N/N
		Pyrexia/ Fever#	4	26FEB2021	1/2	1	Yes	NA/TCN		R (27FEB2021)	N/N
	NERV	Headache/ Headache#	4	26FEB2021	1/2	1	Yes	NA/TCN		R (27FEB2021)	N/N
16-55/ C4591001 1174 11741034	GENRL	Chills/ Chills#	3	08JAN2021	2/2	1	Yes	NA/TC		R (09JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1174 11741038	GENRL	Fatigue/ Fatigue#	3	08JAN2021	2/2	1	Yes		NA/TC	R (09JAN2021)	N/N
		Pain/ Generalized aches and pain#	3	08JAN2021	2/3	1	Yes		NA/TC	R (10JAN2021)	N/N
		Fatigue/ Fatigue	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1174 11741045	MUSC	Pyrexia/ Feverish	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
	MUSC	Pain in extremity/ Left arm soreness	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1174 11741045	MUSC	Myalgia/ Myalgia	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1174 11741046	MUSC	Pain in extremity/ Right arm soreness#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1174 11741049	GENRL	Fatigue/ Fatigue#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
	MUSC	Pain in extremity/ Right arm soreness#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
	GENRL	Pain/ Generalized aches and pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1174 11741050	GENRL	Fatigue/ Fatigue	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
		Pyrexia/ Fever	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	19DEC2020	2/1	1	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1174 11741051	MUSC	Pain in extremity/ Soreness in the left arm#	3	19DEC2020	2/1	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
		Pyrexia/ Low grade fever#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1174 11741053	GENRL	Chills/ Chills	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1174 11741053	MUSC	Pain in extremity/ Left arm soreness#	3	21JAN2021	1/2	1	Yes		NA/TCN	R (22JAN2021)	N/N
	MUSC	Pain in extremity/ Left arm soreness#	4	13FEB2021	2/2	1	Yes		NA/TCN	R (14FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1174 11741055	MUSC	Pain in extremity/ Left arm soreness#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1174 11741056	GENRL	Pyrexia/ Fever	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1174 11741057	MUSC	Myalgia/ Myalgia	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1174 11741057	INJ&P	Ligament rupture/ Torn ACL Left Knee	2	04JAN2021	78/C	1	No	O	NA	N	N/N
16-55/ C4591001 1174 11741058	GENRL	Chills/ Chills#	4	29JAN2021	2/1	1	Yes		NA	R (29JAN2021)	N/N
		Pain/ Generalized aches#	4	29JAN2021	2/1	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1174 11741058	GENRL	Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Fatigue/ Fatigue	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Pyrexia/ Fever	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	MUSC	Pain in extremity/ Right arm soreness	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001	MUSC	Pain in extremity/ Left arm soreness#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1174 11741060 16-55/ C4591001	MUSC	Arthritis/ Arthritis in the right hand#	4	29JAN2021	17/C	1	No	O	NA/TCN	RG	N/N
1174 11741063 16-55/ C4591001	GENRL	Pyrexia/ Fever	1	18SEP2020	2/2	1	Yes		NA/TCN	R (19SEP2020)	N/N
1174 11741065	MUSC	Myalgia/ Myalgia	1	18SEP2020	2/2	1	Yes		NA/TCN	R (19SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08OCT2020	2/2	1	Yes		NA/TCN	R (09OCT2020)	N/N
		Pyrexia/ Fever	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	08OCT2020	2/2	1	Yes		NA/TCN	R (09OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	30SEP2020	3/2	1	Yes		NA	R (01OCT2020)	N/N
1174 11741071	MUSC	Pain in extremity/ Left arm soreness	1	30SEP2020	3/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001	GASTR	Nausea/ Nausea#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
1174 11741072		Vomiting/ Vomiting#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		Pyrexia/ Fever#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	MUSC	Pain in extremity/ Left arm soreness#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1177 11771001	NERV	Headache/ HEADACHE	2	16OCT2020	45/1	2	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1177 11771030	NERV	Dizziness/ Dizziness	1	27AUG2020	15/4	2	No	O	NA	R (30AUG2020)	N/N
16-55/ C4591001 1177 11771050	GENRL	Fatigue/ FATIGUE	1	18AUG2020	2/29	1	No	O	NA	R (15SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Pyrexia/ FEVER	2	08SEP2020	1/2	1	Yes		NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1177 11771051	GENRL	Injection site pain/ Injection Site Pain	1	18AUG2020	2/4	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001 1177 11771066	GENRL	Injection site pain/ Injection Site Pain	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1177 11771078	GASTR	Diarrhoea/ DIARRHEA	1	29AUG2020	11/2	1	No	O	NA	R (30AUG2020)	N/N	
16-55/ C4591001 1177 11771096	GENRL	Chills/ Chills	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N	
16-55/ C4591001 1177 11771105	GENRL	Chills/ CHILLS	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N	
		Injection site pain/ PAIN AT INJECTION SITE (LEFT ARM)	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N	
		Pain/ BODY ACHES	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N	
		Pyrexia/ FEVER	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N	
16-55/ C4591001 1177 11771114	GASTR	Diarrhoea/ DIARRHEA	1	25AUG2020	5/2	1	No	O	NA	R (26AUG2020)	N/N	
	INFEC	Tooth infection/ TOOTH INFECTION	2	08OCT2020	28/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1177 11771117	GENRL	Pain/ Generalized Body Aches	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001	INFEC	Suspected COVID-19/ Potential COVID-19 Symptoms#	4	01MAR2021	8/4	1	No	O	NA	R (04MAR2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1177 11771118	MUSC	Back pain/ BACK PAIN, INTERMITTENT	2	30SEP2020	17/C	1	No	O	NA	N	N/N
16-55/ C4591001 1177 11771119	EYE	Glaucoma/ Glaucoma, OD#	2	26JAN2021	134/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1177 11771134	INFEC	Otitis externa/ EXTERNAL OTITIS, LEFT EAR	1	09SEP2020	15/10	2	No	O	NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1177 11771155	GENRL	Injection site pain/ Injection Site Pain	2	17SEP2020	2/24	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1177 11771156	GENRL	Pain/ WORSENING BODY ACHES	2	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1177 11771159	INFEC	Sinusitis/ SINUS INFECTION	2	03OCT2020	19/14	2	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1177 11771160	GASTR	Nausea/ NAUSEA	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Pain/ GENERALIZED BODY ACHES	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1177 11771162	GENRL	Injection site pain/ Injection Site Pain	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1177 11771166	GENRL	Pyrexia/ FEVER	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1177 11771167	GENRL	Pyrexia/ FEVER	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001 1177 11771170	GENRL	Pain/ BODY ACHES	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1177 11771172	GENRL	Injection site pain/ Injection Site Pain#	4	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1177 11771182	GENRL	Pain/ BODY ACHES	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		Pyrexia/ FEVER	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001	GENRL	Pain/ Generalized Body Aches	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1177 11771186 16-55/ C4591001 1177 11771197	GENRL	Pain/ Generalized Body Aches	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
1177 11771197 16-55/ C4591001 1177 11771198	GENRL	Pyrexia/ Fever Pain/ Generalized Body Aches#	2 3	19SEP2020 26FEB2021	2/1 1/2	2 1	Yes Yes		NA/TC NA	R (19SEP2020) R (27FEB2021)	N/N N/N
1177 11771219 16-55/ C4591001 1177 11771219	GASTR	Abdominal pain upper/ Stomach Pain	1	08SEP2020	9/1	2	No	O	NA/TC	R (08SEP2020)	N/N
1177 11771222 16-55/ C4591001 1177 11771222	GASTR	Nausea/ NAUSEA	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
1177 11771222 16-55/ C4591001 1177 11771224	GENRL	Pain/ BODY ACHES	2	21SEP2020	1/3	3	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	21SEP2020	1/3	2	Yes		NA	R (23SEP2020)	N/N
	PREG	Abortion spontaneous/ Abortion Spontaneous#	2	23DEC2020	94/1		No	O	NA	R (23DEC2020)	Y/N
16-55/ C4591001 1177 11771224	GENRL	Pain/ Generalized Body Aches	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1177 11771241	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Chills/ Chills	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
		Pain/ Generalized Body Aches	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1177 11771242	NERV	Headache/ Headache	1	02SEP2020	1/2	1	Yes		NA/TC	R (03SEP2020)	N/N
16-55/ C4591001 1177 11771254	MUSC	Myalgia/ Muscle Pain, Left Arm	1	03SEP2020	2/8	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1177 11771283	GENRL	Injection site pain/ Injection Site Pain	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1177 11771297	MUSC	Muscle spasms/ MUSCLE CRAMP, LEFT SIDE OF BODY	1	10SEP2020	6/1	1	Yes		NA	R (10SEP2020)	N/N
	NERV	Paraesthesia/ TINGLING SENSATION, LEFT ARM	1	10SEP2020	6/1	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1177 11771310	GENRL	Fatigue/ FATIGUE	1	08SEP2020	1/2	3	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1177 11771322	MUSC	Pyrexia/ FEVER	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
		Myalgia/ MUSCLE PAIN	1	08SEP2020	1/5	2	Yes		NA	R (12SEP2020)	N/N	
	NERV	Headache/ HEADACHE	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
		Headache/ HEADACHE	2	29SEP2020	1/3	1	Yes		NA/TC	R (01OCT2020)	N/N	
	GASTR	Diarrhoea/ DIARRHEA	2	01OCT2020	3/1	1	Yes		NA/TC	R (01OCT2020)	N/N	
	GENRL	Pyrexia/ Fever#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N	
	16-55/ C4591001 1177 11771323	MUSC	Arthralgia/ Left Shoulder Pain	2	09OCT2020	10/28	1	No	O	NA	R (05NOV2020)	N/N
	16-55/ C4591001 1177 11771330	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1177 11771331	GENRL	Chills/ Chills	1	11SEP2020	2/1	2	Yes		NA	R (11SEP2020)	N/N	
16-55/ C4591001 1177 11771355	GENRL	Chills/ Chills#	4	05MAR2021	1/3	3	Yes		NA/TC	R (07MAR2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1177 11771361	NERV	Pain/ Body Aches#	4	05MAR2021	1/3	3	Yes		NA/TC	R (07MAR2021)	N/N	
		Dizziness/ Dizziness#	3	05MAR2021	22/C	2	Yes		NA/TC	RG	N/N	
	GENRL	Headache/ Headache#	4	05MAR2021	1/3	1	Yes		NA/TC	R (07MAR2021)	N/N	
		Pyrexia/ FEVER	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	
		GENRL	Pain/ Body Aches#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
			Chills/ Chills	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N	
		IN FEC	Herpes zoster/ Shingles	1	11OCT2020	20/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1177 11771429	GENRL	Injection site pain/ Injection Site Pain, Left Deltoid	2	14OCT2020	1/6	1	Yes		NA	R (19OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1177 11771441	INFEC	Pain/ Generalized Body Aches	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N	
16-55/ C4591001 1177 11771441	INFEC	Urinary tract infection/ Urinary Tract Infection	2	26JAN2021	103/10	1	No	O	NA/TC	R (04FEB2021)	N/N	
16-55/ C4591001 1177 11771443	INJ&P	Hand fracture/ Fracture: 5th Metacarpal, Right	2	05FEB2021	113/34	1	No	O	NA	R (10MAR2021)	N/N	
16-55/ C4591001 1177 11771445	GENRL	Pain/ Generalized Body Aches	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
	GENRL	Chills/ Chills	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N	
	MUSC	Myalgia/ Muscle Aches, Neck and Shoulders	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N	
	NERV	Headache/ Headache	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001 1177 11771465	GASTR	Vomiting/ Vomiting#	4	01MAR2021	1/2	1	Yes		NA	R (02MAR2021)	N/N	
16-55/ C4591001 1177 11771475	SKIN	Rash/ Generalized Rash#	3	20DEC2020	3/4	1	Yes		NA	R (23DEC2020)	N/N	
16-55/ C4591001	GENRL	Pain/ Body Aches#	4	23FEB2021	2/5	1	Yes		NA/TC	R (27FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1177 11771484 16-55/ C4591001 1177 11771501	GENRL	Chills/ Chills	2	04NOV2020	2/1	1	Yes		NA	R (04NOV2020)	N/N	
16-55/ C4591001 1177 11771510	GENRL	Injection site pain/ INJECTION SITE PAIN	1	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N	
16-55/ C4591001 1177 11771515	GENRL	Chills/ Chills	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N	
	NERV	Headache/ Headache	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N	
16-55/ C4591001 1177 11771520	INFEC	Urinary tract infection/ Urinary Tract Infection	2	03DEC2020	28/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1177 11771539	GENRL	Chest pain/ Chest Pain	1	20OCT2020	1/12	1	No	O	NA	R (31OCT2020)	N/N	
16-55/ C4591001 1177 11771551	GENRL	Pain/ Body Aches#	3	29DEC2020	1/4	1	Yes		NA	R (01JAN2021)	N/N	
		Pyrexia/ Fever#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781019	NERV	Headache/ Headache#	3	29DEC2020	1/4	1	Yes		NA	R (01JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ chills	2	15SEP2020	2/1	1	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1178 11781029		Fatigue/ fatigue	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
	GENRL	Injection site pain/ soreness, left arm at injection site	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ chills	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1178 11781030		Pain/ Achiness	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site.	1	27AUG2020	1/3	1	Yes		NA/TC	R (29AUG2020)	N/N
	GENRL	Chills/ Chills	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ soreness at injection site	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
	INJ&P	Road traffic accident/ Motor Vehicle Accident	1	14SEP2020	19/1	1	No	O	NA	R (14SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1178 11781036	MUSC	Neck pain/ Neck pain	1	14SEP2020	19/3	1	No	O	NA/TC	R (16SEP2020)	N/N	
	GENRL	Injection site pain/ injection site tenderness#	3	13JAN2021	1/2	1	Yes		NA/TC	R (14JAN2021)	N/N	
	MUSC	Myalgia/ myalgias#	3	13JAN2021	1/2	2	Yes		NA	R (14JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N	
	INV	Body temperature increased/ elevated temperature#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N	
	MUSC	Myalgia/ generalized myalgia#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N	
16-55/ C4591001 1178 11781040	GENRL	Fatigue/ Fatigue#	3	29JAN2021	2/3	2	Yes		NA	R (31JAN2021)	N/N	
		Injection site pain/ Soreness at Injection Site#	3	29JAN2021	2/2	1	Yes		NA/TC	R (30JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N	
		Injection site pain/ tenderness at injection site#	4	26FEB2021	2/2	1	Yes		NA/TC	R (27FEB2021)	N/N	
16-55/ C4591001 1178 11781041	GENRL	Fatigue/ fatigue#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection site soreness	1	28AUG2020	1/2	1	Yes		NA/TC	R (29AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1178 11781043	NERV	Headache/ Headache	1	29AUG2020	2/2	1	Yes		NA/TC	R (30AUG2020)	N/N	
16-55/ C4591001 1178 11781044	GENRL	Injection site pain/ Pain at injection site.	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	
		Malaise/ Malaise	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	
16-55/ C4591001 1178 11781051	MUSC	Bursitis/ Bursitis exacerbation left shoulder	2	09OCT2020	19/32	2	No	O	NA/TCN	R (09NOV2020)	N/N	
	GENRL	Injection site pain/ left arm soreness (injection site)#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N	
	MUSC	Myalgia/ myalgias#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N	
	NERV	Headache/ headache#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N	
16-55/ C4591001 1178 11781052	GENRL	Fatigue/ fatigue	1	02SEP2020	3/2	2	Yes		NA	R (03SEP2020)	N/N	
		Injection site pain/ Injection Site Muscle Soreness	1	02SEP2020	3/7	1	Yes		NA	R (08SEP2020)	N/N	
	NERV	Headache/ Headache	1	02SEP2020	3/2	2	Yes		NA/TC	R (03SEP2020)	N/N	
	GENRL	Chills/ Chills	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1178 11781054	MUSC	Fatigue/ Fatigue	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N	
		Pyrexia/ Fever	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N	
		Myalgia/ Myalgia	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N	
		NERV	Headache/ Headache	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
	MUSC	Arthralgia/ Diffuse Arthralgia	2	23SEP2020	3/2	1	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Injection site pain/ soreness at injection site#	3	24DEC2020	2/2	1	Yes		NA	R (25DEC2020)	N/N	
	16-55/ C4591001 1178 11781055	GENRL	Injection site pain/ Pain at injection site	1	31AUG2020	1/2	1	Yes		NA/TC	R (01SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	21SEP2020	1/4	1	Yes		NA/TC	R (24SEP2020)	N/N	
	GENRL	Chills/ chills	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
	16-55/ C4591001 1178 11781058	NERV	Syncope/ syncope	1	18SEP2020	18/1	1	No	O	NA	R (18SEP2020)	N/N
GENRL	Injection site pain/ soreness at injection site#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N		
GENRL	Fatigue/ fatigue#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N		

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781061	GENRL	Chills/ Chills	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
		Injection site pain/ injection site soreness	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
	MUSC	Myalgia/ myalgias	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
	NERV	Headache/ headache	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
	INJ&P	Exposure during pregnancy/ partner exposure during pregnancy	1	02OCT2020	32/C		No	O	NA	UNK	N/N
	MUSC	Bone pain/ sternum pain	2	15OCT2020	2/C	1	No	O	NA	N	N/N
16-55/ C4591001 1178 11781067	GENRL	Injection site pain/ Pain at injection site.	2	22SEP2020	2/4	1	Yes		NA/TC	R (25SEP2020)	N/N
		Injection site pain/ Tenderness at injection site.	2	22SEP2020	2/4	1	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1178 11781069	GENRL	Fatigue/ Fatigue	2	22SEP2020	1/5	1	Yes		NA	R (26SEP2020)	N/N
		Injection site pain/ Left deltoid injection site soreness	2	22SEP2020	1/5	1	Yes		NA	R (26SEP2020)	N/N
	MUSC	Myalgia/ Body aches (generalized muscle aches)	2	22SEP2020	1/5	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1178 11781070		Injection site pain/ soreness at injection site#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N	
16-55/ C4591001 1178 11781071	EYE	Visual impairment/ visual disturbance#	3	02FEB2021	8/3	1	Yes		NA	R (04FEB2021)	N/N	
	NERV	Headache/ headache#	3	02FEB2021	8/2	1	Yes		NA	R (03FEB2021)	N/N	
	MUSC	Musculoskeletal stiffness/ stiff neck#	3	03FEB2021	9/2	1	Yes		NA	R (04FEB2021)	N/N	
16-55/ C4591001 1178 11781072	GENRL	Pyrexia/ fever	2	23SEP2020	2/4	1	Yes		NA/TC	R (26SEP2020)	N/N	
	BLOOD	Lymphadenopathy/ bilateral axillary lymphadenopathy	2	25SEP2020	4/3	2	Yes		NA/TC	R (27SEP2020)	N/N	
16-55/ C4591001 1178 11781073	SKIN	Rash/ left shoulder blade rash	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/N	
	INJ&P	Skin laceration/ right arch cut	1	05SEP2020	4/45	1	No	O	NA/TC	R (19OCT2020)	N/N	
16-55/ C4591001 1178 11781074	GENRL	Injection site pain/ left arm soreness (injection site)#	2	27JAN2021	127/3	1	Yes		NA/TC	R (29JAN2021)	N/N	
16-55/ C4591001	GENRL	Fatigue/ fatigue#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1178 11781082		Injection site pain/ injection site tenderness#	3	18JAN2021	1/6	1	Yes		NA	R (23JAN2021)	N/N	
	GENRL	Injection site pain/ tenderness at injection site#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	
	INV	Body temperature increased/ increased temp#	4	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N	
	MUSC	Myalgia/ myalgia#	4	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N	
16-55/ C4591001 1178 11781084	GENRL	Injection site pain/ pain at injection site	1	02SEP2020	1/4	2	Yes		NA	R (05SEP2020)	N/N	
	GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N	
		Injection site erythema/ Redness at injection site	2	24SEP2020	2/7	1	Yes		NA	R (30SEP2020)	N/N	
		Injection site pain/ Injection site pain	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N	
		Pyrexia/ Fever	2	24SEP2020	2/3	1	Yes		NA/TC	R (26SEP2020)	N/N	
16-55/ C4591001 1178 11781087	GENRL	Injection site pain/ soreness at injection site#	3	28JAN2021	2/4	1	Yes		NA	R (31JAN2021)	N/N	
	NERV	Headache/ headache#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ soreness at injection site#	4	22FEB2021	1/C	1	Yes		NA	N	N/N
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	2/C	1	Yes		NA	N	N/N
	NERV	Headache/ headache#	4	23FEB2021	2/C	1	Yes		NA	N	N/N
16-55/ C4591001 1178 11781089	GENRL	Injection site pain/ injection site pain	1	03SEP2020	1/5	1	Yes		NA	R (07SEP2020)	N/N
	GENRL	Thirst/ increased sense of thirst	1	12SEP2020	10/C	1	No	O	NA	N	N/N
	GENRL	Pyrexia/ fever	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
	16-55/ C4591001 1178 11781092	GENRL	Fatigue/ fatigue#	3	26JAN2021	1/2	2	Yes		NA	R (27JAN2021)
	INV	Body temperature increased/ increased temperature#	3	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
	MUSC	Myalgia/ generalized myalgia#	3	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
	NERV	Headache/ headache#	3	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1178 11781095	GENRL	Injection site pain/ Pain at injection site	1	03SEP2020	1/4	2	Yes		NA	R (06SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	08SEP2020	6/3	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1178 11781096	GENRL	Fatigue/ fatigue	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
	MUSC	Myalgia/ muscle aches	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N	
	GENRL	Chills/ chills#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N	
			Fatigue/ fatigue#	4	11FEB2021	2/1	2	Yes		NA	R (11FEB2021)	N/N
			Pyrexia/ fever#	4	11FEB2021	2/2	3	Yes		NA/TC	R (12FEB2021)	N/N
	NERV	Headache/ headache#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N	
	SKIN	Rash, inner left arm, left fingers, right flank	1	14SEP2020	11/3	1	Yes		NA/TC	R (16SEP2020)	N/N	
	GENRL	Pyrexia/ Fever	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N	
	GENRL	Injection site pain/ pain at injection site	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N	
	GENRL	Injection site pain/ soreness at injection site#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N	
16-55/ C4591001	RESP	Pulmonary embolism/ Pulmonary embolism	2	20OCT2020	28/102	2	No	O	NA/TC	R (29JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1178 11781104 16-55/ C4591001	GENRL	Injection site pain/ injection site soreness#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N
1178 11781106 16-55/ C4591001	GENRL	Injection site erythema/ injection site redness	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
1178 11781107		Injection site pain/ injection site muscle soreness	1	04SEP2020	1/3	2	Yes		NA	R (06SEP2020)	N/N
		Injection site warmth/ injection site warmth	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Chills/ chills	1	05SEP2020	2/1	1	Yes		NA/TC	R (05SEP2020)	N/N
	BLOOD	Lymphadenopathy/ right axilla lymphadenopathy	1	16SEP2020	13/66	2	Yes		P/TC	R (20NOV2020)	Y/N
16-55/ C4591001	GENRL	Injection site pain/ soreness at injection site#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
1178 11781110											
16-55/ C4591001	GENRL	Injection site pain/ Arm soreness - Right (injection site)	1	08SEP2020	1/2	1	Yes		NA/TCN	R (09SEP2020)	N/N
1178 11781113											
	GENRL	Chills/ chills	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ injection site soreness	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781114	GENRL	Pain/ generalized body ache	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N
		Pyrexia/ fever#	4	02FEB2021	2/2	2	Yes		NA/TC	R (03FEB2021)	N/N
	MUSC	Myalgia/ myalgias#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	NERV	Headache/ headache#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1178 11781120	GENRL	Injection site pain/ soreness at injection site#	3	05JAN2021	2/2	1	Yes		NA/TC	R (06JAN2021)	N/N
16-55/ C4591001 1178 11781121	GENRL	Fatigue/ Fatigue	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
		Fatigue/ fatigue	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Injection site pain/ left deltoid injection site soreness	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
		Feeling hot/ feeling of warmth - generalized	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1178 11781128	GENRL	Chills/ Chills	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781130	MUSC	Injection site pain/ Injection site muscle soreness	1	10SEP2020	2/2	2	Yes	NA	NA	R (11SEP2020)	N/N
		Myalgia/ Myalgias	1	10SEP2020	2/2	1	Yes	NA/TC	NA/TC	R (11SEP2020)	N/N
	GENRL	Chills/ Chills	2	01OCT2020	2/2	2	Yes	NA/TC	NA/TC	R (02OCT2020)	N/N
		Fatigue/ Fatigue	2	01OCT2020	2/2	2	Yes	NA	NA	R (02OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	01OCT2020	2/2	1	Yes	NA	NA	R (02OCT2020)	N/N
		Fatigue/ Fatigue	1	09SEP2020	1/2	1	Yes	NA	NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	09SEP2020	1/2	1	Yes	NA	NA	R (10SEP2020)	N/N
		Fatigue/ fatigue	2	02OCT2020	1/3	1	Yes	NA	NA	R (04OCT2020)	N/N
		Injection site pain/ Injection site soreness	2	02OCT2020	1/3	1	Yes	NA/TC	NA/TC	R (04OCT2020)	N/N
		Pain/ generalized body ache	2	02OCT2020	1/3	1	Yes	NA	NA	R (04OCT2020)	N/N
16-55/ C4591001 1178 11781133	GENRL	Injection site pain/ Left deltoid soreness, injection site	1	09SEP2020	1/4	1	Yes	NA	NA	R (12SEP2020)	N/N
NERV	Headache/ headache	1	29SEP2020	21/3	1	Yes	NA	NA	R (01OCT2020)	N/N	
GENRL	Injection site pain/ tenderness at injection site	2	30SEP2020	2/3	1	Yes	NA	NA	R (02OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1178 11781135	GENRL	Malaise/ generalized malaise	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N	
		Injection site pain/ Pain at injection site	1	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N	
16-55/ C4591001 1178 11781137	SKIN	Night sweats/ Night sweats	1	11SEP2020	3/1	1	Yes		NA	R (11SEP2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site	2	30SEP2020	1/15	1	Yes		NA	R (14OCT2020)	N/N	
16-55/ C4591001 1178 11781137	GENRL	Injection site pain/ Tenderness at injection site	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N	
16-55/ C4591001 1178 11781145	GENRL	Injection site pain/ Soreness at injection site*		10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N	
16-55/ C4591001 1178 11781149	NERV	Headache/ Headache	1	23SEP2020	14/1	1	No	O	NA/TC	R (23SEP2020)	N/N	
	GENRL	Injection site pain/ tenderness at injection site	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
16-55/ C4591001 1178 11781149	GENRL	Injection site pain/ Injection site myalgia	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N	
16-55/ C4591001 1178 11781149	INJ&P	Skin laceration/ laceration, left index finger	2	22OCT2020	23/12	2	No	O	NA	R (02NOV2020)	N/N	
	GENRL	Injection site pain/ Left arm soreness (injection site)#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1178 11781150	GENRL	Fatigue/ fatigue#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N	
		Injection site pain/ soreness at injection site#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N	
	MUSC	Myalgia/ myalgia#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N	
	GENRL	Chills/ Chills	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N	
		Pain/ Body aches	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N	
	MUSC	Myalgia/ Upper arm myalgia, left#	3	17DEC2020	1/4	1	Yes		NA	R (20DEC2020)	N/N	
	GENRL	Pyrexia/ low grade temperature	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N	
	GENRL	Injection site pain/ tenderness at injection site#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N	
	GENRL	Injection site pain/ Soreness at injection site	1	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N	
	GENRL	Malaise/ General malaise	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781168	GENRL	Injection site pain/ Injection site tenderness	1	14SEP2020	1/3	1	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Injection site pain/ Tenderness at injection site	2	05OCT2020	1/3	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1178 11781170	GENRL	Injection site pain/ pain at injection site	2	14OCT2020	1/1	1	Yes		NA	R (14OCT2020)	N/Y
	INFEC	Bacterial vaginosis/ bacterial vaginosis	1	14OCT2020	31/31	2	No	O	NA/TC	R (13NOV2020)	N/N
	GENRL	Injection site pain/ injection site soreness#	3	26JAN2021	1/4	1	Yes		NA	R (29JAN2021)	N/Y
	NERV	Migraine/ migraine#	3	26JAN2021	1/1	2	No	O	NA	R (26JAN2021)	N/N
	MUSC	Pain in extremity/ upper and lower left arm tenderness#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1178 11781171	GENRL	Injection site pain/ Injection site tenderness#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/Y
16-55/ C4591001 1178 11781175	GENRL	Fatigue/ fatigue	1	15SEP2020	1/4	2	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ soreness at injection site	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ myalgia	1	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781179	NERV	Headache/ headache	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Chills/ chills	1	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N
	GENRL	Chills/ chills	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
		Pyrexia/ fever	2	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
	MUSC	Myalgia/ myalgias	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	1	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Chills/ rigors	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
		Injection site pain/ injection site pain	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
	NERV	Headache/ headache	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1178 11781181	GENRL	Injection site pain/ Injection site tenderness - Right arm	1	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1178 11781182	NERV	Headache/ Headache	2	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N	
	GASTR	Nausea/ Intermittent nausea	2	10OCT2020	6/29	1	No	O	NA	R (07NOV2020)	N/N	
16-55/ C4591001 1178 11781183	GENRL	Chills/ chills	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N	
16-55/ C4591001 1178 11781185		Fatigue/ fatigue	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N	
	GENRL	Injection site pruritus/ Itchiness at injection site	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N	
16-55/ C4591001 1178 11781186	GENRL	Injection site pain/ injection site tenderness	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001 1178 11781187	GENRL	Fatigue/ fatigue	1	19SEP2020	4/2	1	Yes		NA	R (20SEP2020)	N/N	
	MUSC	Myalgia/ generalized myalgia	2	09OCT2020	4/3	1	Yes		NA/TC	R (11OCT2020)	N/N	
	GENRL	Injection site pain/ injection site soreness#	3	21JAN2021	1/2	1	Yes		NA/TC	R (22JAN2021)	N/Y	
	GENRL	Injection site pain/ Injection site soreness - Left deltoid*		16SEP2020	1/4	1	Yes		NA	R (19SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1178 11781188	GENRL	Injection site erythema/ Erythema at injection site	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	
	GENRL	Injection site pain/ tenderness at injection site	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N	
	GASTR	Nausea/ nausea	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N	
	GENRL	Chills/ Chills	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N	
	GENRL	Chills/ chills	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
			Fatigue/ fatigue	1	16SEP2020	1/4	2	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ left arm pain at injection site	1	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N	
	GENRL	Chills/ Chills	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N	
			Fatigue/ Fatigue	2	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
MUSC		Myalgia/ Myalgias	2	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N	
16-55/ C4591001 1178 11781189	SKIN	Ingrowing nail/ ingrown toenail (left big toe)#	3	02JAN2021	17/10	2	No	O	NA/TC	R (11JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	06JAN2021	2/3	1	Yes		NA/TC	R (08JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1178 11781194	MUSC	Malaise/ Malaise#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N	
		Myalgia/ Myalgias#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N	
		Headache/ Headache#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N	
	GENRL	Injection site pain/ soreness at injection#	3	22DEC2020	2/3	1	Yes		NA	R (24DEC2020)	N/N	
	GENRL	Injection site pain/ soreness at injection site#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue	1	17SEP2020	2/5	1	Yes		NA	R (21SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N	
	GENRL	Fatigue/ fatigue	1	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N	
	NERV	Headache/ Headache	1	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N	
	GENRL	Chills/ Chills	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N	
MUSC	Myalgia/ Diffuse myalgias	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N		
16-55/ C4591001	GENRL	Fatigue/ increased fatigue	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1178 11781208	GENRL	Fatigue/ fatigue	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1178 11781210	GENRL	Injection site pain/ Left deltoid soreness at injection site	1	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/Y
16-55/ C4591001 1178 11781211	GENRL	Injection site pain/ soreness at injection site	2	09OCT2020	1/4	1	Yes		NA/TC	R (12OCT2020)	N/N
16-55/ C4591001 1178 11781211	GENRL	Fatigue/ fatigue#	4	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/Y
16-55/ C4591001 1178 11781214	GENRL	Chills/ chills, intermittent	2	09OCT2020	1/5	1	Yes		NA/TC	R (13OCT2020)	N/N
	GENRL	Fatigue/ increased fatigue	2	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N
	METAB	Decreased appetite/ decreased appetite	2	11OCT2020	3/3	1	Yes		NA	R (13OCT2020)	N/N
	GENRL	Chills/ chills#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
		Fatigue/ fatigue#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
		Injection site pain/ pain at injection site#	3	21JAN2021	1/3	1	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Chills/ chills#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781217	INV	Body temperature increased/ elevated temperature#	4	11FEB2021	2/1	1	Yes		NA/TC	R (11FEB2021)	N/N
	GENRL	Injection site pain/ Injection site tenderness	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1178 11781218	GENRL	Injection site pain/ injection site tenderness	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
	MUSC	Arthralgia/ Left knee pain	2	20OCT2020	9/28	2	No	O	NA/TC/TCN	R (16NOV2020)	N/N
16-55/ C4591001 1178 11781219	INV	Body temperature increased/ increased temp#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	NERV	Headache/ headache#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ injection site tenderness	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ tenderness at injection site	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Pain/ generalized body ache	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	NERV	Headache/ head ache	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	3	22FEB2021	1/5	1	Yes		NA	R (26FEB2021)	N/N	
		Injection site pain/ burning at injection site#	3	22FEB2021	1/5	1	Yes		NA	R (26FEB2021)	N/N	
16-55/ C4591001 1178 11781223	GENRL	Injection site pain/ pain at injection site	1	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
	INJ&P	Clavicle fracture/ right clavicle fracture	1	03OCT2020	13/C	1	No	O	NA/TC/TCN	N	N/N	
16-55/ C4591001 1178 11781224	GENRL	Injection site pain/ soreness at injection site	1	21SEP2020	1/4	1	Yes		NA/TC	R (24SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
	INFEC	Pharyngitis streptococcal/ Strep throat	1	28SEP2020	8/11	1	No	O	NA	R (08OCT2020)	N/N	
	SKIN	Livedo reticularis/ livedo reticularis intermittent	1	28SEP2020	8/9	1	No	O	NA	R (06OCT2020)	N/N	
16-55/ C4591001 1178 11781226	GENRL	Chills/ Chills#	3	19DEC2020	3/3	1	Yes		NA	R (21DEC2020)	N/N	
		Fatigue/ fatigue#	3	19DEC2020	3/3	1	Yes		NA	R (21DEC2020)	N/N	
		Pain/ Body aches#	3	19DEC2020	3/3	1	Yes		NA	R (21DEC2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1178 11781227	GENRL	Chills/ chills#	4	06JAN2021	2/2	1	Yes		NA/TC	R (07JAN2021)	N/N	
	MUSC	Myalgia/ myalgia#	4	06JAN2021	2/2	1	Yes		NA/TC	R (07JAN2021)	N/N	
	GENRL	Malaise/ malaise	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N	
	GENRL	Injection site pain/ soreness at injection site#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N	
	GENRL	Injection site pain/ Tenderness at injection site	1	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	2	15OCT2020	3/3	1	Yes		NA	R (17OCT2020)	N/N	
	NERV	Headache/ headache	2	15OCT2020	3/3	1	Yes		NA	R (17OCT2020)	N/N	
	GENRL	Injection site pain/ soreness at injection site, left deltoid	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Malaise/ generalized malaise	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Injection site pain/ injection site soreness#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781237	GENRL	Injection site pain/ tenderness at injection site	1	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ injection site tenderness	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1178 11781239	GENRL	Fatigue/ fatigue#	3	11FEB2021	1/1	2	Yes		NA	R (11FEB2021)	N/N
		Injection site pain/ injection site soreness#	3	11FEB2021	1/1	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1178 11781244	GENRL	Injection site pain/ Pain at injection site.	1	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Pain in extremity/ Left intermittent forearm pain.	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Malaise/ malaise	2	13OCT2020	1/4	1	Yes		NA/TC	R (16OCT2020)	N/N
		Pyrexia/ fever	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
	MUSC	Myalgia/ myalgias	2	13OCT2020	1/4	1	Yes		NA	R (16OCT2020)	N/N
	NERV	Headache/ headache	2	13OCT2020	1/4	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1178 11781245	GENRL	Injection site pain/ pain at injection site	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/Y

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781247	GENRL	Injection site pain/ soreness at injection site#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	07JAN2021	1/4	1	Yes		NA	R (10JAN2021)	N/N
		Injection site pain/ soreness at injection site#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1178 11781248	NERV	Headache/ headache#	3	07JAN2021	1/4	1	Yes		NA/TC	R (10JAN2021)	N/N
	GASTR	Diarrhoea/ diarrhea	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Chills/ chills	2	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1178 11781249		Fatigue/ fatigue	2	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
		Pyrexia/ fever	2	16OCT2020	1/3	1	Yes		NA/TC	R (18OCT2020)	N/N
	NERV	Headache/ headache	2	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
	MUSC	Myalgia/ myalgias	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ soreness, left arm beyond injection site	1	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1178 11781251	GENRL	Chills/ chills#	3	25FEB2021	1/2	1	Yes		NA	R (26FEB2021)	N/N	
		Injection site pain/ soreness at injection site#	3	25FEB2021	1/6	1	Yes		NA/TC	R (02MAR2021)	N/N	
16-55/ C4591001 1178 11781253	NERV	Headache/ Headache	1	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
		Pain/ Body ache	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
	GENRL	Chills/ chills	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N	
		Pyrexia/ Fever	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N	
	MUSC	Myalgia/ mayalgias	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N	
16-55/ C4591001 1178 11781254	GENRL	Injection site pain/ Soreness at injection site	1	25SEP2020	2/1	2	Yes		NA/TCN	R (25SEP2020)	N/N	
16-55/ C4591001 1178 11781257	NEOPL	Breast cancer/ left breast carcinoma	2	13JAN2021	90/C	3	No	O	NA	N	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781258	BLOOD	Lymphadenopathy/ left axillary adenopathy with cortical thickening#	3	27JAN2021	6/C	1	Yes		NA	N	N/N
		Lymphadenopathy/ right axillary adenopathy with cortical thickening#	3	27JAN2021	6/C	1	Yes		NA	N	N/N
	BLOOD	Anaemia/ anemia#	4	25FEB2021	16/C	1	No	O	NA	N	N/N
	INJ&P	Seroma/ seroma (left axilla)#	4	26FEB2021	17/C	2	No	O	NA	N	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	22DEC2020	1/2	1	Yes		NA/TC	R (23DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
	GENRL	Injection site pain/ tenderness at injection site#	4	13JAN2021	1/4	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	14JAN2021	2/2	3	Yes		NA	R (15JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	14JAN2021	2/2	2	Yes		NA/TC	R (15JAN2021)	N/N
	MUSC	Musculoskeletal stiffness/ left shoulder stiffness#	4	10FEB2021	29/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1178 11781260	GENRL	Chills/ chills#	3	19DEC2020	2/2	1	Yes		NA/TC	R (20DEC2020)	N/N
		Fatigue/ fatigue#	3	19DEC2020	2/2	1	Yes		NA/TC	R (20DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1178 11781262	MUSC	Malaise/ malaise#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N	
		Myalgia/ myalgia#	3	19DEC2020	2/2	1	Yes		NA/TC	R (20DEC2020)	N/N	
		Myalgia/ myalgias#	3	19DEC2020	2/2	1	Yes		NA/TC	R (20DEC2020)	N/N	
	GENRL	Chills/ rigor#	4	06JAN2021	1/3	1	Yes		NA/TC	R (08JAN2021)	N/N	
		Pyrexia/ pyrexia#	4	06JAN2021	1/3	2	Yes		NA/TC	R (08JAN2021)	N/N	
	MUSC	Myalgia/ myalgia#	4	06JAN2021	1/3	3	Yes		NA/TC	R (08JAN2021)	N/N	
	GENRL	Pain/ body aches#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
	SKIN	Night sweats/ night sweats#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N	
	16-55/ C4591001 1178 11781263	GENRL	Chills/ Chills	1	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
			Injection site pain/ Injection site pain	1	28SEP2020	1/3	2	Yes		NA	R (30SEP2020)	N/N
RESP		Upper-airway cough syndrome/ post nasal drip	1	01OCT2020	4/23	1	No	O	NA	R (23OCT2020)	N/N	
GENRL		Chills/ chills	2	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N	
		Pyrexia/ fever	2	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ generalized muscle aches	2	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
	NERV	Headache/ headache	2	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	RESP	Upper-airway cough syndrome/ post nasal drip	2	30DEC2020	72/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1178 11781266	GENRL	Injection site pain/ pain at injection site	1	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1178 11781267	GENRL	Pyrexia/ fever#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1178 11781268	GENRL	Fatigue/ Fatigue	1	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	NERV	Headache/ Headache	1	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Chills/ chills	2	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	21OCT2020	2/12	1	Yes		NA	R (01NOV2020)	N/N
	NERV	Headache/ Headache	2	21OCT2020	2/12	1	Yes		NA/TC	R (01NOV2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ soreness at injection site#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1178 11781269	GENRL	Fatigue/ fatigue#	4	12JAN2021	1/2	1	Yes	NA	NA	R (13JAN2021)	N/N
		Injection site pain/ injection site soreness#	4	12JAN2021	1/2	1	Yes	NA/TC	NA/TC	R (13JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	4	12JAN2021	1/2	1	Yes	NA	NA	R (13JAN2021)	N/N
	NERV	Headache/ headache#	4	12JAN2021	1/2	1	Yes	NA	NA	R (13JAN2021)	N/N
	PSYCH	Insomnia/ insomnia#	4	13JAN2021	2/1	1	Yes	NA	NA	R (13JAN2021)	N/N
16-55/ C4591001 1178 11781270	GENRL	Injection site pain/ Soreness at injection site	1	29SEP2020	1/3	1	Yes	NA	NA	R (01OCT2020)	N/N
	GENRL	Vessel puncture site bruise/ Bruising at the site for blood draw	1	30SEP2020	2/10	1	Yes	NA	NA	R (09OCT2020)	N/N
	GENRL	Injection site pain/ tenderness at injection site	2	20OCT2020	1/3	1	Yes	NA	NA	R (22OCT2020)	N/Y
	GENRL	Injection site pain/ Soreness at injection site	2	21OCT2020	2/3	1	Yes	NA	NA	R (23OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	21OCT2020	2/2	1	Yes	NA/TC	NA/TC	R (22OCT2020)	N/N
		Myalgia/ myalgia	2	21OCT2020	2/2	2	Yes	NA/TC	NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1178 11781271	GENRL	Injection site pain/ injection site soreness	1	29SEP2020	1/6	1	Yes	NA	NA	R (04OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Pain at injection site	2	19OCT2020	1/4	1	Yes		NA/TC	R (22OCT2020)	N/N
		Pyrexia/ Fever	2	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C4591001 1178 11781275	GENRL	Injection site erythema/ erythema at injection site#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
		Injection site pain/ injection site tenderness#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1178 11781279	GENRL	Injection site pain/ soreness at injection site, right deltoid	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1178 11781284	GENRL	Injection site bruising/ Bruising at injection site	1	06OCT2020	1/15	1	Yes		NA	R (20OCT2020)	N/N
	NERV	Headache/ Headache	1	06OCT2020	1/1	1	Yes		NA	R (06OCT2020)	N/N
	GENRL	Injection site pain/ tenderness at injection site#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	GASTR	Nausea/ nausea#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Chills/ chills#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
		Fatigue/ fatigue#	4	07JAN2021	2/1	1	Yes		NA/TC	R (07JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781285	NERV	Headache/ headache#	4	07JAN2021	2/1	1	Yes		NA/TC	R (07JAN2021)	N/N
	GENRL	Injection site pain/ Tenderness at injection site	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		Pain/ Body aches	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1178 11781288	GENRL	Chills/ Chills	2	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
		Pain/ Generalized body aches	2	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection pain	1	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	27OCT2020	2/1	1	Yes		NA/TC	R (27OCT2020)	N/N
	MUSC	Myalgia/ Generalized myalgias	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001 1178 11781290	GENRL	Injection site pain/ tenderness at injection site	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Chills/ chills	2	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N
	NERV	Headache/ headache	2	28OCT2020	2/1	1	Yes		NA/TC	R (28OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1178 11781291	GENRL	Injection site pain/ Tenderness at injection site	1	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N	
	GENRL	Chills/ Chills	2	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N	
		Fatigue/ Fatigue	2	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N	
16-55/ C4591001 1178 11781295	INFEC	Sinusitis/ Sinus infection	2	25NOV2020	28/7	1	No	O	NA/TC	R (01DEC2020)	N/N	
	MUSC	Pain in extremity/ Arm pain, entire left arm#	3	18DEC2020	2/2	1	Yes		NA/TC	R (19DEC2020)	N/N	
	MUSC	Myalgia/ Left upper arm myalgia#	4	05JAN2021	1/7	1	Yes		NA	R (11JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	06JAN2021	2/1	1	Yes		NA	R (06JAN2021)	N/N	
	MUSC	Myalgia/ Myalgias#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N	
16-55/ C4591001 1178 11781296	INFEC	Gonorrhoea/ gonorrhea	2	04NOV2020	2/9	2	No	O	NA/TC	R (12NOV2020)	N/N	
	GENRL	Fatigue/ fatigue#	4	24FEB2021	1/2	2	Yes		NA	R (25FEB2021)	N/N	
		Injection site pain/ soreness at injection site#	4	24FEB2021	1/C	1	Yes		NA/TC	N	N/N	
16-55/ C4591001	INFEC	Hordeolum/ Left eye stye	1	19OCT2020	6/23	2	No	O	NA/TC	R (10NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1178 11781300	GASTR	Nausea/ nausea#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Injection site pain/ tenderness at injection site#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
		Pain/ body aches#	3	21DEC2020	1/4	1	Yes		NA/TC	R (24DEC2020)	N/N
	NERV	Headache/ Headache#	3	21DEC2020	1/4	1	Yes		NA	R (24DEC2020)	N/N
	GASTR	Nausea/ nausea#	4	12JAN2021	1/3	3	Yes		NA	R (14JAN2021)	N/N
	GENRL	Chills/ chills#	4	12JAN2021	1/3	3	Yes		NA	R (14JAN2021)	N/N
		Pain/ body ache#	4	12JAN2021	1/3	3	Yes		NA	R (14JAN2021)	N/N
		Pyrexia/ fever#	4	12JAN2021	1/3	1	Yes		NA/TC	R (14JAN2021)	N/N
	NERV	Headache/ headache#	4	12JAN2021	1/3	3	Yes		NA	R (14JAN2021)	N/N
	BLOOD	Lymphadenopathy/ left axillary lymphadenopathy#	4	13JAN2021	2/8	1	Yes		NA	R (20JAN2021)	N/N
	SKIN	Lichen sclerosus/ lichen sclerosus#	4	19JAN2021	8/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1178 11781309	GENRL	Chills/ chills	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
		Injection site pain/ soreness at injection site	1	21OCT2020	2/5	1	Yes		NA	R (25OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1178 11781310	MUSC	Myalgia/ myalgias	1	21OCT2020	2/1	1	Yes		NA/TC	R (21OCT2020)	N/N	
	GENRL	Chills/ chills	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N	
		Injection site pain/ pain at injection site	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N	
	MUSC	Myalgia/ generalized muscle ache	2	12NOV2020	1/3	1	Yes		NA/TC	R (14NOV2020)	N/N	
	NERV	Headache/ headache	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N	
	GENRL	Axillary pain/ left axillary pain	2	13NOV2020	2/3	2	Yes		NA	R (15NOV2020)	N/N	
		Fatigue/ fatigue	2	13NOV2020	2/1	2	Yes		NA	R (13NOV2020)	N/N	
		Injection site pain/ pain at injection site	2	13NOV2020	2/1	2	Yes		NA	R (13NOV2020)	N/N	
	MUSC	Myalgia/ body aches/myalgia	2	13NOV2020	2/1	2	Yes		NA	R (13NOV2020)	N/N	
	NERV	Headache/ headache	2	13NOV2020	2/1	2	Yes		NA	R (13NOV2020)	N/N	
16-55/ C4591001 1178 11781312	GENRL	Injection site pain/ injection site tenderness#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N	
	GENRL	Chills/ chills#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N	
		Pyrexia/ fever#	4	22FEB2021	1/3	2	Yes		NA/TC	R (24FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1179 11791002	MUSC	Myalgia/ myalgia#	4	22FEB2021	1/3	3	Yes		NA	R (24FEB2021)	N/N
	NERV	Headache/ headache#	4	22FEB2021	1/2	2	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1179 11791030	GENRL	Chills/ Chills#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Fatigue/ Fatigue# Injection site pain/ Injection Site Soreness#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1179 11791058	NERV	Headache/ Headache#	3	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N
	GENRL	Chills/ CHILLS#	4	09JAN2021	1/2	1	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1179 11791066	NERV	Pain/ BODY ACHES#	4	09JAN2021	1/2	1	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	09JAN2021	1/2	1	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1179 11791066	MUSC	Pain in extremity/ Arm Soreness#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1179 11791079 16-55/ C4591001 1179 11791091	GENRL	Fatigue/ Fatigue#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
		Pyrexia/ Fever#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1179 11791101	GENRL	Fatigue/ Fatigue#	3	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
		Pain/ Body Aches#	3	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
		Pyrexia/ Fever#	3	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1179 11791107	GENRL	Chills/ Chills#	3	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
		Injection site pain/ Injection Site Soreness#	3	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001 1179 11791109	GENRL	Injection site pain/ Injection Site Soreness#	3	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS#	3	21DEC2020	3/2	1	Yes		NA	R (22DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1179 11791118	GENRL	Injection site pain/ Injection Site Soreness#	4	11JAN2021	1/2	1	Yes	NA	NA	R (12JAN2021)	N/N
16-55/ C4591001 1179 11791126	GENRL	Fatigue/ Fatigue#	4	05FEB2021	1/3	1	Yes	NA	NA	R (07FEB2021)	N/N
16-55/ C4591001 1179 11791130	GENRL	Injection site pain/ Injection Site Soreness#	4	05FEB2021	1/3	1	Yes	NA	NA	R (07FEB2021)	N/N
16-55/ C4591001 1179 11791130	GENRL	Injection site pain/ Injection Site Soreness#	4	26JAN2021	1/2	1	Yes	NA	NA	R (27JAN2021)	N/N
16-55/ C4591001 1179 11791136	GENRL	Injection site pain/ Injection Site Soreness#	4	05FEB2021	1/2	1	Yes	NA	NA	R (06FEB2021)	N/N
16-55/ C4591001 1179 11791158	GASTR	Pyrexia/ Fever#	4	05FEB2021	1/2	1	Yes	NA	NA	R (06FEB2021)	N/N
		Diarrhoea/ Mild Diarrhea	2	16NOV2020	1/2	1	Yes	NA/TC	NA/TC	R (17NOV2020)	N/N
		Nausea/ Nausea	2	16NOV2020	1/2	1	Yes	NA/TC	NA/TC	R (17NOV2020)	N/N
		Vomiting/ Vomiting	2	16NOV2020	1/2	1	Yes	NA/TC	NA/TC	R (17NOV2020)	N/N
	NERV	Headache/ Headache	2	16NOV2020	1/2	1	Yes	NA/TC	NA/TC	R (17NOV2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1179 11791162	NERV	Headache/ Headache	2	19NOV2020	1/2	1	Yes		NA/TC	R (20NOV2020)	N/N
16-55/ C4591001 1185 11851032	MUSC	Myalgia/ myalgia#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	NERV	Somnolence/ drowsiness#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1185 11851048	GENRL	Chills/ Chills#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	NERV	Headache/ headache#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1185 11851050	MUSC	Intervertebral disc protrusion/ vertebral slipped disc cervicobrachial C5/C6#	2	13FEB2021	88/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1185 11851054	INJ&P	Arthropod bite/ tick bite right lower leg	1	11NOV2020	14/1	1	No	O	NA	R (11NOV2020)	N/N
16-55/ C4591001 1185 11851055	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	02NOV2020	5/C		No	O	NA	UNK	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1185 11851060	NERV	Somnolence/ Drowsiness#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1185 11851064	GENRL	Fatigue/ Fatigue#	3	09FEB2021	1/8	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1194 11941004	NERV	Headache/ Headache#	3	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1194 11941004	GENRL	Injection site pain/ Pain at injection site#	3	11JAN2021	1/3	2	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1194 11941014	GENRL	Fatigue/ Fatigue#	4	02FEB2021	2/1	2	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1194 11941014	GENRL	Injection site pain/ Pain at injection site#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1194 11941016	GENRL	Fatigue/ Fatigue#	3	27JAN2021	3/4	2	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1194 11941024	GENRL	Injection site pain/ Pain at injection site#	3	27JAN2021	3/25	2	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1194 11941024	GENRL	Injection site pain/ Pain at injection site#	3	25JAN2021	1/6	2	Yes		NA	R (30JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1194 11941026	MUSC	Myalgia/ Muscle pain#	3	26JAN2021	2/5	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1194 11941030	NERV	Headache/ Headache#	4	17FEB2021	15/4	2	Yes		NA	R (20FEB2021)	N/N
	RESP	Asthma/ Worsening of Asthma	2	07NOV2020	1/5	2	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1194 11941032	GENRL	Injection site pain/ Pain at injection site#	3	26JAN2021	2/5	2	Yes		NA	R (30JAN2021)	N/N
	NERV	Headache/ Headache (intermittent)#	3	26JAN2021	2/14	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1194 11941033	GENRL	Injection site pain/ Pain at injection site#	3	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N
	BLOOD	Lymphadenopathy/ Lymphadenopathia (axillar left)#	4	04FEB2021	3/3	2	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1194 11941041	GENRL	Injection site pain/ Pain at injection site#	3	26JAN2021	2/3	2	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1194 11941045	GENRL	Injection site pain/ Pain injection site#	3	29JAN2021	1/4	2	Yes		NA	R (01FEB2021)	N/N	
1194 11941046	GENRL	Injection site pain/ Pain at injection site#	3	26JAN2021	2/4	2	Yes		NA	R (29JAN2021)	N/N	
1194 11941047	GENRL	Fatigue/ Fatigue#	4	15FEB2021	1/4	1	Yes		NA	R (18FEB2021)	N/N	
1194 11941048	GENRL	Injection site pain/ Pain at injection site#	4	15FEB2021	1/5	2	Yes		NA	R (19FEB2021)	N/N	
16-55/ C4591001 1194 11941048	GENRL	Injection site pain/ Pain at injection site#	3	13JAN2021	1/1	1	Yes		NA	R (13JAN2021)	N/N	
16-55/ C4591001 1194 11941054	GENRL	Fatigue/ Fatigue#	4	03FEB2021	1/4	2	Yes		NA	R (06FEB2021)	N/N	
16-55/ C4591001 1194 11941054	GENRL	Injection site pain/ Pain at injection site#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N	
16-55/ C4591001 1194 11941058	GENRL	Injection site pain/ Pain at injection site#	3	12JAN2021	1/4	2	Yes		NA	R (15JAN2021)	N/N	
1194 11941058	NERV	Headache/ Headache#	4	03FEB2021	2/9	2	Yes		NA	R (11FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1194 11941067	BLOOD	Lymphadenopathy/ Swelling lymph node (axillar right)#	4	04FEB2021	3/8	2	Yes		NA	R (11FEB2021)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	4	04FEB2021	3/8	2	Yes		NA	R (11FEB2021)	N/N	
	MUSC	Arthralgia/ Pain at thumb base joint#	4	04FEB2021	3/8	2	Yes		NA	R (11FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	3	15JAN2021	1/6	3	Yes		NA	R (20JAN2021)	N/N	
		Injection site pain/ Pain at injection site#	3	15JAN2021	1/6	2	Yes		NA	R (20JAN2021)	N/N	
		Injection site swelling/ Swelling at injection pain#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N	
	NERV	Headache/ Headache#	3	16JAN2021	2/3	2	Yes		NA	R (18JAN2021)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	4	05FEB2021	1/7	2	Yes		NA	R (11FEB2021)	N/N	
	16-55/ C4591001 1194 11941072	GENRL	Fatigue/ Fatigue#	4	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
		GENRL	Injection site pain/ Pain at injection site#	4	08FEB2021	11/3	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1194 11941080	GENRL	Injection site pain/ Pain at injection site#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1194 11941081	GENRL	Injection site pain/ Pain at injection site#	3	28JAN2021	1/3	2	Yes	NA	NA	R (30JAN2021)	N/N
1194 11941086	NERV	Headache/ Headache#	3	29JAN2021	2/2	2	Yes	NA	NA	R (30JAN2021)	N/N
1194 11941086	NERV	Headache/ Headache#	4	19FEB2021	2/3	2	Yes	NA	NA	R (21FEB2021)	N/N
16-55/ C4591001 1194 11941087	GENRL	Fatigue/ Fatigue#	3	28JAN2021	1/2	2	Yes	NA	NA	R (29JAN2021)	N/N
16-55/ C4591001 1194 11941087	GENRL	Injection site pain/ Pain at injection site#	3	28JAN2021	1/3	2	Yes	NA	NA	R (30JAN2021)	N/N
16-55/ C4591001 1194 11941089	GENRL	Injection site pain/ Pain at injection site#	2	28JAN2021	78/3	2	Yes	NA	NA	R (30JAN2021)	N/N
16-55/ C4591001 1194 11941089	NERV	Headache/ Headache#	2	29JAN2021	79/2	2	Yes	NA	NA	R (30JAN2021)	N/N
16-55/ C4591001 1194 11941090	GENRL	Injection site pain/ Pain at injection site#	3	26JAN2021	1/2	2	Yes	NA	NA	R (27JAN2021)	N/N
16-55/ C4591001 1194 11941090	GENRL	Injection site pain/ Pain at injection site#	4	16FEB2021	1/3	2	Yes	NA	NA	R (18FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site#	3	27JAN2021	2/3	2	Yes	NA	NA	R (29JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1194 11941092	GENRL	Injection site pain/ Pain at injection site#	3	26JAN2021	1/3	2	Yes		NA	R (28JAN2021)	N/N
1194 11941098	GENRL	Injection site pain/ Pain at injection site#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
1194 11941100	MUSC	Arthralgia/ generalized joint pain#	3	28JAN2021	2/3	2	Yes		NA	R (30JAN2021)	N/N
	GASTR	Abdominal pain upper/ Stomach ache#	4	21FEB2021	5/C	2	Yes		NA	N	N/N
16-55/ C4591001 1194 11941103	GENRL	Injection site pain/ Pain at injection site#	3	13JAN2021	2/4	1	Yes		NA	R (16JAN2021)	N/N
16-55/ C4591001 1194 11941106	GENRL	Injection site pain/ Pain at the injection site#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1195 11951003	MUSC	Spondylolisthesis/ Spondylolisthesis L4/5#	2	05FEB2021	93/33	2	No	O	NA	R (09MAR2021)	Y/N
	NERV	Headache/ Headache#	4	10MAR2021	1/3	2	Yes		NA	R (12MAR2021)	N/N
	EAR	Vertigo/ Vertigo#	4	11MAR2021	2/2	1	Yes		NA	R (12MAR2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1195 11951004	GASTR	Nausea/ Nausea#	4	11MAR2021	2/1	1	Yes		NA	R (11MAR2021)	N/N
	GENRL	Chills/ Chills#	4	10MAR2021	1/2	2	Yes		NA	R (11MAR2021)	N/N
16-55/ C4591001 1195 11951008	NERV	Headache/ Headache#	4	11MAR2021	2/1	2	Yes		NA	R (11MAR2021)	N/N
	GENRL	Chills/ Chills#	4	10FEB2021	2/2	2	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1195 11951009	MUSC	Pain in extremity/ limb pain#	4	10FEB2021	2/2	2	Yes		NA	R (11FEB2021)	N/N
	GASTR	Anal prolapse/ anal prolapse#	4	18FEB2021	10/10	3	No	O	NA	R (27FEB2021)	Y/N
	GASTR	Anal fistula/ anal fistula#	4	25FEB2021	17/1	2	Yes		NA	R (25FEB2021)	N/N
	INFEC	Abscess/ Abscess#	4	27FEB2021	19/1	2	No	O	NA	R (27FEB2021)	N/N
	NERV	Sciatica/ Lumboischialgia	1	02NOV2020	19/7	1	No	O	NA/TCN	R (08NOV2020)	N/N
	MUSC	Spondylolisthesis/ worsening of Spondylolisthesis	2	19DEC2020	47/29	3	No	O	NA/TC	R (16JAN2021)	Y/N
	VASC	Hypertension/ worsening Hypertension#	2	20JAN2021	77/C	1	No	O	NA/TC	RG	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1195 11951018	GASTR	Gastritis/ acute Gastritis#	3	30JAN2021	10/7	2	No	O	NA/TC	R (05FEB2021)	N/N
	PSYCH	Sleep disorder/ Sleep disorder#	3	05FEB2021	16/11	1	No	O	NA	R (15FEB2021)	N/N
16-55/ C4591001 1195 11951020	INJ&P	Contusion/ Contusion thorax right#	3	11FEB2021	17/C	3	No	O	NA	RG	N/N
		Fall/ Fall#	3	11FEB2021	17/1	3	No	O	NA	R (11FEB2021)	N/N
16-55/ C4591001 1195 11951023	MUSC	Intervertebral disc protrusion/ herniated disc cervical vertebra	2	16NOV2020	13/5	1	No	O	NA/TC/TCN	R (20NOV2020)	Y/N
	MUSC	Intervertebral disc protrusion/ worsening herniated disc cervical vertebra#	3	29JAN2021	1/C	3	No	O	NA	RG	N/N
	GASTR	Diarrhoea/ Diarrhoea#	4	20FEB2021	2/1	2	Yes		NA	R (20FEB2021)	N/N
		Vomiting/ Vomiting#	4	20FEB2021	2/1	2	Yes		NA	R (20FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	20FEB2021	2/1	2	Yes		NA	R (20FEB2021)	N/N
	GENRL	Injection site erythema/ Redness injection site#	4	21FEB2021	3/7	2	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001	MUSC	Back pain/ lower back pain	2	18NOV2020	13/6	1	No	O	NA/TC	R (23NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1195 11951027 16-55/ C4591001	NERV	Sciatica/ Lumboischialgia	1	19OCT2020	4/39	1	No	O	NA	R (26NOV2020)	N/N
1195 11951030 16-55/ C4591001	MUSC	Myalgia/ Myalgia#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
1195 11951041	NERV	Headache/ Headache#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	16FEB2021	1/2	2	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	1/2	2	Yes		NA	R (17FEB2021)	N/N
	GENRL	Chills/ Chills#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1195 11951053	GENRL	Chills/ Chills#	3	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
		Injection site pain/ Pain injection site#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Chills/ Chills#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	20FEB2021	2/1	2	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	4	12MAR2021	1/C	2	Yes		NA	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1195 11951064	MUSC	Myalgia/ muscle pain#	4	12MAR2021	1/C	2	Yes		NA	N	N/N	
16-55/ C4591001 1195 11951066	GENRL	Chills/ Chills#	3	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N	
16-55/ C4591001 1195 11951070	GENRL	Injection site pain/ Pain injection side#	3	27JAN2021	2/4	2	Yes		NA	R (30JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	
	NERV	Headache/ Headache#	3	27JAN2021	2/2	2	Yes		NA	R (28JAN2021)	N/N	
16-55/ C4591001 1195 11951075	GENRL	Chills/ Chills#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N	
16-55/ C4591001 1195 11951076	GENRL	Chills/ Chills#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N	
	NERV	Headache/ Headache#	4	10FEB2021	2/1	2	Yes		NA	R (10FEB2021)	N/N	
16-55/ C4591001 1195 11951100	GASTR	Vomiting/ Emesis	1	18OCT2020	1/1	1	No	O	NA	R (18OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1195 11951117	MUSC	Back pain/ Lumbago	2	03DEC2020	27/5	1	No	O	NA/TC	R (07DEC2020)	N/N
16-55/ C4591001 1195 11951134	GENRL	Injection site erythema/ Redness injection site#	3	18FEB2021	1/5	1	Yes		NA/TC	R (22FEB2021)	N/N
		Injection site swelling/ Swelling injection site#	3	18FEB2021	1/5	1	Yes		NA/TC	R (22FEB2021)	N/N
	SKIN	Urticaria/ intermittent generalized Urticaria#	3	21FEB2021	4/1	2	Yes		NA	R (21FEB2021)	N/N
	SKIN	Urticaria/ Urticaria Arm left#	3	22FEB2021	5/9	3	Yes		NA/TC	R (02MAR2021)	N/N
	GENRL	Injection site erythema/ Redness injection site#	4	11MAR2021	1/C	2	Yes		NA/TC	N	N/N
		Injection site swelling/ Swelling injection site#	4	11MAR2021	1/C	2	Yes		NA/TC	N	N/N
16-55/ C4591001 1195 11951135	INJ&P	Epicondylitis/ Epicondylitis humeri radialis right	2	30NOV2020	20/56	1	No	O	NA	R (24JAN2021)	N/N
16-55/ C4591001 1195 11951136	GENRL	Injection site pain/ pain on the injection site#	3	08FEB2021	1/4	2	Yes		NA	R (11FEB2021)	N/N
	GASTR	Nausea/ Nausea#	4	02MAR2021	2/3	2	Yes		NA	R (04MAR2021)	N/N
	NERV	Headache/ Headache#	4	02MAR2021	2/3	2	Yes		NA	R (04MAR2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1195 11951141	MUSC	Intervertebral disc protrusion/ herniated disc thoracic spine	1	21OCT2020	2/C	2	No	O	NA/TC/TCN	RG	N/N	
	MUSC	Osteochondrosis/ Osteochondrosis	1	02NOV2020	14/C	1	No	O	NA	N	N/N	
		Scoliosis/ Scoliosis	1	02NOV2020	14/C	1	No	O	NA	N	N/N	
	MUSC	Intervertebral disc protrusion/ herniated disc cervical spine	1	09NOV2020	21/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1195 11951148	MUSC	Spinal disorder/ cervical spine syndrome	1	02NOV2020	14/45	1	No	O	NA/TC	R (16DEC2020)	N/N	
	GENRL	Injection site pain/ pain injection site#	3	09FEB2021	2/7	2	Yes		NA	R (15FEB2021)	N/N	
	GASTR	Nausea/ Nausea#	3	24FEB2021	17/2	1	Yes		NA/TC	R (25FEB2021)	N/N	
16-55/ C4591001 1197 11971003	VASC	Hypertension/ hypertension	1	01NOV2020	18/18	2	No	O	NA/TC	R (18NOV2020)	N/N	
	GENRL	Fatigue/ fatigue#	3	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N	
	GENRL	Injection site pain/ pain at injection site#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N	
	NERV	Headache/ headache#	4	19FEB2021	1/2	2	Yes		NA/TC	R (20FEB2021)	N/N	
	GENRL	Peripheral swelling/ arm swelling#	4	20FEB2021	2/1	2	Yes		NA	R (20FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1197 11971015	MUSC	Myalgia/ muscle pain#	4	20FEB2021	2/2	2	Yes		NA/TC	R (21FEB2021)	N/N
	MUSC	Tendon pain/ Worsening of Achillodynia	2	22NOV2020	17/55	2	No	O	NA/TC/TCN	R (15JAN2021)	N/N
16-55/ C4591001 1197 11971017	GENRL	Pyrexia/ Fever#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1197 11971019	NERV	Dizziness/ lightheadedness	1	22OCT2020	7/1	2	No	O	NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1197 11971020	GASTR	Gastritis/ Gastritis#	3	07FEB2021	17/6	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1197 11971026	NERV	Headache/ Headache#	4	17FEB2021	5/2	2	No	O	NA/TC	R (18FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site left arm#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	26FEB2021	1/4	1	Yes		NA	R (01MAR2021)	N/N
16-55/ C4591001	NERV	Headache/ headache#	4	27FEB2021	2/3	1	Yes		NA	R (01MAR2021)	N/N
	PSYCH	Depression/ depression	2	12NOV2020	9/51	1	No	O	NA/TCN	R (01JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1197 11971028 16-55/ C4591001 1197 11971031	MUSC	Tenosynovitis/ Tenosynovitis right forearm	2	15JAN2021	71/C	2	No	O	NA/TC	N	N/N	
1197 11971031	NERV	Headache/ headache#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N	
16-55/ C4591001 1197 11971035	MUSC	Pain in extremity/ pain at arm#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N	
	NERV	Headache/ headache#	3	31JAN2021	3/1	1	Yes		NA	R (31JAN2021)	N/N	
	GENRL	Pyrexia/ Fever#	4	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N	
	GENRL	Injection site pain/ pain at injection site left arm#	4	19FEB2021	2/5	1	Yes		NA	R (23FEB2021)	N/N	
16-55/ C4591001 1197 11971039	VASC	Hypertension/ worsening hypertension	1	01NOV2020	16/C	2	No	O	NA/TC	N	N/N	
	GENRL	Fatigue/ Fatigue#	2	08FEB2021	94/C	2	Yes		NA	N	N/N	
	PSYCH	Adjustment disorder/ Adapt Problems#	2	08FEB2021	94/C	2	No	O	NA	N	N/N	
	SOCCI	Job dissatisfaction/ Place of Employment Problems#	2	08FEB2021	94/C	2	No	O	NA	N	N/N	
16-55/ C4591001	GENRL	Fatigue/ fatigue#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1197 11971040	MUSC	Myalgia/ muscle pain arm#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	3	01FEB2021	4/4	1	Yes		NA	R (04FEB2021)	N/N	
	MUSC	Myalgia/ muscle pain#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N	
16-55/ C4591001 1197 11971041	MUSC	Pain in extremity/ arm pain#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N	
	NERV	Headache/ headache#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N	
16-55/ C4591001 1197 11971053	MUSC	Back pain/ worsening back pain	2	19NOV2020	13/13	2	No	O	NA/TC	R (01DEC2020)	N/N	
16-55/ C4591001 1197 11971060	GENRL	Injection site pain/ pain at injection site let arm#	3	03FEB2021	1/2	2	Yes		NA	R (04FEB2021)	N/N	
	GENRL	Pyrexia/ Fever#	4	27FEB2021	2/1	2	Yes		NA/TC	R (27FEB2021)	N/N	
	MUSC	Myalgia/ muscle pain#	4	27FEB2021	2/2	2	Yes		NA/TC	R (28FEB2021)	N/N	
	NERV	Headache/ headache#	4	27FEB2021	2/2	2	Yes		NA/TC	R (28FEB2021)	N/N	
16-55/ C4591001	INFEC	Epididymitis/ Epididymitis right#	2	02FEB2021	89/C	2	No	O	NA/TC	RG	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1197 11971064	MUSC	Myalgia/ Musclepain#	3	05FEB2021	1/3	2	Yes		NA	R (07FEB2021)	N/N
	MUSC	Myalgia/ Muscle Pain#	4	26FEB2021	1/2	1	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001	NERV	Carpal tunnel syndrome/ Carpal Tunnel Syndrome Right Hand#	2	15FEB2021	102/C	2	No	O	NA/TCN	N	N/N
1197 11971068	GENRL	Chills/ Chills#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001	GENRL	Pyrexia/ fever#	3	05FEB2021	1/2	2	Yes		NA	R (06FEB2021)	N/N
1197 11971069	GENRL	Pyrexia/ fever#	4	26FEB2021	1/2	2	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Musclepain under the injection Point#	3	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
1197 11971088	GENRL	Malaise/ Indisposed#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection siede#	4	24FEB2021	1/3	2	Yes		NA/TC	R (26FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
	GENRL	Pain/ generalized pain#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1197 11971093	NERV	Headache/ Headache#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N	
	GENRL	Fatigue/ fatigue#	3	22JAN2021	1/10	1	Yes		NA	R (31JAN2021)	N/N	
		Pyrexia/ fever (38.5C)#	3	22JAN2021	1/2	2	Yes		NA/TC	R (23JAN2021)	N/N	
	MUSC	Pain in extremity/ pain left arm#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N	
	GENRL	Chills/ shivering#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N	
	GENRL	Chills/ chills#	4	13FEB2021	1/2	2	Yes		NA	R (14FEB2021)	N/N	
		Fatigue/ fatigue#	4	13FEB2021	1/3	2	Yes		NA	R (15FEB2021)	N/N	
16-55/ C4591001 1197 11971094		Pyrexia/ fever#	4	13FEB2021	1/2	1	Yes		NA	R (14FEB2021)	N/N	
	NERV	Headache/ headache#	4	13FEB2021	1/3	2	Yes		NA/TC	R (15FEB2021)	N/N	
	MUSC	Back pain/ back pain	2	20NOV2020	14/9	2	No	O	NA/TC	R (28NOV2020)	N/N	
	GENRL	Injection site pain/ pain art injection site#	3	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	3	30JAN2021	2/1	1	Yes		NA	R (30JAN2021)	N/N	
	GENRL	Injection site pain/ pain at injection site#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
		Pyrexia/ fever#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1197 11971096	NERV	Migraine/ worsening migraine	1	21OCT2020	3/3	2	No	O	NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1203 12031004	REPRO	Dysmenorrhoea/ menstrual pain	1	04NOV2020	20/1	2	No	O	NA/TC	R (04NOV2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	03MAR2021	1/5	2	Yes		NA/TC	R (07MAR2021)	N/N
	GENRL	Fatigue/ fatigue#	3	04MAR2021	2/2	1	Yes		NA	R (05MAR2021)	N/N
16-55/ C4591001 1203 12031005	NERV	Headache/ headache	2	01DEC2020	26/1	2	No	O	NA/TC	R (01DEC2020)	N/N
	GASTR	Umbilical hernia/ hernia umbilicalis	2	08JAN2021	64/48	2	No	O	NA/TC	R (24FEB2021)	N/N
	GENRL	Vaccination site reaction/ local vaccination reaction#	3	01MAR2021	1/3	2	Yes		NA	R (03MAR2021)	N/N
16-55/ C4591001 1203 12031015	NERV	Headache/ headache	1	28OCT2020	10/5	3	No	O	NA/TC	R (01NOV2020)	N/N
	NERV	Headache/ headache	1	05NOV2020	18/1	2	No	O	NA/TC	R (05NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1203 12031020	GENRL	Injection site pain/ tenderness at injection site#	3	10FEB2021	1/1	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1203 12031020	GENRL	Injection site pain/ tenderness at injection site#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1203 12031026	NERV	Headache/ headache	1	07NOV2020	19/1	2	No	O	NA/TC	R (07NOV2020)	N/N
	GASTR	Inguinal hernia/ inguinal hernia left	1	09NOV2020	21/103	2	No	O	NA/TC/TCN	R (19FEB2021)	Y/N
	NERV	Headache/ systemic vaccination reaction headache#	3	01MAR2021	1/1	2	Yes		NA/TC	R (01MAR2021)	N/N
16-55/ C4591001 1203 12031031	SKIN	Urticaria/ urticaria upper and lower body	1	22OCT2020	3/7	2	No	O	NA/TC	R (28OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	11FEB2021	2/3	2	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1203 12031032	GENRL	Injection site pain/ tenderness at injection site#	3	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
	SKIN	Hyperhidrosis/ sweating#	3	12FEB2021	1/2	2	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1203 12031033	NERV	Disturbance in attention/ concentration deficite	1	21OCT2020	1/8	2	Yes		NA	R (28OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Disturbance in attention/ concentration deficite	2	11NOV2020	1/11	2	Yes		NA	R (21NOV2020)	N/N
	NERV	Aphasia/ dysphasia	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
	NERV	Dizziness/ dizziness	2	13NOV2020	3/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1203 12031034	GENRL	Injection site pain/ pain at injection site#	3	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1203 12031037	INFEC	Rhinitis/ rhinitis	1	02NOV2020	13/15	1	No	O	NA/TC	R (16NOV2020)	N/N
	INFEC	Oral herpes/ herpes labialis	1	07NOV2020	18/10	1	No	O	NA	R (16NOV2020)	N/N
16-55/ C4591001 1203 12031044	INFEC	Cystitis/ cystitis	1	30OCT2020	10/5	2	Yes		NA/TC	R (03NOV2020)	N/N
	NERV	Headache/ headache	1	04NOV2020	15/1	2	No	O	NA/TC	R (04NOV2020)	N/N
	GASTR	Odynophagia/ pain when swallowing	1	05NOV2020	16/4	1	No	O	NA	R (08NOV2020)	N/N
	INFEC	Cystitis/ cystitis	2	21NOV2020	11/5	2	Yes		NA/TC	R (25NOV2020)	N/N
	GENRL	Injection site pain/ tenderness at injection site#	3	08FEB2021	1/4	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ tenderness at injection site#	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1203 12031047	GENRL	Malaise/ Malaise#	4	03MAR2021	1/3	2	Yes		NA	R (05MAR2021)	N/N
	MUSC	Arthralgia/ Arthralgia#	4	03MAR2021	1/3	2	Yes		NA	R (05MAR2021)	N/N
	GENRL	Pyrexia/ Fever#	4	04MAR2021	2/2	1	Yes		NA/TC	R (05MAR2021)	N/N
16-55/ C4591001 1203 12031048	GENRL	Injection site pain/ pain at injection site#	3	10FEB2021	1/6	2	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1203 12031051	INFEC	Pustule/ pustulas frontal head and cheeks	1	26OCT2020	4/6	1	Yes		NA	R (31OCT2020)	N/N
16-55/ C4591001 1203 12031056	INJ&P	Lip injury/ laceration Right upper lip	2	14NOV2020	2/13	2	No	O	NA/TC/TCN	R (26NOV2020)	N/N
		Tooth fracture/ tooth fracture	2	14NOV2020	2/49	1	No	O	NA	R (01JAN2021)	N/N
16-55/ C4591001 1203 12031058	INFEC	Rhinitis/ rhinitis	1	06NOV2020	15/10	2	No	O	NA	R (15NOV2020)	N/N
	GENRL	Injection site pain/ tenderness at injection site#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ headache#	3	08FEB2021	1/2	2	Yes		NA	R (09FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1203 12031059	GENRL	Malaise/ malaise#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Medical device pain/ toothache afte totth brace implantation#	2	13JAN2021	62/17	2	No	O	NA/TC	R (29JAN2021)	N/N
	SURG	Orthodontic procedure/ implantation of permanent tooth brace#	2	13JAN2021	62/1	1	No	O	NA	R (13JAN2021)	N/N
	GASTR	Diarrhoea/ diarrhea#	4	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N
		Nausea/ nausea#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	10FEB2021	1/2	3	Yes		NA	R (11FEB2021)	N/N
		Pyrexia/ fever up to 39.8 degree#	4	10FEB2021	1/2	3	Yes		NA/TC	R (11FEB2021)	N/N
	NERV	Headache/ headache#	4	10FEB2021	1/2	2	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1203 12031064	GASTR	Nausea/ nausea	2	17NOV2020	2/3	2	Yes		NA	R (19NOV2020)	N/N
	NERV	Dizziness/ dizziness	2	18NOV2020	3/4	2	Yes		NA	R (21NOV2020)	N/N
	NERV	Headache/ headache	2	30NOV2020	15/1	2	No	O	NA/TC	R (30NOV2020)	N/N
	NERV	Dizziness/ dizziness	2	13DEC2020	28/1	2	No	O	NA	R (13DEC2020)	N/N
16-55/ C4591001	GASTR	Flatulence/ meteorism	2	17NOV2020	2/C	1	No	O	NA	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1203 12031066 16-55/ C4591001 1203 12031067	GENRL	Injection site pain/ pain at injection site#	3	12FEB2021	1/3	2	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1203 12031069	INFEC	Malaise/ malaise#	3	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
	INFEC	Cystitis/ cystitis	2	28NOV2020	13/3	2	No	O	NA/TC	R (30NOV2020)	N/N
	INFEC	Vulvovaginal mycotic infection/ vaginal mycosis	2	30NOV2020	15/9	2	No	O	NA/TC	R (08DEC2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
		Malaise/ malaise#	3	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
	MUSC	Arthralgia/ joint pain#	3	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
	NERV	Headache/ headache due to Vaccination#	3	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1204 12041001	GENRL	Injection site pain/ Injection Site Pain	1	24AUG2020	1/3	1	Yes		NA/TC	R (26AUG2020)	N/N
		Pyrexia/ Fever	1	24AUG2020	1/2	1	Yes		NA/TC	R (25AUG2020)	N/N
	GASTR	Dyspepsia/ Heart Burn	1	12SEP2020	20/2	2	No	O	NA/TC	R (13SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1204 12041005	GASTR	Retching/ gagging lasting 5-10 seconds, with second episode today	1	06SEP2020	13/2	1	No	O	NA	R (07SEP2020)	N/N	
	IMMUN	Hypersensitivity/ allergies, normal per patient.	1	06SEP2020	13/2	1	No	O	NA	R (07SEP2020)	N/N	
16-55/ C4591001 1204 12041006	GENRL	Malaise/ body malaise#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N	
		Pyrexia/ Fever 102 F#	4	05JAN2021	1/3	2	Yes		NA/TC	R (07JAN2021)	N/N	
16-55/ C4591001 1204 12041008	GENRL	Pyrexia/ Fever	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N	
	MUSC	Myalgia/ Grade 1 Myalgias	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N	
	GENRL	Fatigue/ fatigue	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	
	MUSC	Myalgia/ Muscle aches	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001 1204 12041009	GENRL	Fatigue/ Fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
		Pyrexia/ Mild fever	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001	NERV	Headache/ Headache	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Investigational Vaccine Dose/ Subject	Action: Outcome (End Date)	SAE/Imm AE (Yes/No)
1204 12041010	GENRL	Injection site pain/ left arm soreness at injection site#	3	06JAN2021	1/3	1	Yes	NA	R (08JAN2021)	N/N
	GENRL	Chills/ chills#	3	07JAN2021	2/1	1	Yes	NA	R (07JAN2021)	N/N
16-55/ C4591001 1204 12041012	GENRL	Chills/ chills	2	18SEP2020	1/2	1	Yes	NA	R (19SEP2020)	N/N
16-55/ C4591001 1204 12041013	GENRL	Fatigue/ Fatigue	2	19SEP2020	2/3	1	Yes	NA	R (21SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	19SEP2020	2/3	1	Yes	NA	R (21SEP2020)	N/N
16-55/ C4591001 1204 12041015	GENRL	Fatigue/ Fatigue	2	18SEP2020	1/2	1	Yes	NA	R (19SEP2020)	N/N
		Injection site pain/ Muscle pain at injection site	2	18SEP2020	1/2	1	Yes	NA	R (19SEP2020)	N/N
16-55/ C4591001 1204 12041017	GENRL	Chills/ Chills	2	28SEP2020	1/3	1	Yes	NA/TC	R (30SEP2020)	N/N
		Pyrexia/ Fever	2	28SEP2020	1/3	2	Yes	NA/TC	R (30SEP2020)	N/N
16-55/ C4591001	MUSC	Back pain/ Back soreness	2	04OCT2020	7/2	1	Yes	NA/TC	R (05OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1204 12041018	GENRL	Injection site pain/ Pain at the Injection Site	1	31AUG2020	1/3	2	Yes		NA/TC	R (02SEP2020)	N/N	
1204 12041020	GENRL	Injection site pain/ left arm pain (injection site)#	4	06JAN2021	1/3	1	Yes		NA/TC	R (08JAN2021)	N/N	
16-55/ C4591001 1204 12041021	GENRL	Fatigue/ moderate to strong fatigue after the injection lasting days	1	01SEP2020	2/6	1	Yes		NA	R (06SEP2020)	N/N	
1204 12041021	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 1204 12041023	BLOOD	Lymphadenopathy/ swollen lymph node gland on neck	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N	
1204 12041023	GENRL	Injection site pain/ Pain at injection site	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N	
1204 12041023	GENRL	Pyrexia/ Subjective Fever	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N	
1204 12041023	GENRL	Chills/ chills	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 1204 12041025	GENRL	Injection site pain/ left arm pain (injection site)#	3	13JAN2021	1/3	1	Yes		NA/TC	R (15JAN2021)	N/N	
16-55/ C4591001	MUSC	Arthralgia/ Sore Left Shoulder	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1204 12041026	GASTR	Nausea/ nausea	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Chills/ Chills	2	22SEP2020	1/8	1	Yes		NA	R (29SEP2020)	N/N
		Fatigue/ Fatigue	2	22SEP2020	1/8	1	Yes		NA	R (29SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ myalgias	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ Severe headache	2	22SEP2020	1/25	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1204 12041029	NERV	Dizziness/ Dizziness	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1204 12041030	GASTR	Diarrhoea/ non-bloody diarrhea x2 - his fiance who is not participating in the study also experience diarrhea	1	08SEP2020	7/1	1	No	O	NA	R (08SEP2020)	N/N
16-55/ C4591001 1204 12041039	GENRL	Chills/ chills	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	SKIN	Hyperhidrosis/ sweats	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Chills/ Chills	1	25SEP2020	22/2	1	Yes		NA	R (26SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041040	GENRL	Fatigue/ Fatigue	1	25SEP2020	22/2	1	Yes	NA	R	(26SEP2020)	N/N
		Pyrexia/ Fever, 101#	4	28JAN2021	1/4	2	Yes	NA/TC	R	(31JAN2021)	N/N
	EAR	Ear pain/ Right ear pain#	4	29JAN2021	2/3	2	Yes	NA/TC	R	(31JAN2021)	N/N
16-55/ C4591001 1204 12041043	GENRL	Injection site pain/ Pain at injection site	1	04SEP2020	1/3	1	Yes	NA	R	(06SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	05SEP2020	2/2	1	Yes	NA	R	(06SEP2020)	N/N
	NERV	Dizziness/ Dizziness	1	18SEP2020	15/3	1	Yes	NA	R	(20SEP2020)	N/N
	GENRL	Injection site pain/ left arm pain (vac #2 injection site)	2	25SEP2020	1/2	1	Yes	NA	R	(26SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	26SEP2020	2/1	1	Yes	NA	R	(26SEP2020)	N/N
	NERV	Dizziness/ dizziness	2	29SEP2020	5/2	1	Yes	NA	R	(30SEP2020)	N/N
	16-55/ C4591001 1204 12041047	GASTR	Nausea/ Nausea#	3	18FEB2021	2/3	1	Yes	NA	R	(20FEB2021)
GENRL		Pyrexia/ Fever#	3	18FEB2021	2/3	1	Yes	NA	R	(20FEB2021)	N/N
NERV		Headache/ Headache#	3	18FEB2021	2/3	1	Yes	NA	R	(20FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041049	GENRL	Pyrexia/ low grade fever	1	09SEP2020	2/2	2	Yes		NA/TC	R (10SEP2020)	N/N
	GENRL	Pyrexia/ Low grade fever, maximum temp of 100.3 F	2	29SEP2020	1/3	1	Yes		NA/TC	R (01OCT2020)	N/N
	MUSC	Pain in extremity/ left arm pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1204 12041055	GENRL	Injection site pain/ injection site pain	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1204 12041058	GENRL	Fatigue/ Fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	01OCT2020	3/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1204 12041059	GENRL	Chills/ Chills	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1204 12041064	MUSC	Pain in extremity/ left arm pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041066	GENRL	Injection site pain/ left arm soreness (injection site)#	4	04JAN2021	1/3	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N
		Pyrexia/ Low grade fever (100.7F)#	4	05JAN2021	2/2	1	Yes		NA/TC	R (06JAN2021)	N/N
16-55/ C4591001 1204 12041067	GENRL	Injection site pain/ injection site pain	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1204 12041071	GENRL	Pyrexia/ Fever: Temp 101 F	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
	MUSC	Pain in extremity/ right arm pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	NERV	Headache/ Headache	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1204 12041072	GASTR	Diarrhoea/ mild diarrhea	1	11SEP2020	3/2	1	Yes		NA	R (12SEP2020)	N/N
	MUSC	Arthralgia/ left shoulder pain	2	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/N
	INJ&P	Animal bite/ Cat bite, left index finger#	3	28FEB2021	17/C	1	No	O	NA/TC	RG	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041073	NERV	Migraine/ Migraine	1	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1204 12041075	GENRL	Pyrexia/ Low grade fever, 102	1	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
	GENRL	Pyrexia/ Low grade fever, 100	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1204 12041077	GENRL	Influenza like illness/ Flu-like symptoms	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		Vomiting/ Vomiting	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Chills/ Chills	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		Fatigue/ Fatigue	2	01OCT2020	2/5	1	Yes		NA	R (05OCT2020)	N/N
		Pain/ Generalized body aches	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		Pyrexia/ fever 101.2	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N
	NERV	Migraine/ Migraine	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001	BLOOD	Lymphadenopathy/ Swollen lymph nodes neck area (left side )#	4	05FEB2021	2/C	1	Yes		NA	RG	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1204 12041078	GENRL	Chills/ chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
16-55/ C4591001 1204 12041080		Fatigue/ fatigue	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N	
		Injection site pain/ Injection site pain (post administration of injection #2)	2	30SEP2020	1/6	1	Yes		NA	R (05OCT2020)	N/N	
16-55/ C4591001 1204 12041082	INV	Body temperature increased/ elevated temperature, 100.1	1	11SEP2020	2/3	1	Yes		NA/TC	R (13SEP2020)	N/N	
16-55/ C4591001 1204 12041086	GENRL	Chills/ Chills	1	12SEP2020	3/1	2	Yes		NA/TC	R (12SEP2020)	N/N	
	MUSC	Myalgia/ Muscle aches	1	12SEP2020	3/2	1	Yes		NA	R (13SEP2020)	N/N	
	GENRL	Chills/ chills	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001 1204 12041091	GENRL	Pyrexia/ low grade fever, max temp of 100 F	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001 1204 12041093	MUSC	Pain in extremity/ left arm pain (post vaccine #2)	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
		Fatigue/ fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1204 12041095	VASC	Hot flush/ Feeling of hot flushes	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1204 12041097	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1204 12041100	GENRL	Injection site pain/ right arm soreness (injection site)#	3	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1204 12041107	GENRL	Injection site pain/ pain at injection site	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ headache	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1204 12041108	GENRL	Injection site pain/ left arm soreness at injection site#	3	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	27JAN2021	1/2	2	Yes		NA/TC	R (28JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1204 12041110	MUSC	Myalgia/ Myalgia#	4	27JAN2021	1/2	2	Yes		NA/TC	R (28JAN2021)	N/N	
	GENRL	Chills/ chills#	4	07JAN2021	2/2	1	Yes		NA/TC	R (08JAN2021)	N/N	
16-55/ C4591001 1204 12041111	MUSC	Back pain/ back pain#	4	07JAN2021	2/2	1	Yes		NA/TC	R (08JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001 1204 12041112	MUSC	Pain in extremity/ Pain left arm	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N	
	NERV	Headache/ Headache	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N	
16-55/ C4591001 1204 12041116	GENRL	Chills/ Chills#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N	
	INFEC	Fungal skin infection/ fungal infection small toe right foot#	4	28JAN2021	23/14	2	No	O	NA/TC	R (10FEB2021)	N/N	
16-55/ C4591001 1204 12041121	GENRL	Injection site pain/ left upper arm pain (injection site)	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041123	GENRL	Pyrexia/ Low grade fever 100.3 F	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
	MUSC	Back pain/ mild back pain	1	20SEP2020	3/15	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
		Injection site pain/ left arm soreness (vac #2 injection site)	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1204 12041124	GASTR	Diarrhoea/ Diarrhea	1	28SEP2020	11/8	1	No	CD	NA	R (05OCT2020)	N/N
16-55/ C4591001 1204 12041125		Nausea/ Nausea	1	28SEP2020	11/8	1	No	CD	NA	R (05OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Pyrexia/ Feeling hot/feverish	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/Y
16-55/ C4591001 1204 12041125	GENRL	Chills/ Chills	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1204 12041128	GENRL	Fatigue/ fatigue	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
		Pain/ body aches	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041129	MUSC	Pain in extremity/ whole left arm pain	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
	MUSC	Myalgia/ Generalized myalgia#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1204 12041131	NERV	Headache/ Headache#	4	03FEB2021	2/1	2	Yes		NA	R (03FEB2021)	N/N
	MUSC	Pain in extremity/ Right Arm Pain#	3	09FEB2021	1/3	2	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1204 12041133	GENRL	Chills/ Chills	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1204 12041136	MUSC	Myalgia/ Myalgia	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Injection site pain/ left arm soreness (vac#2 injection site)	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1204 12041137	GASTR	Nausea/ Nausea#	4	06JAN2021	1/3	2	Yes		NA	R (08JAN2021)	N/N
	GENRL	Chills/ Chills#	4	06JAN2021	1/3	2	Yes		NA/TC	R (08JAN2021)	N/N
		Malaise/ Body Malaise#	4	06JAN2021	1/3	2	Yes		NA/TC	R (08JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1204 12041138	MUSC	Arthralgia/ opposite shoulder pain intermittent	1	22SEP2020	2/2	1	No	O	NA	R (23SEP2020)	N/N	
	GENRL	Myalgia/ muscle pain - abdominal	1	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
		Fatigue/ Fatigue	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N	
		Injection site pain/ Muscle tenderness at injection site	2	12OCT2020	1/3	1	Yes		NA/TC	R (14OCT2020)	N/N	
	METAB	Polydipsia/ Polydipsia	2	12OCT2020	1/4	2	Yes		NA	R (15OCT2020)	N/N	
	BLOOD	Lymphadenopathy/ Swollen submandibular lymph nodes	2	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N	
	GENRL	Pyrexia/ Low grade fever, 99.0	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N	
16-55/ C4591001 1204 12041139	GENRL	Injection site pain/ Pain left arm at injection site	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N	
	GENRL	Chills/ Chills	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N	
		Pyrexia/ Fever (100.4)	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N	
16-55/ C4591001 1204 12041144	GASTR	Hypoaesthesia oral/ tongue numbness	1	24SEP2020	3/2	1	Yes		NA	R (25SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	1	24SEP2020	3/2	1	Yes		NA	R (25SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041145	GENRL	Chills/ chills	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ Injection site pain	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Low grade fever 100.3 F	1	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Chills/ chills	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
		Pyrexia/ Fever; max temp of 102 F	2	14OCT2020	1/3	2	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1204 12041147	GENRL	Injection site pain/ Muscle tenderness on injection site	1	23SEP2020	1/7	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1204 12041150	GENRL	Fatigue/ Fatigue	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ Headache	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1204 12041153	GENRL	Chills/ Chills	1	30SEP2020	8/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1204 12041154†	GENRL	Fatigue/ tired	1	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041155	GENRL	Fatigue/ fatigue	1	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ headache	1	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1204 12041167	GENRL	Injection site pain/ Muscle tenderness at injection site	1	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Injection site pain/ left arm soreness (vac #2 injection site)	2	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1204 12041170	MUSC	Myalgia/ Muscle aches	1	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Pyrexia/ Fever (100.4)	2	16OCT2020	1/2	1	Yes		NA/TC	R (17OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	16OCT2020	1/2	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 1204 12041176†	GENRL	Pyrexia/ Subjective low grade fever	2	21OCT2020	3/1	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1204 12041178	GENRL	Fatigue/ Fatigue	1	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1204 12041182†	GENRL	Fatigue/ Fatigue	2	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N	
		Injection site pain/ Muscle tenderness at injection site	2	21OCT2020	1/6	1	Yes		NA	R (26OCT2020)	N/N	
	GENRL	Pyrexia/ Low grade fever, 100.6	2	22OCT2020	2/1	1	Yes		NA/TC	R (22OCT2020)	N/N	
	GENRL	Chills/ chills	2	04NOV2020	7/2	1	Yes		NA	R (05NOV2020)	N/N	
		Malaise/ malaise	2	04NOV2020	7/2	1	Yes		NA	R (05NOV2020)	N/N	
	MUSC	Myalgia/ Muscle aches	2	04NOV2020	7/2	1	Yes		NA	R (05NOV2020)	N/N	
	GENRL	Injection site pain/ pain at injection site	1	02OCT2020	1/4	1	Yes		NA	R (05OCT2020)	N/N	
	GENRL	Injection site pain/ injection site pain	2	29OCT2020	1/4	1	Yes		NA	R (01NOV2020)	N/N	
	METAB	Dehydration/ dehydration	2	31OCT2020	9/2	3	No	O	NA	R (01NOV2020)	N/N	
	NERV	Syncope/ syncope	2	31OCT2020	9/2	3	No	O	NA	R (01NOV2020)	N/N	
16-55/ C4591001 1204 12041187	GENRL	Injection site pain/ pain at injection site	1	05OCT2020	1/4	1	Yes		NA	R (08OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041188†	GENRL	Pyrexia/ Low grade fever, 100.4	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
	NERV	Headache/ Headaches	2	26OCT2020	1/1	2	Yes		NA/TC	R (26OCT2020)	N/N
	GENRL	Injection site pain/ Muscle tenderness at injection site	2	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1204 12041191	RESP	Dyspnoea/ mild shortness of breath	1	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
	SKIN	Pruritus/ itching left arm	1	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
		Pruritus/ itching left leg	1	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ Headache	2	26OCT2020	1/2	2	Yes		NA/TC	R (27OCT2020)	N/N
	GENRL	Injection site pain/ Muscle tenderness at injection site	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
		Pyrexia/ Low grade fever, 100.4	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
	SKIN	Rash/ Rash on the back of neck	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	1	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1204 12041192	GASTR	Diarrhoea/ Diarrhea	1	08OCT2020	3/4	1	Yes		NA	R (11OCT2020)	N/N	
	GENRL	Pyrexia/ Fever	1	08OCT2020	3/2	2	Yes		NA/TC	R (09OCT2020)	N/N	
	GENRL	Chills/ Chills	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N	
16-55/ C4591001 1204 12041194†	GENRL	Fatigue/ Fatigue	2	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N	
16-55/ C4591001 1204 12041195	NERV	Headache/ Headache	1	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N	
	GENRL	Injection site pain/ injection site pain	2	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N	
	NERV	Headache/ Headache	2	29OCT2020	2/2	1	Yes		NA/TC	R (30OCT2020)	N/N	
16-55/ C4591001 1204 12041199	INJ&P	Procedural pain/ Pain from hair transplant procedure	2	10NOV2020	12/5	2	No	O	NA/TC	R (14NOV2020)	N/N	
16-55/ C4591001 1204 12041202	NERV	Headache/ Headaches#	4	26JAN2021	1/3	2	Yes		NA/TC	R (28JAN2021)	N/N	
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1204 12041203		Injection site pain/ Muscle tenderness at injection site	1	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain (vac#2 site)	2	29OCT2020	1/4	1	Yes		NA	R (01NOV2020)	N/N	
	NERV	Headache/ headache	2	29OCT2020	1/4	1	Yes		NA/TC	R (01NOV2020)	N/N	
16-55/ C4591001 1204 12041205	GENRL	Pyrexia/ Low grade fever, 100.2	2	30OCT2020	2/1	1	Yes		NA/TC	R (30OCT2020)	N/N	
	MUSC	Myalgia/ Muscle aches	2	30OCT2020	2/2	1	Yes		NA/TC	R (31OCT2020)	N/N	
16-55/ C4591001 1204 12041208	GENRL	Injection site pain/ left arm soreness (injection site)#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	05JAN2021	2/1	1	Yes		NA	R (05JAN2021)	N/N	
16-55/ C4591001 1204 12041209	GENRL	Chills/ Chills	2	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N	
		Injection site pain/ Muscle tenderness at injection site	2	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N	
		Malaise/ Malaise	2	29OCT2020	1/5	1	Yes		NA	R (02NOV2020)	N/N	
	MUSC	Myalgia/ Muscle aches	2	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041210†	GENRL	Injection site pain/ Tenderness at injection site#	3	21JAN2021	2/C	1	Yes		NA	RG	N/N
		Injection site rash/ Localized rash at injection site s/p revaccination#	3	21JAN2021	2/C	2	Yes		NA/TC	RG	N/N
	SKIN	Rash/ Localized rash on left shoulder s/p revaccination#	3	21JAN2021	2/C	2	Yes		NA/TC	RG	N/N
16-55/ C4591001 1204 12041214	GENRL	Chills/ chills	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
		Malaise/ body malaise	1	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
	GENRL	Chills/ Chills	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N
		Pain/ Body aches	2	03NOV2020	2/2	1	Yes		NA/TC	R (04NOV2020)	N/N
16-55/ C4591001 1204 12041220	GASTR	Abdominal discomfort/ stomach discomfort	1	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N
16-55/ C4591001	NERV	Headache/ Headache	1	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1204 12041222	NERV	Headache/ Headache	2	03NOV2020	2/1	1	Yes		NA/TC	R (03NOV2020)	N/N
16-55/ C4591001 1204 12041227	GENRL	Injection site pain/ left arm soreness (vac #1 injection site)	1	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	03NOV2020	1/3	2	Yes		NA	R (05NOV2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
		Pyrexia/ Low grade fever, 100.4	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	03NOV2020	1/3	2	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1204 12041233†	GENRL	Injection site pain/ left arm soreness (injection site)#	3	13JAN2021	1/3	1	Yes		NA/TC	R (15JAN2021)	N/N
16-55/ C4591001 1204 12041234	GENRL	Fatigue/ Fatigue	1	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
		Injection site pain/ Muscle tenderness at injection site	1	15OCT2020	2/4	1	Yes		NA/TC	R (18OCT2020)	N/N
	BLOOD	Lymphadenopathy/ Swollen, tender left axillary lymph node	1	17OCT2020	4/6	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Muscle tenderness at injection site	2	04NOV2020	1/3	1	Yes		NA/TC	R (06NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	BLOOD	Lymphadenopathy/ Right axillary lymph node swelling	2	05NOV2020	2/7	1	Yes		NA	R (11NOV2020)	N/N
	GENRL	Chills/ Chills	2	05NOV2020	2/2	1	Yes		NA/TC	R (06NOV2020)	N/N
		Pyrexia/ Low grade fever, 100.7	2	05NOV2020	2/2	1	Yes		NA/TC	R (06NOV2020)	N/N
	NERV	Headache/ Headache	2	05NOV2020	2/2	2	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1204 12041236	GENRL	Injection site pain/ left arm soreness (vac#1 injection site)	1	15OCT2020	1/1	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1204 12041237	GENRL	Injection site pain/ left arm soreness (vac #1 injection site)	1	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N
		Injection site pain/ Injection site pain	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C4591001 1204 12041239	GENRL	Injection site pain/ left arm soreness (vac#1 injection site)	1	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1204 12041240	NERV	Headache/ Headache	1	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041242	NERV	Headache/ Headache	2	07NOV2020	2/1	1	Yes		NA/TC	R (07NOV2020)	N/N
	GENRL	Injection site pain/ Left Arm Soreness (vac #2 site)	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Chills/ Chills	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
		Pyrexia/ Low Grade Fever (100.4)	2	06NOV2020	2/1	1	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1204 12041248	NERV	Headache/ Headache	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Pyrexia/ low grade fever 100.4F#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1204 12041253	NERV	Headache/ Headache#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
	SKIN	Rash/ rashes at the back of bilateral knees#	4	13JAN2021	2/11	2	Yes		NA/TC	R (23JAN2021)	N/N
		Rash/ rashes in the chest#	4	13JAN2021	2/11	2	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Fatigue/ fatigue	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041255	GENRL	Injection site pain/ left arm soreness (vac#1 injection site)	1	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
		Injection site pain/ left arm soreness (vac#1 injection site)	1	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Fatigue/ fatigue	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
		Pyrexia/ low grade fever; temp 100 F	1	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
	GENRL	Pyrexia/ Low Grade Fever	2	06NOV2020	1/3	1	Yes		NA	R (08NOV2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	06NOV2020	1/3	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C4591001 1204 12041259	GENRL	Fatigue/ Fatigue	1	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1204 12041260	GENRL	Injection site pain/ Pain at injection site	1	16OCT2020	1/4	1	Yes		NA	R (19OCT2020)	N/N
		Pyrexia/ fever - 101.0	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ left arm soreness at injection site#	3	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1204 12041262												
16-55/ C4591001 1204 12041263	GENRL	Injection site pain/ injection site pain	1	19OCT2020	1/4	1	Yes		NA	R (22OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	09NOV2020	1/4	1	Yes		NA	R (12NOV2020)	N/N	
		Injection site pain/ Injection site pain	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N	
	MUSC	Arthralgia/ Generalized Joint Pain	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N	
16-55/ C4591001 1204 12041267	GASTR	Vomiting/ Vomiting	2	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N	
	GENRL	Chills/ Chills	2	17NOV2020	2/3	2	Yes		NA/TC	R (19NOV2020)	N/N	
		Malaise/ Malaise	2	17NOV2020	2/3	2	Yes		NA/TC	R (19NOV2020)	N/N	
		Pain/ Body aches	2	17NOV2020	2/3	2	Yes		NA/TC	R (19NOV2020)	N/N	
16-55/ C4591001 1204 12041268	GENRL	Injection site pain/ Left Arm Soreness (Vaccination #1 Injection Site	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N	
		Malaise/ Body Malaise	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
		Injection site pain/ Left Arm Soreness (vac #2 site)	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N
		Pain/ Body Aches	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1204 12041269	GENRL	Injection site pruritus/ Itchiness in the injection site	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
	NERV	Headache/ Headache	2	10NOV2020	1/1	1	Yes		NA	R (10NOV2020)	N/N
16-55/ C4591001 1204 12041272	GENRL	Injection site pain/ left arm soreness (injection site)#	3	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Malaise/ body malaise#	3	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1204 12041273	GENRL	Injection site pain/ left arm soreness (injection site)#	3	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1204 12041274	GENRL	Injection site pain/ Muscle tenderness at injection site	1	21OCT2020	1/3	1	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1204 12041275	GENRL	Injection site pain/ left arm soreness (vac#1 injection site)	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1204 12041276	NERV	Headache/ headache	1	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N	
	GENRL	Chills/ chills	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N	
		Pyrexia/ low grade fever, 101.0	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N	
	NERV	Headache/ headache	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N	
	GENRL	Chills/ Chills	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N	
		Pain/ Body Aches	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N	
	16-55/ C4591001 1204 12041280	INJ&P	Exposure during pregnancy/ Drug Exposure During Pregnancy	1	21OCT2020	1/20	2	No	O	NA/TC/TCN	R (09NOV2020)	N/N
		SURG	Abortion induced/ Medication abortion	1	09NOV2020	20/1	2	No	O	NA/TC/TCN	R (09NOV2020)	N/N
16-55/ C4591001 1204 12041283	NERV	Headache/ Headache	1	24OCT2020	2/1	2	Yes		NA	R (24OCT2020)	N/N	
	GENRL	Injection site pain/ Muscle Tenderness at the injection site	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N	
	GENRL	Chills/ Chills	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1204 12041285	MUSC	Pyrexia/ Low Grade Fever 101.2	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N	
		Myalgia/ Muscle Aches	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N	
	NERV	Headache/ Headache	2	12NOV2020	2/2	1	Yes		NA/TC	R (13NOV2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N	
16-55/ C4591001 1204 12041287	MUSC	Injection site pain/ Muscle tenderness at injection site Myalgia/ myalgia	2	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N	
	GENRL	Fatigue/ fatigue	1	25OCT2020	3/2	1	Yes		NA	R (26OCT2020)	N/N	
16-55/ C4591001 1204 12041293	GENRL	Pyrexia/ fever	2	14NOV2020	2/1	1	Yes		NA	R (14NOV2020)	N/N	
16-55/ C4591001 1204 12041294	MUSC	Myalgia/ muscle aches	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N	
	NERV	Headache/ headache	2	12NOV2020	2/2	1	Yes		NA/TC	R (13NOV2020)	N/N	
16-55/ C4591001	GENRL	Pyrexia/ fever#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1205 12051004	GENRL	Injection site pain/ muscle pain on injection area#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	
16-55/ C4591001 1205 12051014	GENRL	Injection site pain/ muscle pain on injection area#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N	
16-55/ C4591001 1205 12051028	INV	Blood pressure increased/ Increasing of systolic and diastolic blood pressure*		30OCT2020	/1	2	No	O	NA/W	R (30OCT2020)	N/N	
16-55/ C4591001 1205 12051065	GENRL	Pyrexia/ Fever#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N	
16-55/ C4591001 1205 12051066	MUSC	Myalgia/ muscle pain#	3	06JAN2021	3/2	1	Yes		NA	R (07JAN2021)	N/N	
16-55/ C4591001 1205 12051074	MUSC	Myalgia/ Muscle pain#	4	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N	
16-55/ C4591001 1205 12051075	GENRL	Injection site pain/ muscle pain on injection area#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N	
16-55/ C4591001 1205 12051075	INFEC	Anal abscess/ Anal Abscess	2	04JAN2021	35/3	2	No	O	NA/TC/TCN	R (06JAN2021)	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1205 12051077	NEOPL	Lipoma/ Encapsulated Lipoma	2	11JAN2021	41/10	2	No	O	NA/TC	R (20JAN2021)	Y/N	
	RESP	Nasal septum deviation/ Nasal Septum Deviation	2	11JAN2021	41/10	2	No	O	NA/TC/TCN	R (20JAN2021)	Y/N	
16-55/ C4591001 1207 12071002	RESP	Rhinorrhoea/ runny nose#	2	28FEB2021	108/3	1	No	O	NA	R (02MAR2021)	N/N	
16-55/ C4591001 1207 12071005	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N	
16-55/ C4591001 1207 12071010	GENRL	Injection site pain/ pain at injection site#	3	20JAN2021	1/2	1	Yes		NA/TCN	R (21JAN2021)	N/N	
	GENRL	Pyrexia/ fever 38.3#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N	
	NERV	Tremor/ Body Shaking#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N	
16-55/ C4591001 1207 12071014	GENRL	Fatigue/ FATIGUE#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
		Injection site pain/ PAIN AT INJECTION SITE#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1207 12071018	SKIN	Hyperhidrosis/ SWEATING#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Myalgia/ MUSCLE PAIN#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	25JAN2021	1/3	1	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	25JAN2021	1/3	1	Yes		NA/TC	R (27JAN2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	25JAN2021	1/3	1	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1207 12071021	GENRL	Fatigue/ FATIGUE#	3	05JAN2021	1/4	1	Yes		NA/TC	R (08JAN2021)	N/N
16-55/ C4591001 1207 12071025	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	05JAN2021	1/4	1	Yes		NA/TC	R (08JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	20JAN2021	1/6	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Pyrexia/ fever#	3	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at injection site#	4	09FEB2021	1/4	1	Yes		NA	R (12FEB2021)	N/N
	MUSC	Pain in extremity/ LEFT ARM PAIN#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1207 12071026	GENRL	Injection site erythema/ redness at injection site#	3	05JAN2021	1/4	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1207 12071028	GENRL	Injection site swelling/ Swelling at injection site#	3	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	NERV	Tremor/ body shaking#	4	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N
16-55/ C4591001 1207 12071032	INV	Blood pressure increased/ INCREASE BLOOD PRESSURE#	3	19JAN2021	8/2	1	No	O	NA	R (20JAN2021)	N/N
	NERV	Headache/ HEADACHE#	3	19JAN2021	8/2	1	No	O	NA	R (20JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	02FEB2021	1/4	2	Yes		NA/TC	R (05FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	02FEB2021	1/4	1	Yes		NA/TC	R (05FEB2021)	N/N
	NERV	Headache/ headache#	4	02FEB2021	1/4	1	Yes		NA/TC	R (05FEB2021)	N/N
16-55/ C4591001 1207 12071033	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE#	3	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
	MUSC	Pain in extremity/ ARMACHE#	3	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1207 12071038	GENRL	Fatigue/ FATIGUE#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1207 12071042	GENRL	Injection site pain/ pain at injection site#	3	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1207 12071044	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	GENRL	Pyrexia/ fever#	4	02FEB2021	2/2	1	Yes		NA/TC	R (03FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	02FEB2021	2/2	1	Yes		NA/TC	R (03FEB2021)	N/N
16-55/ C4591001 1207 12071047	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Chills/ chill#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N
		Pyrexia/ fever#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N
	MUSC	Arthralgia/ joint ache#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1207 12071048	GENRL	Injection site pain/ pain at injection site#	3	30DEC2020	1/4	1	Yes		NA	R (02JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Fatigue/ Fatigue#	4	18JAN2021	1/3	1	Yes		NA/TC	R (20JAN2021)	N/N	
	MUSC	Myalgia/ muscle pain#	4	18JAN2021	1/3	1	Yes		NA/TC	R (20JAN2021)	N/N	
	GENRL	Chills/ chill#	4	19JAN2021	2/2	1	Yes		NA/TC	R (20JAN2021)	N/N	
	MUSC	Arthralgia/ Generalized Joint pain#	4	19JAN2021	2/2	1	Yes		NA/TC	R (20JAN2021)	N/N	
16-55/ C4591001 1207 12071050	INJ&P	Road traffic accident/ Motor vehicle Accident	2	24DEC2020	30/1	1	No	O	NA/TC	R (24DEC2020)	N/N	
		Scar/ scar behind the knee	2	24DEC2020	30/17	1	No	O	NA	R (09JAN2021)	N/N	
		Scar/ scar on hand	2	24DEC2020	30/16	1	No	O	NA/TC	R (08JAN2021)	N/N	
16-55/ C4591001 1207 12071051	GENRL	Injection site pain/ Pain at injection site#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N	
	GENRL	Injection site pain/ pain at injection site#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	
16-55/ C4591001 1207 12071053	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N	
		Injection site pain/ pain at injection site#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1207 12071054	MUSC	Arthralgia/ RIGHT LATERALITY SHOULDERACHE	2	03JAN2021	40/C	1	No	O	NA/TC	RG	N/N	
	GENRL	Injection site hypersensitivity/ sensitivity at injection site#	3	20JAN2021	1/5	1	Yes		NA	R (24JAN2021)	N/N	
		Injection site pain/ pain at injection site#	3	20JAN2021	1/5	1	Yes		NA	R (24JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N	
		Injection site pain/ pain at injection site#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N	
	NERV	Headache/ headache#	4	09FEB2021	1/3	1	Yes		NA/TC	R (11FEB2021)	N/N	
16-55/ C4591001 1207 12071059	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N	
	GENRL	Injection site pain/ pain at injection site#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N	
16-55/ C4591001 1207 12071061	GENRL	Fatigue/ fatigue#	4	10FEB2021	1/3	1	Yes		NA/TC	R (12FEB2021)	N/N	
	NERV	Headache/ headache#	4	10FEB2021	1/3	1	Yes		NA/TC	R (12FEB2021)	N/N	
16-55/ C4591001 1207 12071065	MUSC	Pain in extremity/ Left thumbache	2	28DEC2020	32/3	1	No	O	NA/TC	R (30DEC2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	30DEC2020	1/3	1	Yes		NA	R (01JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
	MUSC	Arthralgia/ generalized Joint pain#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
		Myalgia/ muscle pain#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1207 12071067	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	30DEC2020	1/4	1	Yes		NA	R (02JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
	NERV	Headache/ headache#	4	19JAN2021	2/3	1	Yes		NA/TC	R (21JAN2021)	N/N
16-55/ C4591001 1208 12081001	GENRL	Fatigue/ Fatigue	1	05NOV2020	15/2	1	No	O	NA	R (06NOV2020)	N/N
16-55/ C4591001 1208 12081002	INJ&P	Hand fracture/ Finger fracture on the left hand#	3	22JAN2021	12/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1208 12081003	INJ&P	Foot fracture/ Broken Toe	2	07DEC2020	25/26	1	No	O	NA/TC	R (01JAN2021)	N/N
16-55/ C4591001	MUSC	Myalgia/ muscle pain#	3	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1208 12081010 16-55/ C4591001	MUSC	Myalgia/ muscle pain#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N	
1208 12081011 16-55/ C4591001	GASTR	Abdominal pain upper/ Stomachache	2	21DEC2020	29/1	1	No	O	NA/TC	R (21DEC2020)	N/N	
1208 12081021 16-55/ C4591001	GASTR	Gingival pain/ ulalgia	2	07DEC2020	15/5	1	No	O	NA/TC	R (11DEC2020)	N/N	
1208 12081024 16-55/ C4591001	CARD	Arteriospasm coronary/ Coronary Heart Spasm	2	16DEC2020	21/1	1	No	O	NA	R (16DEC2020)	N/N	
1208 12081026 16-55/ C4591001	SKIN	Hand dermatitis/ dermatitis on the right hand	2	30NOV2020	6/	1	No	O	NA/TC	R	N/N	
1208 12081038 16-55/ C4591001	INFEC	Urinary tract infection/ urinary tract infections	1	20NOV2020	15/4	1	No	O	NA/TC	R (23NOV2020)	N/N	
1208 12081044 16-55/ C4591001	RENAL	Dysuria/ dysuria	2	20JAN2021	69/C	1	No	O	NA/TC	RG	N/N	
1209 12091001												

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1209	CARD	Angina pectoris/ Stenocardia	2	05FEB2021	85/2	1	No	O	NA/TC/TCN	R (06FEB2021)	N/N	
	NERV	Headache/ Headache	1	12NOV2020	21/C	1	No	O	NA	RG	N/N	
12091002	GENRL	Injection site pain/ pain at injection site#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N	
16-55/ C4591001 1209			NERV	Headache/ headache#	4	24FEB2021	6/6	1	No	O	NA/TC	R (01MAR2021)
12091003	VASC	Hypertension/ hypertension#	4	24FEB2021	6/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1209	METAB	Insulin resistance/ insulin resistance#	4	26FEB2021	8/C	1	No	O	NA/TC	RG	N/N	
	GENRL	Fatigue/ fatigue#	4	18FEB2021	1/22	1	Yes		NA	R (11MAR2021)	N/N	
12091008	PSYCH	Anxiety/ anxiety#	4	04MAR2021	15/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1209	VASC	Hypertension/ hypertension#	4	04MAR2021	15/C	1	No	O	NA/TC	RG	N/N	
	GENRL	Injection site pain/ pain at injection site#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N	
12091009												

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1209 12091011	NERV	Pyrexia/ fever#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
		Headache/ headache#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1209 12091013	GENRL	Chest pain/ Chest Pain	1	08NOV2020	7/2	1	No	O	NA	R (09NOV2020)	N/N
16-55/ C4591001 1209 12091020	GASTR	Constipation/ constipation	2	15JAN2021	51/7	1	No	O	NA	R (21JAN2021)	N/N
16-55/ C4591001 1210 12101002	GENRL	Chest pain/ chest pain	2	15JAN2021	51/7	1	No	O	NA	R (21JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
	INFEC	Nasopharyngitis/ common cold	1	27OCT2020	6/6	2	No	O	NA/TC	R (01NOV2020)	N/N
16-55/ C4591001 1210 12101010	PSYCH	Anxiety/ anxiety	1	11NOV2020	17/C	1	No	O	NA	N	N/N
16-55/ C4591001	GENRL	Pyrexia/ fever#	3	28DEC2020	1/2	1	Yes		NA/TC	R (29DEC2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1210 12101015	GENRL	Chills/ chills#	4	19JAN2021	2/2	3	Yes		NA/TC	R (20JAN2021)	N/N	
	MUSC	Myalgia/ muscle pain#	4	19JAN2021	2/2	1	Yes		NA/TC	R (20JAN2021)	N/N	
16-55/ C4591001 1210 12101023	GENRL	Pyrexia/ Fever#	3	23JAN2021	2/2	2	Yes		NA/TC	R (24JAN2021)	N/N	
	MUSC	Arthralgia/ General joint pain#	3	23JAN2021	2/2	1	Yes		NA/TC	R (24JAN2021)	N/N	
16-55/ C4591001 1210 12101026	INFEC	Upper respiratory tract infection/ Acute upper respiratory tract infections	1	07NOV2020	9/10	1	No	O	NA	R (16NOV2020)	N/N	
	INFEC	Upper respiratory tract infection/ Acute upper respiratory tract infections	1	16NOV2020	18/22	3	No	O	NA/TC	R (07DEC2020)	Y/N	
16-55/ C4591001 1210 12101029	MUSC	Arthralgia/ joint pain	1	04NOV2020	6/2	3	No	O	NA/TC	R (05NOV2020)	N/N	
	BLOOD	Lymphadenopathy/ Axillary lymphadenopathy on the left.#	4	20JAN2021	2/4	2	Yes		NA	R (23JAN2021)	N/N	
16-55/ C4591001 1210 12101032	INJ&P	Lower limb fracture/ Leg fracture	2	17DEC2020	25/54	3	No	O	NA/TCN	R (08FEB2021)	N/N	
16-55/ C4591001	GASTR	Nausea/ nausea#	3	30DEC2020	2/2	3	Yes		NA	R (31DEC2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1210 12101037		Vomiting/ vomiting#	3	30DEC2020	2/2	3	Yes		NA	R (31DEC2020)	N/N	
	MUSC	Arthralgia/ generalized joint pain#	3	30DEC2020	2/2	1	Yes		NA	R (31DEC2020)	N/N	
	NERV	Headache/ headache#	3	30DEC2020	2/2	3	Yes		NA	R (31DEC2020)	N/N	
16-55/ C4591001 1210 12101048	PSYCH	Anxiety/ anxiety#	4	02FEB2021	15/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1210 12101049	MUSC	Neck pain/ neck pain	1	09NOV2020	6/6	1	No	O	NA	R (14NOV2020)	N/N	
16-55/ C4591001 1210 12101056	GENRL	Pyrexia/ fever#	3	22JAN2021	1/3	1	Yes		NA/TC	R (24JAN2021)	N/N	
	MUSC	Arthralgia/ general joint pain#	3	22JAN2021	1/3	1	Yes		NA/TC	R (24JAN2021)	N/N	
16-55/ C4591001 1212 12121006	MUSC	Myalgia/ mild muscle pain	2	18JAN2021	68/4	1	No	O	NA	R (21JAN2021)	N/N	
16-55/ C4591001 1212 12121019	GENRL	Injection site pain/ injection pain#	3	12JAN2021	2/2	1	No	O	NA	R (13JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1212 12121020†	GENRL	Injection site pain/ Injection Site Pain	2	14DEC2020	21/26	1	Yes		NA/TC	R (08JAN2021)	N/N
16-55/ C4591001 1212 12121024	MUSC	Myalgia/ mild muscle pain#	2	15JAN2021	52/5	1	No	O	NA	R (19JAN2021)	N/N
	CARD	Myocardial infarction/ Heart Attack#	2	03FEB2021	71/1	4	Yes		NA/TC/TCN	R (03FEB2021)	Y/N
16-55/ C4591001 1213 12131003	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	08JAN2021	1/2	2	Yes		NA	R (09JAN2021)	N/N
	MUSC	Myalgia/ MUSCLE PAIN#	3	08JAN2021	1/2	2	Yes		NA	R (09JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N
	SKIN	Hyperhidrosis/ SWEATING#	4	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1213 12131004	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	22JAN2021	1/2	3	Yes		NA	R (23JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ FATIGUE#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1213 12131005	MUSC	Myalgia/ MUSCLE PAIN#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N
		Injection site pain/ PAIN AT INJECTION SITE#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N
	MUSC	Myalgia/ MUSCLE PAIN#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N
16-55/ C4591001 1213 12131006	INFEC	Pharyngotonsillitis/ Tonsillopharyngitis	2	02DEC2020	21/10	1	No	O	NA/TC	R (11DEC2020)	N/N
	GENRL	Fatigue/ FATIGUE#	3	21JAN2021	1/3	2	Yes		NA	R (23JAN2021)	N/N
		Injection site pain/ PAIN AT INJECTION SITE#	3	21JAN2021	1/3	2	Yes		NA	R (23JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
		Pyrexia/ FEVER (38 Celsius)#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1213 12131010	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	08JAN2021	1/1	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	28JAN2021	1/3	2	Yes		NA	R (30JAN2021)	N/N
	MUSC	Arthralgia/ JOINT PAIN#	4	28JAN2021	1/3	2	Yes		NA	R (30JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1213 12131014	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	07JAN2021	1/2	2	Yes		NA	R (08JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	27JAN2021	1/3	2	Yes		NA/TC	R (29JAN2021)	N/N
	MUSC	Myalgia/ MUSCLE PAIN#	4	27JAN2021	1/3	3	Yes		NA/TC	R (29JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	27JAN2021	1/3	2	Yes		NA/TC	R (29JAN2021)	N/N
16-55/ C4591001 1213 12131015	EYE	Dry eye/ DRY EYE#	3	07JAN2021	1/3	2	Yes		NA	R (09JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	07JAN2021	1/3	2	Yes		NA	R (09JAN2021)	N/N
	MUSC	Myalgia/ MUSCLE PAIN#	3	07JAN2021	1/3	2	Yes		NA	R (09JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	27JAN2021	1/3	2	Yes		NA/TC	R (29JAN2021)	N/N
	MUSC	Myalgia/ MUSCLE PAIN#	4	27JAN2021	1/3	2	Yes		NA/TC	R (29JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	27JAN2021	1/3	2	Yes		NA/TC	R (29JAN2021)	N/N
16-55/ C4591001 1213 12131018	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	12JAN2021	1/2	2	Yes		NA	R (13JAN2021)	N/N
	NERV	Headache/ HEADACHE#	3	12JAN2021	1/2	2	Yes		NA	R (13JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1213 12131026	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	01FEB2021	1/3	2	Yes		NA	R (03FEB2021)	N/N
	NERV	Headache/ HEADACHE#	4	01FEB2021	1/3	3	Yes		NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Pyrexia/ FEVER#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1213 12131032	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
	GENRL	Chills/ CHILLS#	4	12FEB2021	1/2	2	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1213 12131034	NERV	Headache/ HEADACHE#	4	12FEB2021	1/2	3	Yes		NA/TC	R (13FEB2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	12JAN2021	1/2	2	Yes		NA	R (13JAN2021)	N/N
	NERV	Headache/ HEADACHE#	3	12JAN2021	1/1	2	Yes		NA	R (12JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	01FEB2021	1/2	2	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1213 12131034	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	01FEB2021	1/2	2	Yes		NA	R (02FEB2021)	N/N
	NERV	Headache/ HEADACHE#	4	01FEB2021	1/2	2	Yes		NA	R (02FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1213 12131035	GENRL	Fatigue/ FATIGUE#	3	22JAN2021	1/2	2	Yes		NA	R (23JAN2021)	N/N	
	NERV	Headache/ HEADACHE#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N	
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	12FEB2021	1/2	2	Yes		NA	R (13FEB2021)	N/N	
16-55/ C4591001 1213 12131039	GENRL	Fatigue/ FATIGUE#	3	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N	
		Pyrexia/ FEVER#	3	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N	
	MUSC	Back pain/ BACKACHE#	3	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N	
		Myalgia/ MUSCLE PAIN#	3	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N	
	NERV	Headache/ HEADACHE#	3	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N	
	GENRL	Chills/ CHILLS#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N	
		Fatigue/ FATIGUE#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N	
		Injection site pain/ PAIN AT INJECTION SITE#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N	
	MUSC	Myalgia/ MUSCLE PAIN#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N	
	NERV	Headache/ HEADACHE#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1213 12131040	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	07JAN2021	1/2	3	Yes		NA	R (08JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
		Injection site pain/ PAIN AT INJECTION SITE#	4	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
	SKIN	Hyperhidrosis/ SWEATING#	4	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1213 12131043	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	11FEB2021	1/3	3	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1213 12131044	GENRL	Chills/ CHILLS#	3	21JAN2021	1/2	2	Yes		NA	R (22JAN2021)	N/N
		Fatigue/ FATIGUE#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
		Injection site pain/ PAIN AT INJECTION SITE#	3	21JAN2021	1/2	2	Yes		NA	R (22JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	10FEB2021	1/2	2	Yes		NA/TC	R (11FEB2021)	N/N
		Injection site pain/ PAIN AT INJECTION SITE#	4	10FEB2021	1/2	2	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1213 12131055	NERV	Dizziness/ DIZZINESS#	3	08JAN2021	1/1	2	Yes		NA	R (08JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N
	MUSC	Myalgia/ MUSCLE PAIN#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N
16-55/ C4591001 1213 12131056	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
	MUSC	Myalgia/ MUSCLE PAIN#	3	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ HEADACHE#	3	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
	GASTR	Diarrhoea/ DIARRHEA#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N
	GENRL	Chills/ CHILLS#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N
		Fatigue/ FATIGUE#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N
		Injection site pain/ PAIN AT INJECTION SITE#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1213 12131057	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	26JAN2021	1/5	2	Yes		NA/TC	R (30JAN2021)	N/N	
	MUSC	Myalgia/ MUSCLE PAIN#	4	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N	
16-55/ C4591001 1213 12131060	GENRL	Chills/ CHILLS#	3	05JAN2021	1/3	2	Yes		NA	R (07JAN2021)	N/N	
		Fatigue/ FATIGUE#	3	05JAN2021	1/3	2	Yes		NA	R (07JAN2021)	N/N	
		Injection site pain/ PAIN AT INJECTION SITE#	3	05JAN2021	1/3	2	Yes		NA	R (07JAN2021)	N/N	
	GENRL	Fatigue/ FATIGUE#	4	25JAN2021	1/4	3	Yes		NA/TC	R (28JAN2021)	N/N	
		Pyrexia/ FEVER (39.9 centigrade degrees )#	4	25JAN2021	1/1	3	Yes		NA/TC	R (25JAN2021)	N/N	
16-55/ C4591001 1214 12141005	GENRL	Fatigue/ Fatigue#	3	31DEC2020	1/2	2	Yes		NA	R (01JAN2021)	N/N	
	MUSC	Pain in extremity/ Arm Pain#	3	31DEC2020	1/2	2	Yes		NA	R (01JAN2021)	N/N	
	GENRL	Injection site pain/ Injection Pain#	4	19JAN2021	1/4	2	Yes		NA/TC	R (22JAN2021)	N/N	
	MUSC	Pain in extremity/ Arm Pain#	4	19JAN2021	1/4	2	Yes		NA/TC	R (22JAN2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ pain at injection site#	3	29JAN2021	1/4	2	Yes		NA	R (01FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1214 12141007	GENRL	Injection site pain/ pain at injection site#	4	18FEB2021	1/2	2	Yes		NA	R (19FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1214 12141009	MUSC	Pain in extremity/ Arm Pain#	3	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	3	30JAN2021	2/1	1	Yes		NA/TC	R (30JAN2021)	N/N
	NERV	Headache/ Headache#	3	30JAN2021	2/1	3	Yes		NA/TC	R (30JAN2021)	N/N
	MUSC	Pain in extremity/ Arm Pain#	4	17FEB2021	1/2	2	Yes		NA	R (18FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/4	3	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1214 12141012	GENRL	Injection site pain/ Pain at injection site#	3	02FEB2021	1/2	2	Yes		NA	R (03FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	03FEB2021	2/2	2	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	3	03FEB2021	2/2	2	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	24FEB2021	1/4	2	Yes		NA	R (27FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1214 12141015	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/2	2	Yes		NA	R (26FEB2021)	N/N	
	NERV	Headache/ Headache#	4	25FEB2021	2/2	2	Yes		NA	R (26FEB2021)	N/N	
	GENRL	Chills/ Chill#	3	02FEB2021	1/1	3	Yes		NA	R (02FEB2021)	N/N	
	MUSC	Pain in extremity/ Arm Pain#	3	02FEB2021	1/3	3	Yes		NA	R (04FEB2021)	N/N	
	NERV	Headache/ Headache#	3	02FEB2021	1/1	2	Yes		NA	R (02FEB2021)	N/N	
	MUSC	Pain in extremity/ Arm Pain#	4	25FEB2021	1/2	1	Yes		NA	R (26FEB2021)	N/N	
	NERV	Headache/ Headache#	4	25FEB2021	1/3	2	Yes		NA	R (27FEB2021)	N/N	
16-55/ C4591001 1214 12141018	MUSC	Intervertebral disc protrusion/ recurrence vertebral disc herniation	1	18NOV2020	17/15	2	No	O	NA/TC/TCN	R (02DEC2020)	Y/N	
16-55/ C4591001 1214 12141020	RESP	Pulmonary embolism/ pulmonary embolism	2	05DEC2020	13/1	2	No	O	NA/TC	R (05DEC2020)	Y/N	
	INFEC	Bartholin's abscess/ BARTHOLIN'S ABSCESS	1	08NOV2020	7/10	1	No	O	NA/TC/TCN	R (17NOV2020)	N/N	
	GENRL	Fatigue/ Fatigue#	3	30DEC2020	1/2	2	Yes		NA/TC	R (31DEC2020)	N/N	
	MUSC	Myalgia/ Muscle Pain#	3	30DEC2020	1/2	2	Yes		NA/TC	R (31DEC2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache#	3	30DEC2020	1/2	2	Yes		NA/TC	R (31DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	19JAN2021	1/3	2	Yes		NA/TC	R (21JAN2021)	N/N
	MUSC	Myalgia/ Muscle Pain#	4	19JAN2021	1/3	2	Yes		NA/TC	R (21JAN2021)	N/N
	NERV	Headache/ Headache#	4	19JAN2021	1/3	2	Yes		NA/TC	R (21JAN2021)	N/N
16-55/ C4591001 1214 12141022	GENRL	Injection site pain/ pain at injection site#	3	01FEB2021	1/3	2	Yes		NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	22FEB2021	1/4	2	Yes		NA	R (25FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	23FEB2021	2/2	2	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1214 12141024	GENRL	Injection site pain/ pain at injection site#	3	01FEB2021	1/2	2	Yes		NA	R (02FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	23FEB2021	2/2	2	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ pain at injection site#	4	23FEB2021	2/2	2	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1214 12141025	INFEC	Pyelonephritis/ Pyelonephritis	1	09NOV2020	7/12	1	No	O	NA/TC	R (20NOV2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at injection site#	3	01FEB2021	1/2	3	Yes		NA	R (02FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1214 12141027	GENRL	Fatigue/ fatigue#	4	23FEB2021	1/2	2	Yes		NA/TC	R (24FEB2021)	N/N
	MUSC	Pain in extremity/ arm pain#	4	23FEB2021	1/2	2	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1214 12141030	GENRL	Injection site pain/ pain at injection site#	3	01FEB2021	1/3	2	Yes		NA/TC	R (03FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	22FEB2021	1/3	2	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1214 12141031	MUSC	Pain in extremity/ Arm Pain#	3	01FEB2021	1/2	3	Yes		NA/TC	R (02FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	02FEB2021	2/1	2	Yes		NA/TC	R (02FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	3	02FEB2021	2/1	3	Yes		NA/TC	R (02FEB2021)	N/N
	MUSC	Pain in extremity/ Arm pain#	4	22FEB2021	1/2	2	Yes		NA	R (23FEB2021)	N/N
	GASTR	Vomiting/ Vomiting#	4	23FEB2021	2/1	2	Yes		NA	R (23FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	23FEB2021	2/2	3	Yes		NA	R (24FEB2021)	N/N
	GENRL	Pyrexia/ fever#	4	23FEB2021	2/1	3	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chill#	2	23FEB2021	1/2	2	Yes		NA	R (24FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1214 12141036	GENRL	Injection site pain/ pain at injection site#	2	24FEB2021	2/1	2	Yes		NA	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	2	24FEB2021	2/1	2	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1214 12141038	MUSC	Myalgia/ Muscle Pain#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	25JAN2021	1/3	3	Yes		NA/TC	R (27JAN2021)	N/N
	MUSC	Myalgia/ Muscle Pain#	4	25JAN2021	1/3	3	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1214 12141039	GASTR	Diarrhoea/ diarrhea	1	26NOV2020	21/2	1	No	O	NA	R (27NOV2020)	N/N
	BLOOD	Lymphadenopathy/ lymphadenomegaly in the right submandibular#	2	06JAN2021	41/10	1	No	O	NA/TC	R (15JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	08FEB2021	1/3	2	Yes		NA/TC	R (10FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	03MAR2021	1/3	2	Yes		NA	R (05MAR2021)	N/N
16-55/ C4591001 1214 12141040	MUSC	Myalgia/ Muscle Pain#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1214 12141041	GENRL	Fatigue/ Fatigue#	4	25JAN2021	1/3	1	Yes		NA/TC	R (27JAN2021)	N/N	
	MUSC	Arthralgia/ Generalized Joint Pain#	4	25JAN2021	1/3	2	Yes		NA/TC	R (27JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	3	01FEB2021	1/1	1	Yes		NA	R (01FEB2021)	N/N	
		Injection site pain/ pain at injection site#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	23FEB2021	1/3	2	Yes		NA/TC	R (25FEB2021)	N/N	
		Injection site pain/ pain at injection site#	4	23FEB2021	1/4	2	Yes		NA/TC	R (26FEB2021)	N/N	
	GENRL	Injection site pain/ pain at injection site#	4	23FEB2021	1/3	2	Yes		NA/TC	R (25FEB2021)	N/N	
	16-55/ C4591001 1214 12141044	MUSC	Myalgia/ Muscle Pain#	3	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/N
	16-55/ C4591001 1214 12141051	INFEC	Pharyngitis/ pharyngitis	2	19DEC2020	19/2	1	No	O	NA	R (20DEC2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	05JAN2021	1/3	2	Yes		NA	R (07JAN2021)	N/N	
		Pyrexia/ fever#	3	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1214 12141053	MUSC	Myalgia/ Muscle Pain#	3	05JAN2021	1/3	2	Yes		NA/TC	R (07JAN2021)	N/N
	INFEC	Oral herpes/ Orolabial Herpes (inside the cheek and close to the left lower anterior tooth)#	3	06JAN2021	2/6	1	Yes		NA	R (11JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
	BLOOD	Lymphadenitis/ lymphadenitis in the left lower cervical#	4	27JAN2021	2/2	2	Yes		NA	R (28JAN2021)	N/N
	INFEC	Oral herpes/ Orolabial Herpes (close to the left molar teeth on both sides of the cheek and inside of the cheek)#	4	27JAN2021	2/9	1	Yes		NA	R (04FEB2021)	N/N
	MUSC	Myalgia/ Muscle Pain#	4	27JAN2021	2/3	2	Yes		NA/TC	R (29JAN2021)	N/N
	MUSC	Pain in extremity/ Arm Pain#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Pain in extremity/ Arm Pain#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	16-55/ C4591001 1214 12141054	MUSC	Pain in extremity/ Arm Pain#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)
MUSC	Pain in extremity/ Arm Pain#	4	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N	
GENRL	Fatigue/ Fatigue#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1217 12171003	SKIN	Seborrheic dermatitis/ seborrheic dermatitis	2	07DEC2020	26/C	1	No	CD	NA/TC/TCN	N	N/N	
	GENRL	Injection site pain/ Arm pain (injection pain)#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N	
	NERV	Headache/ headache#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N	
16-55/ C4591001 1217 12171008	GENRL	Pyrexia/ 37.8C Fever#	3	04JAN2021	1/4	1	Yes		NA	R (07JAN2021)	N/N	
	MUSC	Arthralgia/ Joint pain#	3	04JAN2021	1/4	1	Yes		NA	R (07JAN2021)	N/N	
		Myalgia/ Muscle pain#	3	04JAN2021	1/4	1	Yes		NA	R (07JAN2021)	N/N	
16-55/ C4591001 1217 12171011	GENRL	Fatigue/ lassitude#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N	
		Injection site pain/ Injection pain (arm pain)#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N	
	MUSC	Myalgia/ muscle pain#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N	
16-55/ C4591001 1217 12171014	GENRL	Fatigue/ lassitude#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N	
	SKIN	Rash/ skin rash of neck and upper body#	4	25JAN2021	1/3	1	Yes		NA/TC	R (27JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1217 12171015†	GENRL	Injection site pain/ Arm pain (Injection pain)#	2	25JAN2021	70/2	1	Yes		NA/TC	R (26JAN2021)	N/N
	GENRL	Chills/ Chill#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1217 12171018	MUSC	Myalgia/ Muscle pain#	3	04JAN2021	1/4	1	Yes		NA	R (07JAN2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	25JAN2021	1/2	1	Yes		NA/TC	R (26JAN2021)	N/N
16-55/ C4591001 1217 12171020	GENRL	Injection site pain/ arm pain (injection pain)#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	INFEC	Tonsillitis/ Tonsillitis#	4	14FEB2021	3/3	1	Yes		NA/TC	R (16FEB2021)	N/N
16-55/ C4591001 1217 12171023	INFEC	Cystitis/ cystitis	2	29DEC2020	43/10	1	No	O	NA/TC	R (07JAN2021)	N/N
	GENRL	Chills/ Chill#	4	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
		Injection site pain/ Injection pain (arm pain)#	4	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection pain (Arm pain)#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1217 12171028	GENRL	Chills/ Chill#	4	28JAN2021	1/4	1	Yes		NA/TC	R (31JAN2021)	N/N	
		Fatigue/ Lassitude#	4	28JAN2021	1/4	1	Yes		NA/TC	R (31JAN2021)	N/N	
		Pyrexia/ 37.7 Fever#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N	
16-55/ C4591001 1217 12171031	INJ&P	Exposure during pregnancy/ exposure during pregnancy	1	30OCT2020	1/C		No	O	P	UNK	N/N	
16-55/ C4591001 1217 12171032	GENRL	Injection site pain/ Injection pain (Arm pain)#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N	
	GENRL	Fatigue/ Lassitude#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N	
		Injection site pain/ Injection pain(arm pain)#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N	
16-55/ C4591001 1217 12171035	GENRL	Fatigue/ lassitude#	3	07JAN2021	1/3	1	Yes		NA/TC	R (09JAN2021)	N/N	
		Pyrexia/ 38.5 C Fever#	3	07JAN2021	1/3	1	Yes		NA/TC	R (09JAN2021)	N/N	
	MUSC	Myalgia/ Muscle pain#	3	07JAN2021	1/3	1	Yes		NA/TC	R (09JAN2021)	N/N	
	GENRL	Fatigue/ Lassitude#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1217 12171039	MUSC	Pyrexia/ 39.0 C Fever#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N	
		Myalgia/ muscle pain#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N	
		Headache/ Headache#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N	
	EAR	Deafness unilateral/ Acute hearing loss in right ear	2	JAN2021	38/	1	No	O	NA/TC	R (18JAN2021)	N/N	
	EAR	Tinnitus/ Tinnitus in right ear	2	08JAN2021	45/11	1	No	O	NA/TC	R (18JAN2021)	N/N	
16-55/ C4591001 1217 12171041	MUSC	Pain in extremity/ Injection arm pain#	3	03MAR2021	1/4	1	Yes		NA	R (06MAR2021)	N/N	
	GENRL	Injection site pain/ arm pain (injection pain)#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N	
	GENRL	Pyrexia/ 38 C Fever#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N	
16-55/ C4591001 1217 12171044	PSYCH	Anxiety/ Anxiety	1	21NOV2020	18/104	1	No	O	NA/TC	R (04MAR2021)	N/N	
16-55/ C4591001 1217 12171048	GENRL	Fatigue/ Lassitude#	3	08JAN2021	1/3	1	Yes		NA/TC	R (10JAN2021)	N/N	
	MUSC	Arthralgia/ generalized joint pain#	3	08JAN2021	1/3	1	Yes		NA/TC	R (10JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Investigational Vaccine Dose/ Subject	Action: Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1217 12171054	GENRL	Myalgia/ Muscle pain#	3	08JAN2021	1/3	1	Yes	NA/TC	R (10JAN2021)	N/N
		Fatigue/ Lassitude#	4	29JAN2021	1/2	1	Yes	NA	R (30JAN2021)	N/N
	MUSC	Myalgia/ Muscle pain#	4	29JAN2021	1/2	1	Yes	NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Arm pain (Injection pain)#	3	07JAN2021	1/3	1	Yes	NA	R (09JAN2021)	N/N
	NERV	Pyrexia/ 37.0 C Fever#	3	07JAN2021	1/3	1	Yes	NA	R (09JAN2021)	N/N
		Headache/ Headache#	3	07JAN2021	1/3	1	Yes	NA	R (09JAN2021)	N/N
	GENRL	Fatigue/ Lassitude#	4	28JAN2021	1/2	1	Yes	NA	R (29JAN2021)	N/N
16-55/ C4591001 1217 12171055	GENRL	Injection site pain/ Injection pain (arm pain)#	4	28JAN2021	1/2	1	Yes	NA	R (29JAN2021)	N/N
		Fatigue/ Lassitude#	3	07JAN2021	1/2	1	Yes	NA	R (08JAN2021)	N/N
	GENRL	Injection site pain/ Arm pain (Injection pain)#	3	07JAN2021	1/2	1	Yes	NA	R (08JAN2021)	N/N
		Fatigue/ Lassitude#	4	28JAN2021	1/2	1	Yes	NA/TC	R (29JAN2021)	N/N
	NERV	Pyrexia/ 38.2 C Fever#	4	28JAN2021	1/2	1	Yes	NA/TC	R (29JAN2021)	N/N
Headache/ Headache#		4	28JAN2021	1/2	1	Yes	NA/TC	R (29JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1217 12171061	MUSC	Myalgia/ Muscle pain#	4	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N	
	NERV	Headache/ Headache#	4	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N	
16-55/ C4591001 1217 12171062	GENRL	Fatigue/ fatigue#	4	05FEB2021	1/4	1	Yes		NA/TC	R (08FEB2021)	N/N	
		Injection site pain/ Injection pain (arm pain)#	4	05FEB2021	1/4	1	Yes		NA/TC	R (08FEB2021)	N/N	
16-55/ C4591001 1218 12181001	MUSC	Myalgia/ Muscle pain#	4	05FEB2021	1/4	1	Yes		NA/TC	R (08FEB2021)	N/N	
	GASTR	Abdominal pain/ Abdominal pain	1	03NOV2020	16/4	1	No	O	NA	R (06NOV2020)	N/N	
16-55/ C4591001 1218 12181004	GASTR	Nausea/ Nausea	1	04NOV2020	17/3	1	No	O	NA	R (06NOV2020)	N/N	
	HEPAT	Cholecystitis acute/ Acute cholecystitis#	2	18JAN2021	69/4	3	No	O	NA/TC/TCN	R (21JAN2021)	Y/N	
	GENRL	Injection site pain/ Injection site pain	1	10NOV2020	21/4	1	Yes		NA	R (13NOV2020)	N/N	
16-55/ C4591001		Injection site swelling/ Injection site swelling	1	10NOV2020	21/4	1	Yes		NA	R (13NOV2020)	N/N	
	GENRL	Fatigue/ Fatigue/Tiredness	2	18NOV2020	2/2	3	Yes		NA	R (19NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1218 12181007		Injection site pain/ Injection site pain	2	18NOV2020	2/2	2	Yes		NA	R (19NOV2020)	N/N	
	MUSC	Myalgia/ new muscle pain	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N	
16-55/ C4591001 1218 12181008	PSYCH	Alcohol withdrawal syndrome/ Alcohol withdrawal	2	11DEC2020	25/4	1	No	O	NA	R (14DEC2020)	N/N	
	PSYCH	Alcohol withdrawal syndrome/ Alcohol withdrawal	2	28DEC2020	42/3	1	No	O	NA	R (30DEC2020)	N/N	
	GASTR	Gastritis alcoholic/ Alcoholic gastritis#	2	31JAN2021	76/3	1	No	O	NA/TC	R (02FEB2021)	N/N	
16-55/ C4591001 1218 12181009	PSYCH	Alcohol withdrawal syndrome/ Alcohol Withdrawal	2	11DEC2020	18/4	1	No	O	NA	R (14DEC2020)	N/N	
16-55/ C4591001 1218 12181011	GENRL	Injection site pain/ injection site pain	1	02NOV2020	1/5	1	Yes		NA	R (06NOV2020)	N/Y	
16-55/ C4591001 1218 12181012	PSYCH	Alcohol abuse/ Alcohol abuse	2	09JAN2021	47/C	1	No	O	NA/TCN	RG	Y/N	
16-55/ C4591001 1218 12181013	GENRL	Chills/ Chills#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1218 12181015	NERV	Pain/ Body aches#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
		Facial paralysis/ Bell's Palsy - Left#	3	10JAN2021	4/12	1	Yes		NA/TC/TCN	R (21JAN2021)	N/N
16-55/ C4591001 1218 12181016	INFEC	Cellulitis/ Cellulitis	1	19NOV2020	8/8	1	No	O	NA/TC	R (26NOV2020)	N/N
16-55/ C4591001 1218 12181017	INJ&P	Animal bite/ dog bite	1	19NOV2020	8/8	1	No	O	NA/TC	R (26NOV2020)	N/N
	MUSC	Musculoskeletal chest pain/ Musculoskeletal Chest Pain	1	29NOV2020	17/5	1	No	O	NA/TC	R (03DEC2020)	N/N
16-55/ C4591001 1218 12181023	INJ&P	Thermal burn/ Left Foot Burn#	2	31DEC2020	28/7	1	No	O	NA/TCN	R (06JAN2021)	N/N
	INJ&P	Skin laceration/ Left Leg Laceration#	2	08JAN2021	36/11	1	No	O	NA/TCN	R (18JAN2021)	N/N
	INJ&P	Thermal burn/ Right forearm burn#	4	01MAR2021	28/C	1	No	O	NA/TCN	N	N/N
16-55/ C4591001 1218 12181028	PSYCH	Alcohol withdrawal syndrome/ Alcohol withdrawal#	4	03MAR2021	30/2	2	No	O	NA/TC	R (04MAR2021)	Y/N
	INFEC	Anal abscess/ Perianal abscess	2	26DEC2020	17/C	1	No	O	NA/TC/TCN	RG	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1218 12181034	INJ&P	Fall/ Fall	1	01DEC2020	9/1	1	No	O	NA	R (01DEC2020)	N/N
	INJ&P	Joint injury/ Left knee injury	1	02DEC2020	10/C	2	No	O	NA/TC/TCN	RG	N/N
	INJ&P	Contusion/ Left foot contusion#	2	14JAN2021	32/9	1	No	O	NA/TC/TCN	R (22JAN2021)	N/N
16-55/ C4591001 1218 12181039	INFEC	Otitis media/ right otitis media	1	11DEC2020	12/C	1	No	O	NA/TC	N	N/N
	INFEC	Conjunctivitis/ Bilateral Conjunctivitis	2	31DEC2020	11/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1218 12181042	GENRL	Chills/ Chills	1	01DEC2020	1/2	1	Yes		NA	R (02DEC2020)	N/N
	GASTR	Abdominal pain upper/ Stomach Aches	1	02DEC2020	2/2	1	Yes		NA	R (03DEC2020)	N/N
		Nausea/ Nausea	1	02DEC2020	2/3	1	Yes		NA	R (04DEC2020)	N/N
	GENRL	Pain/ Body Aches	1	02DEC2020	2/1	1	Yes		NA	R (02DEC2020)	N/N
	NERV	Headache/ Headaches	1	02DEC2020	2/3	1	Yes		NA	R (04DEC2020)	N/N
	RESP	Dyspnoea exertional/ winded upon exertion	1	02DEC2020	2/1	1	Yes		NA	R (02DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/Y

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1218 12181043	GASTR	Nausea/ Nausea after 2nd injection	2	21DEC2020	1/1	1	Yes		NA	R (21DEC2020)	N/Y
	GENRL	Injection site pain/ Burning pain at injection site	2	21DEC2020	1/1	1	Yes		NA	R (21DEC2020)	N/Y
		Injection site pain/ Injection site muscle aches	2	21DEC2020	1/5	1	Yes		NA	R (25DEC2020)	N/N
16-55/ C4591001 1218 12181044	SKIN	Rash pruritic/ itchy rash lower legs	1	04DEC2020	3/7	1	No	O	NA	R (10DEC2020)	N/N
	EYE	Eye irritation/ Sensation of Irritation of Eye Proper (right eye)#	3	16JAN2021	20/2	1	No	O	NA	R (17JAN2021)	N/N
16-55/ C4591001 1218 12181046	HEPAT	Cholecystitis acute/ Acute Cholecystitis	1	20DEC2020	19/3	2	No	O	NA/TC	R (22DEC2020)	Y/N
	NEOPL	Ovarian germ cell teratoma benign/ Mature cystic teratoma left ovary	1	20DEC2020	19/3	1	No	O	NA	R (22DEC2020)	N/N
16-55/ C4591001 1218 12181049	GASTR	Abdominal pain lower/ RLQ abdominal pain#	4	17FEB2021	8/2	1	No	O	NA/TCN	R (18FEB2021)	N/N
	MUSC	Back pain/ right lower back pain#	4	17FEB2021	8/2	1	No	O	NA/TCN	R (18FEB2021)	N/N
16-55/ C4591001 1218 12181050	INJ&P	Ligament sprain/ Sprained ankle-right#	3	27DEC2020	5/7	2	No	O	NA/TC/TCN	R (02JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1218 12181051	RESP	Asthma/ Asthma exacerbation#	2	16JAN2021	25/3	1	No	O	NA/TC	R (18JAN2021)	Y/N	
16-55/ C4591001 1218 12181057	GENRL	Injection site pain/ Injection site pain	1	08DEC2020	1/2	1	Yes		NA	R (09DEC2020)	N/Y	
	GASTR	Vomiting/ Vomiting	1	09DEC2020	2/1	1	Yes		NA	R (09DEC2020)	N/N	
	GASTR	Oesophageal varices haemorrhage/ Esophageal varices hemorrhage	1	09JAN2021	33/1	4	No	O	NA/TC/TCN	R (09JAN2021)	Y/N	
	GASTR	Toothache/ Toothache	1	01FEB2021	56/4	1	No	O	NA/TC/TCN	R (04FEB2021)	N/N	
16-55/ C4591001 1219 12191001	GENRL	Injection site reaction/ odd sensation posterior to injection site	1	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1219 12191003	GENRL	Chills/ mild chills	1	01OCT2020	1/1	1	Yes		NA	R (01OCT2020)	N/N	
		Fatigue/ fatigue	1	01OCT2020	1/1	1	Yes		NA	R (01OCT2020)	N/N	
	INFEC	Urinary tract infection/ Urinary tract infection	1	02OCT2020	2/5	1	No	O	NA/TC	R (06OCT2020)	N/N	
	GENRL	Injection site pain/ soreness at injection site#	3	20JAN2021	1/1	1	Yes		NA	R (20JAN2021)	N/Y	
16-55/ C4591001	NERV	Headache/ Headache after hiking 22 miles	1	12OCT2020	5/1	1	No	O	NA/TC	R (12OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1219 12191013	GENRL	Injection site pain/ muscle soreness at injection site	2	27OCT2020	1/3	2	Yes		NA	R (29OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	28OCT2020	2/1	3	Yes		NA	R (28OCT2020)	N/N
	MUSC	Myalgia/ generalized muscle soreness	2	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
	NERV	Headache/ headache	2	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1219 12191014	GENRL	Fatigue/ fatigue	2	28OCT2020	2/1	3	Yes		NA	R (28OCT2020)	N/N
	MUSC	Myalgia/ generalized muscle soreness	2	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
	NERV	Headache/ headache	2	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1219 12191016	GENRL	Fatigue/ fatigue	1	09OCT2020	1/6	1	No	O	NA	R (14OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	01NOV2020	5/1	1	Yes		NA	R (01NOV2020)	N/N
	NERV	Headache/ Headache, waxing and waning	2	01NOV2020	5/10	1	Yes		NA	R (10NOV2020)	N/N
	PSYCH	Depressed mood/ depressed mood	2	20NOV2020	24/46	1	No	O	NA	R (04JAN2021)	N/N
	GENRL	Fatigue/ tiredness#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/Y

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1219 12191017	GENRL	Injection site pain/ injection site pain#	3	22DEC2020	1/4	1	Yes		NA	R (25DEC2020)	N/Y	
		Fatigue/ tiredness#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/Y	
		Injection site pain/ injection site pain#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/Y	
	REPRO	Amenorrhoea/ secondary amenorrhea	2	24DEC2020	53/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1219 12191022	GENRL	Injection site pain/ injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
	INFEC	Onychomycosis/ onychomycosis	1	29OCT2020	10/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1219 12191028	METAB	Type 2 diabetes mellitus/ Diabetes Mellitus Type 2	1	29OCT2020	10/C	1	No	O	NA/TC	N	N/N	
	GENRL	Fatigue/ Fatigue	1	30OCT2020	4/7	1	Yes		NA	R (05NOV2020)	N/N	
	MUSC	Back pain/ Low Back Pain	1	02NOV2020	7/4	1	Yes		NA	R (05NOV2020)	N/N	
		Myalgia/ Muscle aches	1	02NOV2020	7/4	1	Yes		NA	R (05NOV2020)	N/N	
	INJ&P	Contusion/ left knee contusion	2	16DEC2020	28/10	1	No	O	NA	R (25DEC2020)	N/N	
	Fall/ fall	2	16DEC2020	28/1	1	No	O	NA	R (16DEC2020)	N/N		

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1219 12191030	GENRL	Injection site pain/ injection site soreness#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/Y
	GENRL	Fatigue/ tiredness	1	29OCT2020	1/6	1	Yes		NA	R (03NOV2020)	N/Y
	NERV	Headache/ slight headache	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/Y
	GENRL	Pain/ Body aches	1	30OCT2020	2/2	1	Yes		NA	R (31OCT2020)	N/N
	NERV	Headache/ Headache	1	03NOV2020	6/1	1	Yes		NA	R (03NOV2020)	N/N
16-55/ C4591001 1219 12191033	NERV	Headache/ headache	1	11NOV2020	14/9	1	No	O	NA	R (19NOV2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	07DEC2020	1/C	1	Yes		NA	N	N/Y
	GENRL	Injection site pain/ Soreness at injection site	2	01DEC2020	1/2	1	Yes		NA	R (02DEC2020)	N/N
	MUSC	Arthralgia/ right elbow joint soreness	2	02DEC2020	2/2	1	Yes		NA	R (03DEC2020)	N/N
	GENRL	Injection site discolouration/ hypopigmented skin patch at prior injection site, right upper arm	2	15DEC2020	15/C	1	Yes		NA	N	N/N
16-55/ C4591001 1219 12191034	GENRL	Injection site pain/ mild soreness at injection site	1	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/Y
	GENRL	Injection site pain/ soreness at injection site	2	01DEC2020	1/3	1	Yes		NA	R (03DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1219 12191039	INJ&P	Contusion/ contusion to right elbow and back#	3	20JAN2021	15/3	1	No	O	NA/TCN	R (22JAN2021)	N/N
	MUSC	Back pain/ back pain#	3	20JAN2021	15/3	1	No	O	NA/TCN	R (22JAN2021)	N/N
	SKIN	Rash/ rash to right hand#	3	20JAN2021	15/8	1	No	O	NA/TCN	R (27JAN2021)	N/N
16-55/ C4591001 1219 12191040	GENRL	Injection site pain/ injection site soreness	1	17NOV2020	1/2	1	Yes		NA	R (18NOV2020)	N/N
		Pain/ body aches	1	17NOV2020	1/2	2	Yes		NA	R (18NOV2020)	N/N
	GENRL	Injection site pain/ injection site soreness	2	07DEC2020	1/2	2	Yes		NA	R (08DEC2020)	N/N
		Pain/ body aches	2	07DEC2020	1/C	2	Yes		NA	N	N/N
16-55/ C4591001 1219 12191044	GENRL	Injection site pain/ injection site pain#	3	02MAR2021	1/4	1	Yes		NA	R (05MAR2021)	N/N
	MUSC	Myalgia/ muscle aches#	3	03MAR2021	2/1	2	Yes		NA	R (03MAR2021)	N/N
16-55/ C4591001 1219 12191047	INJ&P	Burns second degree/ second degree burn, right wrist	1	30NOV2020	6/8	2	No	O	NA/TCN	R (07DEC2020)	N/N
16-55/ C4591001	NERV	Headache/ headache	1	25NOV2020	1/1	1	Yes		NA	R (25NOV2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1219 12191048	GENRL	Fatigue/ tiredness#	3	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N	
		Injection site pain/ injection site pain#	3	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N	
	MUSC	Myalgia/ muscle aches#	3	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N	
16-55/ C4591001 1219 12191050	GASTR	Nausea/ nausea#	3	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/N	
	GENRL	Fatigue/ tiredness#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N	
	NERV	Dizziness/ dizziness#	3	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/N	
		Headache/ headache#	3	12JAN2021	1/2	1	Yes		NA/TC	R (13JAN2021)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	13JAN2021	2/2	2	Yes		NA/TC	R (14JAN2021)	N/N	
16-55/ C4591001 1219 12191056	GENRL	Injection site pain/ injection site pain#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N	
16-55/ C4591001 1220 12201004	GENRL	Injection site pain/ soreness at injection site#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N	
16-55/ C4591001	REPRO	Pelvic pain/ pelvic pain	2	01JAN2021	72/30	2	No	O	NA	R (30JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1220 12201009	REPRO	Cervical dysplasia/ mild cervical dysplasia on PAP smear#	2	17FEB2021	119/C	1	No	O	NA/TCN	N	N/N
16-55/ C4591001 1220 12201013	INFECTION	Ear infection/ Ear Infection (left)	2	10NOV2020	13/37	1	No	O	NA/TC	R (16DEC2020)	N/N
	MUSC	Temporomandibular joint syndrome/ TMJ pain	2	16DEC2020	49/3	1	No	O	NA/TC	R (18DEC2020)	N/N
	GASTR	Nausea/ Nausea#	3	04JAN2021	1/1	1	Yes		NA	R (04JAN2021)	N/Y
	GENRL	Chills/ Chills#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
		Fatigue/ fatigue#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
		Pain/ Body aches#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1220 12201017	GENRL	Injection site pain/ Soreness at injection site left arm	2	06NOV2020	1/1	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1220 12201018	NERV	Headache/ headache	1	18OCT2020	3/1	1	Yes		NA	R (18OCT2020)	N/N
		Hypoaesthesia/ facial numbness	1	18OCT2020	3/16	1	No	O	NA	R (02NOV2020)	N/N
		Hypoaesthesia/ leg numbness	1	18OCT2020	3/25	1	No	O	NA	R (11NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1220 12201020	GASTR	Diarrhoea/ diarrhea	1	17OCT2020	2/3	1	Yes		NA	R (19OCT2020)	N/N	
	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	1	23OCT2020	8/55	3	No	O	NA/TCN	R (16DEC2020)	N/N	
	GASTR	Vomiting/ Vomiting	2	07NOV2020	2/1	2	Yes		NA	R (07NOV2020)	N/N	
	GENRL	Injection site pain/ Soreness at Injection site (left deltoid)	2	07NOV2020	2/3	2	Yes		NA	R (09NOV2020)	N/N	
	NERV	Headache/ Headache	2	07NOV2020	2/1	2	Yes		NA	R (07NOV2020)	N/N	
16-55/ C4591001 1220 12201021	GENRL	Fatigue/ fatigue#	3	24JAN2021	4/1	1	Yes		NA	R (24JAN2021)	N/N	
16-55/ C4591001 1220 12201022	GENRL	Injection site pain/ soreness at injection site	1	20OCT2020	1/8	1	Yes		NA	R (27OCT2020)	N/Y	
	MUSC	Myalgia/ Muscle aches#	4	19FEB2021	3/2	1	Yes		NA	R (20FEB2021)	N/N	
16-55/ C4591001 1220 12201026	GENRL	Fatigue/ tiredness	1	27OCT2020	1/1	1	Yes		NA	R (27OCT2020)	N/N	
	INV	Body temperature increased/ body temperature increased	2	16NOV2020	1/1	1	Yes		NA	R (16NOV2020)	N/N	
	NERV	Dysgeusia/ taste in mouth	2	16NOV2020	1/1	1	Yes		NA	R (16NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1220 12201027	GENRL	Injection site pain/ pain at injection site#	3	04JAN2021	1/1	1	Yes		NA/TC	R (04JAN2021)	N/N
	GENRL	Injection site pain/ Soreness at Injection site (left Deltoid)#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	NERV	Headache/ Headache#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1220 12201028	MUSC	Myalgia/ myalgia#	3	16DEC2020	1/1	1	Yes		NA	R (16DEC2020)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
16-55/ C4591001 1220 12201030	GENRL	Injection site pain/ soreness at injection site	1	29OCT2020	1/3	1	Yes		NA	R (31OCT2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	18NOV2020	1/8	2	Yes		NA	R (25NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	19NOV2020	2/1	2	Yes		NA	R (19NOV2020)	N/N
	MUSC	Myalgia/ myalgia	2	19NOV2020	2/1	2	Yes		NA	R (19NOV2020)	N/N
16-55/ C4591001 1220 12201031	GENRL	Injection site pain/ injection site tenderness	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1220 12201032	GENRL	Injection site pain/ Injection site soreness	2	23NOV2020	1/2	1	Yes		NA	R (24NOV2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	3	18DEC2020	2/2	1	Yes		NA	R (19DEC2020)	N/N
	GASTR	Nausea/ nausea#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Chills/ chills#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
		Fatigue/ fatigue#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
		Pyrexia/ fever#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	NERV	Dysgeusia/ metallic taste in mouth#	4	05JAN2021	1/1	1	Yes		NA	R (05JAN2021)	N/Y
		Headache/ headache#	4	05JAN2021	1/1	1	Yes		NA	R (05JAN2021)	N/Y
	GENRL	Pain/ generalized body aches#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1220 12201033	GENRL	Fatigue/ fatigue#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
		Injection site pain/ soreness at injection site#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
	MUSC	Myalgia/ myalgia#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1220 12201035	GENRL	Fatigue/ fatigue#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
		Injection site pain/ soreness at injection site#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	GENRL	Injection site erythema/ redness at injection site	1	04NOV2020	2/3	1	Yes		NA	R (06NOV2020)	N/N
		Injection site pain/ soreness at injection site	1	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
16-55/ C4591001 1220 12201037	INFEC	Tooth abscess/ Periodontal Abscess	2	02DEC2020	9/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	21DEC2020	1/2	1	Yes		NA/TC	R (22DEC2020)	N/N
	MUSC	Myalgia/ myalgia#	3	21DEC2020	1/2	1	Yes		NA/TC	R (22DEC2020)	N/N
16-55/ C4591001 1220 12201039	GASTR	Diarrhoea/ diarrhea#	4	13JAN2021	2/2	2	Yes		NA/TC	R (14JAN2021)	N/N
	MUSC	Myalgia/ muscle aches#	4	13JAN2021	2/2	2	Yes		NA/TC	R (14JAN2021)	N/N
	INJ&P	Foot fracture/ Acute mid foot fracture left foot	2	04JAN2021	34/36	3	No	O	NA/TC	R (08FEB2021)	N/N
	NERV	Headache/ headache#	3	01MAR2021	1/1	1	Yes		NA	R (01MAR2021)	N/Y
16-55/ C4591001	INJ&P	Soft tissue injury/ soft tissue injury L foot	1	21NOV2020	10/12	2	No	O	NA/TCN	R (02DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1220 12201041	GENRL	Injection site pain/ soreness at injection site#	3	17DEC2020	1/1	1	Yes	NA	NA	R (17DEC2020)	N/N
	NERV	Headache/ headache#	3	17DEC2020	1/1	1	Yes	NA/TC	NA/TC	R (17DEC2020)	N/N
	GASTR	Diarrhoea/ diarrhea#	3	23DEC2020	7/1	1	Yes	NA	NA	R (23DEC2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	05JAN2021	1/2	1	Yes	NA	NA	R (06JAN2021)	N/Y
16-55/ C4591001 1220 12201042	GENRL	Fatigue/ fatigue	1	13NOV2020	1/6	1	Yes	NA	NA	R (18NOV2020)	N/N
		Injection site pain/ Soreness at injection site left arm	1	13NOV2020	1/2	1	Yes	NA	NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	04DEC2020	1/2	1	Yes	NA	NA	R (05DEC2020)	N/N
	NERV	Headache/ Headache	2	04DEC2020	1/2	1	Yes	NA	NA	R (05DEC2020)	N/N
16-55/ C4591001 1220 12201043	GENRL	Injection site pain/ Soreness at Injection site	1	14NOV2020	2/3	1	Yes	NA	NA	R (16NOV2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	08DEC2020	2/1	1	Yes	NA	NA	R (08DEC2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	08DEC2020	2/2	1	Yes	NA	NA	R (09DEC2020)	N/N
	NERV	Headache/ headache	2	08DEC2020	2/1	1	Yes	NA	NA	R (08DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1220 12201044	BLOOD	Lymphadenopathy/ lymphadenopathy#	3	22DEC2020	2/8	2	Yes		NA	R (29DEC2020)	N/N	
	GENRL	Chills/ chills#	3	22DEC2020	2/3	2	Yes		NA	R (24DEC2020)	N/N	
		Pain/ body aches#	3	22DEC2020	2/3	2	Yes		NA	R (24DEC2020)	N/N	
		Pyrexia/ fever#	3	22DEC2020	2/3	2	Yes		NA	R (24DEC2020)	N/N	
16-55/ C4591001 1220 12201045	GENRL	Injection site pain/ Soreness at injection site	1	17NOV2020	2/3	1	Yes		NA	R (19NOV2020)	N/N	
	GENRL	Fatigue/ fatigue	2	10DEC2020	2/1	1	Yes		NA	R (10DEC2020)	N/N	
		Injection site pain/ Soreness at injection site	2	10DEC2020	2/2	1	Yes		NA	R (11DEC2020)	N/N	
	INFEC	Papilloma viral infection/ Diagnosis of Human Papilloma virus injection	2	15DEC2020	7/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1220 12201048	GENRL	Injection site pain/ Soreness at injection site left arm	1	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N	
	GENRL	Injection site pain/ Soreness at Injection site	2	08DEC2020	2/3	1	Yes		NA	R (10DEC2020)	N/N	
16-55/ C4591001 1220 12201050	GENRL	Fatigue/ fatigue#	3	16DEC2020	1/3	1	Yes		NA	R (18DEC2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue#	4	07JAN2021	1/2	3	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ headache#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Injection site erythema/ Redness at Injection site#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
		Injection site swelling/ Swelling at Injection Site#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
		Pain/ Body aches#	4	08JAN2021	2/1	2	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1220 12201051	GENRL	Injection site pain/ soreness at injection site	1	18NOV2020	1/1	1	Yes		NA	R (18NOV2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	18DEC2020	2/1	1	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1220 12201052	GENRL	Injection site pain/ Soreness at injection site	1	19NOV2020	2/1	1	Yes		NA	R (19NOV2020)	N/N
	GENRL	Chills/ Chills	2	08DEC2020	1/2	1	Yes		NA	R (09DEC2020)	N/N
		Injection site pain/ Soreness at injection site	2	08DEC2020	1/2	1	Yes		NA	R (09DEC2020)	N/N
	BLOOD	Lymphadenopathy/ Lymphadenopathy Left axillary	2	09DEC2020	2/6	1	Yes		NA	R (14DEC2020)	N/N
	GENRL	Malaise/ Malaise	2	09DEC2020	2/2	2	Yes		NA	R (10DEC2020)	N/N
	NERV	Headache/ headache	2	09DEC2020	2/2	2	Yes		NA	R (10DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1220 12201053	GENRL	Injection site pain/ soreness at injection site#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	4	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1220 12201057	GENRL	Injection site pain/ soreness at injection site	1	21NOV2020	2/3	1	Yes		NA	R (23NOV2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	12DEC2020	2/1	1	Yes		NA	R (12DEC2020)	N/N
16-55/ C4591001 1220 12201059	GENRL	Fatigue/ fatigue	1	25NOV2020	2/2	1	Yes		NA	R (26NOV2020)	N/N
	GENRL	Chills/ chills#	2	16DEC2020	1/2	2	Yes		NA	R (17DEC2020)	N/N
		Pyrexia/ fever#	2	16DEC2020	1/2	2	Yes		NA	R (17DEC2020)	N/N
	MUSC	Myalgia/ myalgias#	2	16DEC2020	1/2	2	Yes		NA	R (17DEC2020)	N/N
16-55/ C4591001 1220 12201061	GASTR	Nausea/ nausea	1	01DEC2020	7/1	2	No	O	NA	R (01DEC2020)	N/N
		Vomiting/ vomiting	1	01DEC2020	7/1	2	No	O	NA	R (01DEC2020)	N/N
	MUSC	Flank pain/ R flank pain	1	01DEC2020	7/1	2	No	O	NA	R (01DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1220 12201063	RENAL	Haematuria/ 1+ hematuria	1	01DEC2020	7/C	1	No	O	NA	N	N/N	
	GENRL	Injection site pain/ soreness at injection site#	3	17DEC2020	1/2	1	Yes		NA/TC	R (18DEC2020)	N/N	
	GENRL	Injection site pain/ soreness at injection site#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N	
	NERV	Dysgeusia/ Taste in mouth	1	25NOV2020	1/1	1	Yes		NA	R (25NOV2020)	N/Y	
	NERV	Dysgeusia/ Metallic taste in mouth#	2	25FEB2021	1/1	1	Yes		NA	R (25FEB2021)	N/Y	
	GENRL	Chills/ Chills#	2	26FEB2021	2/2	2	Yes		NA	R (27FEB2021)	N/N	
	GENRL	Pain/ Body aches#	2	26FEB2021	2/2	2	Yes		NA	R (27FEB2021)	N/N	
16-55/ C4591001 1220 12201065	NERV	Pyrexia/ Fever#	2	26FEB2021	2/2	2	Yes		NA	R (27FEB2021)	N/N	
	NERV	Headache/ headache#	2	26FEB2021	2/2	2	Yes		NA	R (27FEB2021)	N/N	
	NERV	Headache/ headache	1	02DEC2020	1/2	1	Yes		NA	R (03DEC2020)	N/N	
	GENRL	Fatigue/ fatigue	1	04DEC2020	3/3	1	Yes		NA	R (06DEC2020)	N/N	
	GENRL	Fatigue/ fatigue#	3	01MAR2021	1/1	1	Yes		NA	R (01MAR2021)	N/N	
NERV	Dizziness/ dizziness#	3	01MAR2021	1/1	1	Yes		NA	R (01MAR2021)	N/N		

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1221 12211003	GENRL	Injection site pain/ Injection site pain	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1221 12211005	GASTR	Diarrhoea/ Diarrhea	1	19OCT2020	5/5	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1221 12211007	INFEC	Abscess jaw/ Abscess in left jaw	1	31OCT2020	16/33	3	No	O	NA/TC/TCN	R (02DEC2020)	N/N
	INFEC	Otitis externa/ Left Otitis Externa	1	06NOV2020	22/13	1	No	O	NA/TC	R (18NOV2020)	N/N
	INJ&P	Exposure to communicable disease/ STD Exposure	1	06NOV2020	22/1	1	No	O	NA/TC	R (06NOV2020)	N/N
	INFEC	Meningitis bacterial/ Meningitis Bacterial	1	10NOV2020	26/23	3	No	O	NA/TC	R (02DEC2020)	Y/N
16-55/ C4591001 1221 12211013	GENRL	Fatigue/ Fatigue	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1221 12211014	GENRL	Fatigue/ Fatigue	1	23OCT2020	2/2	2	Yes		NA/TC	R (24OCT2020)	N/N
16-55/ C4591001 1221 12211020	MUSC	Pain in extremity/ Right Forearm Pain#	3	20FEB2021	4/C	2	No	O	NA/TCN	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1221 12211024	GENRL	Injection site pain/ Injection site soreness	1	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N	
		Malaise/ Malaise	1	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N	
	GENRL	Injection site pain/ Injection Site Soreness	2	10DEC2020	1/3	1	Yes		NA	R (12DEC2020)	N/N	
		Malaise/ Maliase	2	10DEC2020	1/3	1	Yes		NA	R (12DEC2020)	N/N	
	GENRL	Pain/ Body aches	2	11DEC2020	2/2	2	Yes		NA	R (12DEC2020)	N/N	
16-55/ C4591001 1221 12211026	GENRL	Chills/ Chills#	4	05JAN2021	1/3	1	Yes		NA/TC	R (07JAN2021)	N/N	
		Pain/ Body Aches#	4	05JAN2021	1/3	1	Yes		NA/TC	R (07JAN2021)	N/N	
16-55/ C4591001 1221 12211036	GENRL	Chills/ Chills	1	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N	
		Fatigue/ Fatigue	1	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N	
16-55/ C4591001 1221 12211037	GENRL	Injection site pain/ Injection site soreness#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N	
	GASTR	Vomiting/ Vomiting#	3	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1221 12211043	GENRL	Chills/ Body chills#	3	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
	NERV	Migraine/ Migraine#	3	09MAR2021	20/1	2	No	O	NA	R (09MAR2021)	N/N
	GENRL	Chills/ Chills#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Pain/ Body Aches# Injection site pain/ Injection site arm soreness	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1221 12211044	GENRL	Injection site pain/ Injection site arm soreness	1	18NOV2020	1/4	1	Yes		NA	R (21NOV2020)	N/N
16-55/ C4591001 1221 12211045	GENRL	Fatigue/ Fatigue	1	19NOV2020	2/3	2	Yes		NA	R (21NOV2020)	N/N
	MUSC	Myalgia/ myalgias	1	19NOV2020	2/3	2	Yes		NA	R (21NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	09DEC2020	2/1	2	Yes		NA	R (09DEC2020)	N/N
	MUSC	Myalgia/ Achiness (Myalgia)	2	09DEC2020	2/1	2	Yes		NA	R (09DEC2020)	N/N
	NERV	Headache/ Headache	1	19NOV2020	2/1	1	Yes		NA/TC	R (19NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	23NOV2020	1/2	1	Yes		NA	R (24NOV2020)	N/N
	16-55/ C4591001 1221 12211056	GENRL	Injection site pain/ Injection site pain	1	23NOV2020	1/2	1	Yes		NA	R (24NOV2020)

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1221 12211069	GENRL	Chills/ Chills#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
		Pain/ Bodyaches#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
	NERV	Headache/ Headache#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1221 12211072	GENRL	Chills/ Chills	1	02DEC2020	2/2	1	Yes		NA	R (03DEC2020)	N/N
		Fatigue/ Fatigue	1	02DEC2020	2/2	2	Yes		NA	R (03DEC2020)	N/N
		Injection site pain/ Right Arm injection site soreness	1	02DEC2020	2/2	1	Yes		NA	R (03DEC2020)	N/N
16-55/ C4591001 1221 12211083	MUSC	Pain in extremity/ Left Arm Soreness	1	04DEC2020	2/1	1	Yes		NA	R (04DEC2020)	N/N
16-55/ C4591001 1221 12211088	INJ&P	Contusion/ Right forearm contusion	2	23JAN2021	27/C	1	No	O	NA/TC	RG	N/N
		Contusion/ Right wrist contusion	2	23JAN2021	27/C	1	No	O	NA/TC	RG	N/N
	RESP	Epistaxis/ Epistaxis	2	23JAN2021	27/1	1	No	O	NA	R (23JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ arm pain at injection site#	2	17FEB2021	155/3	1	Yes		NA	R (19FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1223 12231001	GENRL	Injection site pain/ injection site pain#	3	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N
1223 12231005	GENRL	Fatigue/ fatigue#	4	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N
1223 12231008	MUSC	Back pain/ back pain#	4	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001	INFEC	Appendicitis/ appendicitis	2	11JAN2021	116/4	4	No	O	NA/TC/TCN	R (14JAN2021)	Y/N
1223 12231014	GENRL	Injection site pain/ injection site pain#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
	NERV	Headache/ headache#	3	12FEB2021	2/2	2	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001	MUSC	Myalgia/ myalgias	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
1223 12231022	RESP	Throat irritation/ scratcy throat	2	28SEP2020	11/5	1	No	O	NA	R (02OCT2020)	N/N
1223 12231024	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	07NOV2020	51/C	1	No	O	NA	UNK	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ injection site pain#	3	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1223 12231025	GENRL	Injection site pain/ injection site pain#	3	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1223 12231028	GENRL	Injection site pain/ mild injection site pain#	3	21DEC2020	2/2	1	Yes		NA	R (22DEC2020)	N/N
16-55/ C4591001 1223 12231031	GENRL	Injection site pain/ injection site pain#	3	28JAN2021	1/7	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1223 12231034	PSYCH	Abnormal dreams/ Vivid Dreams	1	29AUG2020	1/2	2	Yes		NA	R (30AUG2020)	N/N
	GENRL	Chills/ chills	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
		Pyrexia/ fever	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	MUSC	Myalgia/ myalgias	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	INJ&P	Hip fracture/ fractured hip pain	2	03JAN2021	105/1	1	No	O	NA/TC	R (03JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1223 12231035	GENRL	Injection site pain/ injection site pain#	3	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1223 12231036	GENRL	Fatigue/ fatigue#	3	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1223 12231045	GENRL	Injection site pain/ pain at injection site#	3	01MAR2021	1/4	1	Yes		NA	R (04MAR2021)	N/N
16-55/ C4591001 1223 12231050	INFEC	Herpes zoster/ Shingles	2	29SEP2020	8/17	1	No	O	NA/TC	R (15OCT2020)	N/N
	MUSC	Arthralgia/ Knee pain	2	18OCT2020	27/15	1	No	O	NA/TC	R (01NOV2020)	N/N
16-55/ C4591001 1223 12231051	GENRL	Injection site pain/ injection site pain#	3	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1223 12231055	GENRL	Chills/ chills#	3	08JAN2021	20/2	1	Yes		NA/TC	R (09JAN2021)	N/N
		Fatigue/ fatigue#	3	08JAN2021	20/33	1	Yes		NA	R (09FEB2021)	N/N
	MUSC	Arthralgia/ generalized arthralgia#	3	08JAN2021	20/2	1	Yes		NA	R (09JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1223 12231057	GENRL	Fatigue/ Fatigue	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1223 12231062	INJ&P	Post procedural swelling/ facelift swelling	2	13OCT2020	21/1	1	No	O	NA/TC	R (13OCT2020)	N/N
		Procedural pain/ pain from facelift	2	13OCT2020	21/13	2	No	O	NA	R (25OCT2020)	N/N
16-55/ C4591001 1223 12231066	GENRL	Pyrexia/ fever#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
	MUSC	Pain in extremity/ sore arm#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
	NERV	Headache/ headache#	3	18FEB2021	1/2	2	Yes		NA	R (19FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	3	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1223 12231073	GASTR	Nausea/ nausea	2	04OCT2020	13/2	2	No	O	NA	R (05OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Dizziness/ Dizziness	2	04OCT2020	13/2	2	No	O	NA	R (05OCT2020)	N/N
	GENRL	Chills/ chills#	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ headache#	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1223 12231074	INJ&P	Skin laceration/ left inner finger laceration	2	05JAN2021	105/9	2	No	O	NA/TCN	R (13JAN2021)	N/N
16-55/ C4591001 1223 12231075	GENRL	Chills/ chills#	4	06JAN2021	1/1	1	Yes		NA	R (06JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	06JAN2021	1/1	1	Yes		NA	R (06JAN2021)	N/N
	NERV	Headache/ intermittent headaches#	4	07JAN2021	2/20	1	Yes		NA	R (26JAN2021)	N/N
	GASTR	Gastrointestinal necrosis/ Bowel necrosis#	4	04FEB2021	30/C	4	No	O	NA/TC/TCN	N	Y/N
	INJ&P	Postoperative ileus/ Postoperative ileus#	4	11FEB2021	37/5	3	No	O	NA/TC	R (15FEB2021)	Y/N
	GASTR	Small intestinal obstruction/ Small Bowel Obstruction#	4	16FEB2021	42/4	3	No	O	NA/TC	R (19FEB2021)	Y/N
16-55/ C4591001 1223 12231077	MUSC	Arthralgia/ joint aches	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N
		Myalgia/ muscle aches	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1223 12231084	GENRL	Injection site pain/ injection site pain#	3	19FEB2021	1/3	2	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1223 12231086	GENRL	Fatigue/ fatigue#	3	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
		Injection site pain/ injection site pain#	2	19FEB2021	150/2	2	Yes		NA	R (20FEB2021)	N/N
	NERV	Headache/ headaches#	3	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1223 12231090	GENRL	Peripheral swelling/ left arm swelling	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/Y
	SKIN	Erythema/ Left arm redness	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/Y
16-55/ C4591001 1223 12231094	NERV	Headache/ headache	2	25SEP2020	1/1	2	Yes		NA/TC	R (25SEP2020)	N/N
	SKIN	Hyperhidrosis/ sweats	1	25SEP2020	24/2	2	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1223 12231095	MUSC	Arthralgia/ right elbow pain	2	30SEP2020	6/2	2	No	O	NA	R (01OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	22FEB2021	1/4	1	Yes		NA	R (25FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1223 12231099	GENRL	Fatigue/ fatigue#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
		Pyrexia/ low grade fever#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1223 12231101	GENRL	Injection site pain/ injection site pain#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
	INFEC	Herpes zoster/ shingles, 1 dermatome#	4	12JAN2021	2/21	1	No	O	NA/TC	R (01FEB2021)	N/N
16-55/ C4591001 1223 12231105	GENRL	Injection site pain/ injection site pain#	3	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1223 12231112	GENRL	Fatigue/ fatigue	2	20OCT2020	23/3	1	Yes		NA/TC	R (22OCT2020)	N/N
	GASTR	Diarrhoea/ diarrhea#	3	22FEB2021	1/1	1	Yes		NA	R (22FEB2021)	N/N
16-55/ C4591001 1223 12231113	GENRL	Injection site pain/ injection site pain#	2	18FEB2021	144/1	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1223 12231118	GENRL	Chills/ chills	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1223 12231121	MUSC	Pain in extremity/ left arm soreness	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Chills/ chills#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1223 12231122	GENRL	Fatigue/ fatigue#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain#	3	24FEB2021	1/2	1	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1223 12231133	GENRL	Fatigue/ fatigue#	3	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
	MUSC	Myalgia/ generalized myalgias#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1223 12231135	MUSC	Pain in extremity/ arm soreness#	3	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1223 12231137	GENRL	Fatigue/ fatigue	2	30SEP2020	1/3	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001	MUSC	Myalgia/ muscle pain	2	30SEP2020	1/3	1	Yes		NA/TC	R (02OCT2020)	N/N
	GENRL	Chills/ chills#	4	09JAN2021	2/1	1	Yes		NA/TC	R (09JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1223 12231141		Chills/ rigors#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
		Fatigue/ fatigue#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1223 12231145	GASTR	Diarrhoea/ Diarrhea	1	11SEP2020	3/1	2	No	O	NA	R (11SEP2020)	N/N
	NERV	Tension headache/ tension headaches	2	14OCT2020	15/11	2	No	O	NA/TC	R (24OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
	GASTR	Diarrhoea/ loose stools#	3	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1223 12231147	GENRL	Pyrexia/ fever 100.1 F#	4	04FEB2021	1/4	1	Yes		NA/TC/TCN	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	4	06FEB2021	3/4	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1223 12231151	GENRL	Injection site pain/ injection site pain#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1223 12231154	GENRL	Chills/ chills*		10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1223 12231157	GENRL	Fatigue/ fatigue	1	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N
		Chills/ chills#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
		Pyrexia/ fever#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Pain in extremity/ Exertional Left arm soreness	1	10SEP2020	1/4	3	Yes		NA/TC	R (13SEP2020)	N/N
	NERV	Headache/ Headache	1	10SEP2020	1/2	3	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1223 12231160	GENRL	Pyrexia/ mild fever	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		Fatigue/ fatigue	1	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Pain in extremity/ arm pain	2	06OCT2020	2/2	2	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1223 12231161	GENRL	Fatigue/ fatigue	2	07OCT2020	3/2	2	Yes		NA	R (08OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1223 12231166	METAB	Gout/ exacerbation of gout in shoulder	1	04OCT2020	21/C	1	No	O	NA/TC	N	N/N	
	VASC	Hypertensive urgency/ hypertensive urgency	2	28OCT2020	22/9	2	No	O	NA/TC	R (05NOV2020)	Y/N	
16-55/ C4591001 1223 12231175	GENRL	Pyrexia/ fever	2	06OCT2020	2/2	2	Yes		NA/TC	R (07OCT2020)	N/N	
16-55/ C4591001 1223 12231181	GENRL	Asthenia/ generalized weakness#	4	09JAN2021	2/3	1	Yes		NA	R (11JAN2021)	N/N	
		Injection site pain/ injection site pain#	4	09JAN2021	2/3	1	Yes		NA/TC	R (11JAN2021)	N/N	
	GASTR	Abdominal pain/ abdominal pain#	4	31JAN2021	24/C	3	Yes		NA/TC	RG	N/N	
	BLOOD	Lymphadenopathy/ Submandibular lymphadenopathy#	4	01FEB2021	25/C	2	Yes		NA/TC	RG	N/N	
16-55/ C4591001 1223 12231184	GENRL	Chills/ chills	2	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N	
16-55/ C4591001 1223 12231187	GENRL	Fatigue/ fatigue	2	10OCT2020	5/1	2	Yes		NA	R (10OCT2020)	N/N	
	NERV	Headache/ headache	2	10OCT2020	5/1	2	Yes		NA/TC	R (10OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1223 12231192	GASTR	Nausea/ nausea	1	19SEP2020	2/1	3	Yes		NA/TCN	R (19SEP2020)	N/N
	GENRL	Injection site bruising/ bruising at injection site#	3	28FEB2021	3/11	1	Yes		NA	R (10MAR2021)	N/N
16-55/ C4591001 1223 12231197	GENRL	Chills/ CHILLS#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
		Fatigue/ FATIGUE#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
		Pyrexia/ FEVER#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1223 12231204	GENRL	Chills/ chills	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
		Pain/ bodyaches	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	NERV	Headache/ headache	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Pyrexia/ fever#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1223 12231212	GENRL	Injection site pain/ pain at injection site#	3	02MAR2021	2/4	1	Yes		NA	R (05MAR2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1223 12231213	GENRL	Injection site pain/ injection site pain	1	21OCT2020	22/3	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Chills/ chills	2	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
		Malaise/ malaise	2	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1223 12231220	GENRL	Injection site pain/ injection site pain#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
	MUSC	Arthralgia/ Arthralgia ankles and knees#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1223 12231221	GASTR	Diarrhoea/ Diarrhea*		01OCT2020	1/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1223 12231226	MUSC	Pain in extremity/ right arm soreness	1	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1223 12231229	GENRL	Injection site pain/ injection site pain#	3	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001	NERV	Headache/ headache*		08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1223 12231230 16-55/ C4591001	MUSC	Myalgia/ muscle aches	2	03NOV2020	2/1	2	Yes		NA/TC	R (03NOV2020)	N/N	
1223 12231236		Pain in extremity/ arm pain	2	03NOV2020	2/1	1	Yes		NA	R (03NOV2020)	N/N	
	VASC	Flushing/ generalized flushing	2	03NOV2020	2/1	1	Yes		NA	R (03NOV2020)	N/N	
16-55/ C4591001	GENRL	Fatigue/ fatigue	1	14OCT2020	1/3	2	Yes		NA	R (16OCT2020)	N/N	
1223 12231242	MUSC	Pain in extremity/ left arm soreness	1	14OCT2020	1/4	2	Yes		NA	R (17OCT2020)	N/N	
	MUSC	Pain in extremity/ arm pain	2	06NOV2020	1/3	1	Yes		NA	R (08NOV2020)	N/N	
16-55/ C4591001	MUSC	Pain in extremity/ arm pain	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/Y	
1223 12231243	GENRL	Pyrexia/ subjective fever#	4	09JAN2021	1/2	1	Yes		NA	RS (10JAN2021)	N/N	
	MUSC	Myalgia/ deltoid pain#	4	10JAN2021	2/4	1	Yes		NA	R (13JAN2021)	N/N	
16-55/ C4591001	GENRL	Pyrexia/ fever	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N	
1223 12231244												

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1223 12231245	MUSC	Pain in extremity/ sore arm post vaccine	1	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
	INV	Body temperature/ temperature	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
	MUSC	Pain in extremity/ arm pain	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/Y
	GENRL	Injection site pain/ left arm injection pain	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
	BLOOD	Lymph node pain/ tenderness left axillary lymph node	2	06NOV2020	2/4	1	Yes		NA	R (09NOV2020)	N/N
	NERV	Headache/ headache	1	30OCT2020	16/3	2	No	O	NA/TC	R (01NOV2020)	N/N
	NERV	Headache/ headache	2	06NOV2020	2/2	1	Yes		NA/TC	R (07NOV2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
	GENRL	Chills/ chills#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	16-55/ C4591001 1223 12231247†	MUSC	Myalgia/ myalgia#	4	09JAN2021	2/2	1	Yes		NA/TC	R (10JAN2021)
16-55/ C4591001 1223 12231251	MUSC	Pain in extremity/ left arm pain	1	06NOV2020	22/1	1	Yes		NA	R (06NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1223 12231252	MUSC	Pain in extremity/ left arm pain	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Malaise/ malaise	2	05NOV2020	2/2	2	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1223 12231253	GENRL	Injection site pain/ pain in injection site	1	12NOV2020	21/4	1	Yes		NA	R (15NOV2020)	N/N
16-55/ C4591001 1223 12231256	MUSC	Pain in extremity/ sore arm#	3	02MAR2021	1/3	1	Yes		NA	R (04MAR2021)	N/N
16-55/ C4591001 1223 12231258	NERV	Headache/ headache#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1224 12241010	EYE	Lacrimation increased/ Watery eyes	2	02SEP2020	2/C	1	No	O	NA	N	N/N
	RESP	Rhinorrhoea/ Runny Nose	2	02SEP2020	2/C	1	No	O	NA	N	N/N
16-55/ C4591001 1224 12241065	GASTR	Diarrhoea/ Diarrhea	1	24AUG2020	1/14	2	Yes		NA	R (06SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	24AUG2020	1/10	2	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1224 12241079	INV	Pyrexia/ Feverish Chills	1	24AUG2020	1/10	2	Yes		NA	R (02SEP2020)	N/N
		Blood pressure increased/ Increased Blood Pressure	1	24AUG2020	1/18	2	Yes		NA	R (10SEP2020)	N/N
	GENRL	Heart rate irregular/ Irregular Heart Rate	1	24AUG2020	1/18	2	Yes		P	R (10SEP2020)	N/N
		Asthenia/ Weakness	1	27AUG2020	3/2	1	No	O	NA	R (28AUG2020)	N/N
16-55/ C4591001 1224 12241083	PSYCH	Fatigue/ Fatigue	1	27AUG2020	3/2	1	No	O	NA	R (28AUG2020)	N/N
	DEPRESSION	Depression/ Depression	1	27AUG2020	3/2	1	No	O	NA	R (28AUG2020)	N/N
16-55/ C4591001 1224 12241083	CARD	Cardiac disorder/ Left Atrial Abnormality	1	01SEP2020	7/C	1	No	O	NA	N	N/N
16-55/ C4591001 1224 12241114	MUSC	Arthritis/ Arthritis - Left hip	2	01NOV2020	41/93	3	No	O	NA/TC/TCN	R (01FEB2021)	N/N
16-55/ C4591001 1224 12241118	GENRL	Chills/ Chills	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ Fever (100.6)	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1224 12241119	NERV	Headache/ Headache	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
	ENDO	Thyroid cyst/ Thyroid Nodule/Cyst	2	20OCT2020	29/43	2	No	O	NA/TC/TCN	RS (01DEC2020)	N/N
16-55/ C4591001 1224 12241121	GENRL	Feeling abnormal/ Brain Fog	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1224 12241126		Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1224 12241126		Lethargy/ Lethargy	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N
	GASTR	Dry mouth/ Dry Mouth	1	02SEP2020	1/1	2	Yes		NA	R (02SEP2020)	N/Y
16-55/ C4591001 1224 12241131	GASTR	Dry mouth/ Dry Mouth	2	23SEP2020	1/1	2	Yes		NA	R (23SEP2020)	N/Y
	GENRL	Pyrexia/ Low Grade Fever	1	08SEP2020	6/1	1	Yes		NA	R (08SEP2020)	N/N
	GENRL	Pyrexia/ Low Grade Fever	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Myalgia/ Achy Muscles	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1224 12241135	GENRL	Fatigue/ Exhaustion	1	07SEP2020	4/4	2	Yes		NA	R (10SEP2020)	N/N	
16-55/ C4591001 1224 12241138	RESP	Sinus congestion/ Sinus Congestion	1	18SEP2020	15/7	1	No	O	NA	R (24SEP2020)	N/N	
16-55/ C4591001 1224 12241168	GENRL	Pyrexia/ Fever - 101.0F	2	18DEC2020	9/1	1	Yes		NA/TC	R (18DEC2020)	N/N	
	SKIN	Rash/ Rash - bilateral upper arms	2	18DEC2020	9/1	1	Yes		NA/TC	R (18DEC2020)	N/N	
16-55/ C4591001 1226 12261002	GENRL	Injection site pain/ Pain at injection site#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N	
	NERV	Headache/ Headache#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N	
	GENRL	Pyrexia/ fever (38,3 C)#	4	10FEB2021	1/3	2	Yes		NA/TC	R (12FEB2021)	N/N	
	MUSC	Myalgia/ myalgia#	4	10FEB2021	1/3	2	Yes		NA/TC	R (12FEB2021)	N/N	
	NERV	Headache/ headache#	4	10FEB2021	1/3	2	Yes		NA/TC	R (12FEB2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site#	3	22JAN2021	1/2	2	Yes		NA	R (23JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12261004	GENRL	Injection site pain/ Pain at the injection site#	4	11FEB2021	2/1	1	Yes		NA/TC	R (11FEB2021)	N/N	
16-55/ C4591001 1226 12261005	GENRL	Injection site pain/ pain at the injection site#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N	
16-55/ C4591001 1226 12261010	GENRL	Injection site pain/ pain at the injection site#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/Y	
16-55/ C4591001 1226 12261013	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	1/1	1	Yes		NA/TC	R (23JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	3	23JAN2021	1/2	1	Yes		NA/TC	R (24JAN2021)	N/N	
	NERV	Headache/ Headache#	3	23JAN2021	1/2	1	Yes		NA/TC	R (24JAN2021)	N/N	
	GENRL	Injection site pain/ pain at the injection site#	4	12FEB2021	1/2	2	Yes		NA	R (13FEB2021)	N/N	
	GENRL	Pyrexia/ fever (38,3 C)#	4	13FEB2021	2/3	2	Yes		NA/TC	R (15FEB2021)	N/N	
16-55/ C4591001 1226 12261014	NERV	Tremor/ Tremors	1	06AUG2020	2/2	2	Yes		NA/TC	R (07AUG2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ pain at the injection site#	3	30JAN2021	1/2	2	Yes		NA/TC	R (31JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12261016	NERV	Headache/ headache#	3	31JAN2021	2/1	2	Yes		NA/TC	R (31JAN2021)	N/N	
	GENRL	Injection site pain/ Pain at the injection site#	4	19FEB2021	1/4	1	Yes		NA/TC	R (22FEB2021)	N/N	
	INV	Body temperature increased/ Increased body temperature 37.3 C#	4	19FEB2021	1/4	1	Yes		NA/TC	R (22FEB2021)	N/N	
16-55/ C4591001 1226 12261017	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	1/2	1	Yes		NA	R (31JAN2021)	N/N	
	GENRL	Injection site pain/ pain at the injection site#	4	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N	
16-55/ C4591001 1226 12261018	GENRL	Fatigue/ fatigue#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N	
	MUSC	Myalgia/ Muscle pain#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N	
	GENRL	Pain/ Body pain#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N	
16-55/ C4591001 1226 12261019	GENRL	Chills/ chills#	3	09FEB2021	2/3	2	Yes		NA/TC	R (11FEB2021)	N/N	
		Injection site pain/ pain at the injection site#	3	09FEB2021	2/3	2	Yes		NA/TC	R (11FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261025	MUSC	Myalgia/ muscle pain#	3	09FEB2021	2/3	2	Yes		NA/TC	R (11FEB2021)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N	
16-55/ C4591001 1226 12261026	GENRL	Chills/ chills#	3	30JAN2021	1/1	1	Yes		NA/TC	R (30JAN2021)	N/N	
16-55/ C4591001 1226 12261027	GENRL	Injection site pain/ pain at the injection site#	3	30JAN2021	1/2	1	Yes		NA/TC	R (31JAN2021)	N/N	
		Chills/ chills#	4	20FEB2021	1/1	1	Yes		NA/TC	R (20FEB2021)	N/N	
		Injection site pain/ pain at the injection site#	4	20FEB2021	1/1	1	Yes		NA/TC	R (20FEB2021)	N/N	
		Myalgia/ muscle pain#	4	20FEB2021	1/1	1	Yes		NA/TC	R (20FEB2021)	N/N	
16-55/ C4591001 1226 12261027	RESP	Cough/ Dry cough	1	14AUG2020	9/28	1	No	O	NA	R (10SEP2020)	N/N	
16-55/ C4591001 1226 12261030	NERV	Headache/ Headache	2	28AUG2020	4/1	1	Yes		NA	R (28AUG2020)	N/N	
16-55/ C4591001 1226 12261031	GENRL	Injection site pain/ pan at the injection site#	3	30JAN2021	1/3	1	Yes		NA	R (01FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261032	GENRL	Injection site pain/ pain at the injection site#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Pain/ body pain#	3	31JAN2021	2/2	1	Yes		NA	R (01FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	20FEB2021	1/3	1	Yes		NA/TC	R (22FEB2021)	N/N
16-55/ C4591001 1226 12261037		Pyrexia/ fever (38 C)#	4	20FEB2021	1/3	1	Yes		NA/TC	R (22FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	1	18AUG2020	12/2	1	No	O	NA	R (19AUG2020)	N/N
	MUSC	Myalgia/ Muscular pain	2	28AUG2020	3/2	1	Yes		NA	R (29AUG2020)	N/N
	MUSC	Myalgia/ Muscular pain	2	30AUG2020	5/1	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	2/1	1	Yes		NA	R (30JAN2021)	N/N
	INFEC	Rhinitis/ Coryza#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1226 12261038	NERV	Headache/ headache	2	26NOV2020	91/3	2	Yes		NA/TC	R (28NOV2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at the injection site#	3	30JAN2021	1/2	2	Yes		NA/TC	R (31JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261041	MUSC	Myalgia/ myalgia#	3	30JAN2021	1/2	2	Yes		NA/TC	R (31JAN2021)	N/N
16-55/ C4591001 1226 12261043	INFEC	Herpes zoster oticus/ Ramsay Hunt Syndrome#	2	25JAN2021	153/21	4	No	O	NA/TC	RS (14FEB2021)	Y/N
16-55/ C4591001 1226 12261044	MUSC	Back pain/ Backache	2	29SEP2020	35/7	1	No	O	NA/TC	R (05OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	03FEB2021	2/3	2	Yes		NA/TC	R (05FEB2021)	N/N
16-55/ C4591001 1226 12261045	MUSC	Back pain/ Backache	2	11SEP2020	17/9	2	No	O	NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1226 12261049	GENRL	Pyrexia/ fever (38 C)	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
	NERV	Headache/ Headache	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1226 12261052	GENRL	Fatigue/ fatigue#	4	16FEB2021	2/4	1	Yes		NA	R (19FEB2021)	N/N
		Injection site pain/ pain at the injection site#	4	16FEB2021	2/4	1	Yes		NA	R (19FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261055	MUSC	Myalgia/ myalgia#	4	16FEB2021	2/4	1	Yes		NA	R (19FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	23FEB2021	2/4	1	Yes		NA	R (26FEB2021)	N/N	
		Injection site pain/ Pain at the injection site#	4	23FEB2021	2/3	1	Yes		NA/TC	R (25FEB2021)	N/N	
		Pyrexia/ Fever 38.5 C#	4	23FEB2021	2/3	1	Yes		NA/TC	R (25FEB2021)	N/N	
16-55/ C4591001 1226 12261065	MUSC	Myalgia/ Muscle pain#	4	23FEB2021	2/3	1	Yes		NA/TC	R (25FEB2021)	N/N	
	NERV	Headache/ headache#	3	30JAN2021	1/2	1	Yes		NA	R (31JAN2021)	N/N	
16-55/ C4591001 1226 12261067	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N	
	RENAL	Nephrolithiasis/ Worsening of nephrolithiasis	2	09NOV2020	70/18	3	No	O	NA/TC	R (26NOV2020)	Y/N	
	GENRL	Injection site haematoma/ Hematoma at injection site#	3	23JAN2021	2/5	1	Yes		NA	R (27JAN2021)	N/N	
	GENRL	Injection site pain/ Pain at the injection site#	4	12FEB2021	2/2	2	Yes		NA/TC	R (13FEB2021)	N/N	
		Pain/ Body pain#	4	12FEB2021	2/2	2	Yes		NA/TC	R (13FEB2021)	N/N	
		Pyrexia/ Fever 38.5#	4	12FEB2021	2/2	2	Yes		NA/TC	R (13FEB2021)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261072	MUSC	Myalgia/ Muscle pain (shoulders and neck, on the right body side)	1	18AUG2020	8/C	2	Yes		P/TC/W	N	N/N
16-55/ C4591001 1226 12261073	INFEC	Rhinitis/ Coryza	1	03SEP2020	24/2	1	Yes		NA	R (04SEP2020)	N/N
	RESP	Nasal congestion/ Nasal congestion	2	04SEP2020	1/1	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1226 12261074	EYE	Blepharitis/ blepharitis	2	28SEP2020	25/3	1	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1226 12261076	INFEC	Urinary tract infection/ Urinary tract infection	1	18AUG2020	8/3	2	No	O	NA/TC	R (20AUG2020)	N/N
16-55/ C4591001 1226 12261082	GASTR	Nausea/ nausea	1	19AUG2020	9/1	1	No	O	NA/TC	R (19AUG2020)	N/N
	MUSC	Torticollis/ torticollis	1	24AUG2020	14/1	1	No	O	NA/TC	R (24AUG2020)	N/N
16-55/ C4591001 1226 12261083	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	1/2	2	Yes		NA	R (31JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	20FEB2021	1/3	1	Yes		NA/TC	R (22FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261084	GENRL	Pain/ body pain#	4	11FEB2021	2/2	2	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1226 12261085	GASTR	Diarrhoea/ diarrhea	2	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
	MUSC	Arthralgia/ arthralgia	2	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001 1226 12261086	GENRL	Injection site pain/ pain at the injection site#	3	30JAN2021	1/4	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Chills/ chill#	3	31JAN2021	2/1	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N
	GENRL	Asthenia/ Asthenia#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
	NERV	Headache/ Headache#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1226 12261087	GENRL	Pyrexia/ Fever 38.4 C#	4	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261088	MUSC	Myalgia/ Muscle pain#	4	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N
	GASTR	Angular cheilitis/ Angular cheilitis	1	20AUG2020	10/22	1	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1226 12261093	INJ&P	Ligament rupture/ Left knee ligament rupture	2	18NOV2020	79/C	2	No	O	NA/TC	RG	N/N
	GENRL	Ligament rupture/ Right knee ligament rupture	2	18NOV2020	79/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1226 12261094	GENRL	Chills/ chills#	4	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N
	GENRL	Pyrexia/ fever (38.5C)#	4	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N
	RENAL	Nephrolithiasis/ Worsening of Nephrolithiasis	2	21DEC2020	112/33	3	No	O	NA/TC/TCN	R (22JAN2021)	Y/N
	INFEC	Urinary tract infection/ Urinary tract infection	2	29DEC2020	120/8	2	No	O	NA/TC	R (05JAN2021)	N/N
16-55/ C4591001 1226 12261100	GENRL	Fatigue/ Fatigue#	3	22JAN2021	1/3	2	Yes		NA/TC	R (24JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	22JAN2021	1/3	2	Yes		NA/TC	R (24JAN2021)	N/N
	GENRL	Pyrexia/ Fever 39 C#	4	11FEB2021	2/3	2	Yes		NA/TC	R (13FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261104	GENRL	Fatigue/ Fatigue	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
	NERV	Headache/ Headache	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	1/3	2	Yes		NA	R (01FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	20FEB2021	1/3	1	Yes		NA	R (22FEB2021)	N/N
	GENRL	Asthenia/ asthenia#	4	21FEB2021	2/2	1	Yes		NA/TC	R (22FEB2021)	N/N
16-55/ C4591001 1226 12261106	NERV	Headache/ Headache	1	21AUG2020	11/1	1	No	O	NA/TC	R (21AUG2020)	N/N
	REPRO	Dysmenorrhoea/ Menstrual cramps	1	22AUG2020	12/1	1	No	O	NA/TC	R (22AUG2020)	N/N
	GENRL	Fatigue/ fatigue	2	02SEP2020	2/3	3	Yes		NA	R (04SEP2020)	N/N
	MUSC	Arthralgia/ joint pain	2	02SEP2020	2/2	3	Yes		NA	R (03SEP2020)	N/N
		Myalgia/ muscle pain	2	02SEP2020	2/2	3	Yes		NA	R (03SEP2020)	N/N
	NERV	Headache/ headache	2	02SEP2020	2/3	3	Yes		NA	R (04SEP2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	02FEB2021	1/2	2	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INV	Body temperature increased/ increased body temperature#	3	02FEB2021	1/2	2	Yes		NA	R (03FEB2021)	N/N
	NERV	Dizziness/ dizziness#	3	03FEB2021	2/1	2	Yes		NA	R (03FEB2021)	N/N
		Headache/ headache#	3	03FEB2021	2/1	2	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1226 12261111	GENRL	Injection site pain/ pain at the injection site#	4	21FEB2021	2/2	1	Yes		NA	R (22FEB2021)	N/N
16-55/ C4591001 1226 12261115	GENRL	Injection site pain/ Pain at the injection site#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
16-55/ C4591001 1226 12261118	MUSC	Back pain/ back pain	2	16SEP2020	14/2	1	No	O	NA/TC	R (17SEP2020)	N/N
		Neck pain/ neck pain	2	16SEP2020	14/2	1	No	O	NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1226 12261120	GENRL	Injection site pain/ pain at the injection site#	3	30JAN2021	1/3	2	Yes		NA/TC	R (01FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	3	30JAN2021	1/3	2	Yes		NA/TC	R (01FEB2021)	N/N
	GENRL	Pyrexia/ fever (37,9 C)#	3	31JAN2021	2/1	2	Yes		NA/TC	R (31JAN2021)	N/N
	GENRL	Chills/ chills#	4	20FEB2021	1/2	1	Yes		NA/TC	R (21FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261121	GENRL	Pyrexia/ fever (38 C)#	4	20FEB2021	1/2	1	Yes		NA/TC	R (21FEB2021)	N/N	
		Injection site pain/ Pain at injection site#	3	31JAN2021	2/2	1	Yes		NA	R (01FEB2021)	N/N	
		Fatigue/ Fatigue#	4	21FEB2021	2/2	1	Yes		NA/TC	R (22FEB2021)	N/N	
		Injection site pain/ Pain at injection site#	4	21FEB2021	2/2	1	Yes		NA/TC	R (22FEB2021)	N/N	
16-55/ C4591001 1226 12261123	INV	Pyrexia/ Fever (38.3 C)#	4	21FEB2021	2/2	1	Yes		NA/TC	R (22FEB2021)	N/N	
		Body temperature increased/ increase of temperature (37,8 C)#	4	19FEB2021	2/1	1	Yes		NA/TC	R (19FEB2021)	N/N	
16-55/ C4591001 1226 12261124	MUSC	Pain in extremity/ Pain in legs	1	19AUG2020	8/3	2	No	O	NA/TC	R (21AUG2020)	N/N	
16-55/ C4591001 1226 12261126	MUSC	Back pain/ acute low back pain	1	20AUG2020	9/C	2	No	O	NA/TC	RG	N/N	
	GENRL	Fatigue/ tiredness#	3	02FEB2021	2/3	2	Yes		NA	R (04FEB2021)	N/N	
	MUSC	Injection site pain/ pain at the injection site#	3	02FEB2021	2/3	2	Yes		NA/TC	R (04FEB2021)	N/N	
Myalgia/ muscle pain#		3	02FEB2021	2/3	2	Yes		NA/TC	R (04FEB2021)	N/N		

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261130	GENRL	Injection site pain/ Pain at the injection site#	4	22FEB2021	1/4	2	Yes		NA/TC	R (25FEB2021)	N/N
		Injection site swelling/ Swelling at the injection site#	4	22FEB2021	1/4	2	Yes		NA/TC	R (25FEB2021)	N/N
	GENRL	Chills/ Chills#	4	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N
	INV	Body temperature increased/ Increased body temperature 37.6 C#	4	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N
	MUSC	Arthralgia/ Joint pain#	4	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	1/3	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Chills/ Chills#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
		Fatigue/ Tiredness#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1226 12261134	GENRL	Malaise/ Malaise#	4	24FEB2021	3/1	1	Yes		NA/TC	R (24FEB2021)	N/N
		Pyrexia/ Fever 38 C#	4	24FEB2021	3/1	1	Yes		NA/TC	R (24FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261135	MUSC	Myalgia/ Muscle pain#	4	24FEB2021	3/1	1	Yes		NA/TC	R (24FEB2021)	N/N	
	GENRL	Fatigue/ tiredness#	3	31JAN2021	2/2	2	Yes		NA	R (01FEB2021)	N/N	
16-55/ C4591001 1226 12261136		Injection site pain/ pain at the injection site#	3	31JAN2021	2/2	2	Yes		NA/TCN	R (01FEB2021)	N/N	
	GENRL	Injection site pain/ pain at the injection site#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N	
16-55/ C4591001 1226 12261136	GASTR	Haemorrhoids/ Hemorrhoid Worsening	2	26JAN2021	145/2	4	No	O	NA/TC/TCN	R (27JAN2021)	Y/N	
16-55/ C4591001 1226 12261137	INJ&P	Fall/ Bicycle fall	2	20SEP2020	18/1	3	No	O	NA/TCN	R (20SEP2020)	N/N	
16-55/ C4591001 1226 12261139		Forearm fracture/ Right forearm fracture	2	20SEP2020	18/10	3	No	O	NA/TC/TCN	R (29SEP2020)	Y/N	
	GASTR	Dental caries/ Dental cavity	1	21AUG2020	10/6	1	No	O	NA/TCN	R (26AUG2020)	N/N	
16-55/ C4591001 1226 12261144	INFEC	Gingivitis/ gingivitis	1	21AUG2020	10/8	1	No	O	NA/TC	R (28AUG2020)	N/N	
	NERV	Headache/ Headache	1	27AUG2020	16/1	1	No	O	NA	R (27AUG2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1226 12261147	GENRL	Injection site pain/ Pain at injection site#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Pain/ body pain#	4	22FEB2021	1/3	1	Yes		NA/TC	R (24FEB2021)	N/N
		Pyrexia/ fever#	4	22FEB2021	1/3	2	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1226 12261148	GENRL	Injection site pain/ Pain at injection site#	4	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1226 12261150	GENRL	Injection site pain/ pain at the injection site#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1226 12261153	GENRL	Injection site pain/ Pain at injection site#	3	30JAN2021	1/4	2	Yes		NA	R (02FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	3	30JAN2021	1/4	2	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1226 12261156	GENRL	Chills/ chills#	4	17FEB2021	2/1	1	Yes		NA/TC	R (17FEB2021)	N/N
		Fatigue/ fatigue#	4	17FEB2021	2/1	1	Yes		NA/TC	R (17FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261158	GENRL	Chills/ Chills#	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N
	NERV	Headache/ Headache#	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N
	GENRL	Chills/ chills#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
		Pain/ body pain#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1226 12261159	PSYCH	Anxiety disorder/ Anxiety disorder	1	14AUG2020	2/C	2	No	O	NA/TC	RG	N/N
	GENRL	Fatigue/ Tiredness#	3	24JAN2021	2/2	1	Yes		NA	R (25JAN2021)	N/N
		Injection site pain/ Pain at the injection site#	3	24JAN2021	2/2	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	16FEB2021	2/2	2	Yes		NA/TC	R (17FEB2021)	N/N
	MUSC	Arthralgia/ Joint pain#	4	16FEB2021	2/2	2	Yes		NA/TC	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	2/2	2	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001	MUSC	Back pain/ Left back pain	2	12OCT2020	40/3	1	No	O	NA	R (14OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261161	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
1226 12261163	BLOOD	Lymph node pain/ sore left axillary lymph node	2	07SEP2020	5/15	1	Yes		NA	R (21SEP2020)	N/N
1226 12261164	MUSC	Back pain/ back pain on the left	2	07SEP2020	5/5	1	Yes		NA	R (11SEP2020)	N/N
		Pain in extremity/ left arm pain	2	07SEP2020	5/5	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1226 12261167	GENRL	Injection site pain/ pain at the injection site#	4	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N
		Pyrexia/ fever#	4	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1226 12261168	GENRL	Injection site erythema/ Redness at injection site	2	18SEP2020	16/1	1	No	O	NA	R (18SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	18SEP2020	16/1	1	No	O	NA	R (18SEP2020)	N/N
	GENRL	Chills/ chills#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
		Injection site pain/ pain at the injection site#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261172	NERV	Dizziness/ dizziness#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N	
		Headache/ headache#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	17FEB2021	1/2	2	Yes		NA/TC	R (18FEB2021)	N/N	
	GENRL	Chills/ chills#	3	30JAN2021	1/2	1	Yes		NA/TC	R (31JAN2021)	N/N	
16-55/ C4591001 1226 12261174	NERV	Headache/ headache#	3	30JAN2021	1/2	1	Yes		NA/TC	R (31JAN2021)	N/N	
	INFEC	Herpes zoster cutaneous disseminated/ multidermatomal herpes zoster	2	25OCT2020	53/27	2	No	O	NA/TC	R (20NOV2020)	N/N	
16-55/ C4591001 1226 12261176	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	1/2	1	Yes		NA	R (31JAN2021)	N/N	
	MUSC	Myalgia/ muscle pain#	4	23FEB2021	2/2	1	Yes		NA/TC	R (24FEB2021)	N/N	
	GENRL	Fatigue/ fatigue#	3	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/Y	
16-55/ C4591001 1226 12261178		Injection site pain/ pain at the injection site#	3	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/Y	
	GASTR	Abdominal pain/ abdominal colic	2	30OCT2020	57/1	1	No	O	NA	R (30OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261185	GENRL	Injection site pain/ Pain at the injection site#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1226 12261186	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N
	NERV	Somnolence/ Somnolence#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1226 12261188	GENRL	Injection site pain/ Pain at the injection site#	3	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1226 12261189	INFEC	Rhinitis/ coryza	2	26OCT2020	53/6	1	No	O	NA/TC	R (31OCT2020)	N/N
	RESP	Nasal congestion/ nasal congestion	2	26OCT2020	53/6	1	No	O	NA/TC	R (31OCT2020)	N/N
16-55/ C4591001 1226 12261190	BLOOD	Lymphadenopathy/ left axillary lymph node enlargement	2	06SEP2020	3/	1	Yes		NA	R	N/N
16-55/ C4591001 1226 12261193	METAB	Glucose tolerance impaired/ Pre-diabetes	2	24NOV2020	82/C	2	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261194	INV	Body temperature increased/ Increased body temperature 37.5 C#	4	10FEB2021	1/30	1	Yes		NA	R (11MAR2021)	N/N
16-55/ C4591001 1226 12261196	GASTR	Dyspepsia/ dyspepsia	2	01DEC2020	89/6	2	No	CD	NA	R (06DEC2020)	N/N
16-55/ C4591001 1226 12261199	GENRL	Asthenia/ Asthenia#	4	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
	INV	Body temperature increased/ Increased body temperature (37.7C)#	4	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1226 12261200	GENRL	Injection site pain/ pain at the injection site#	3	31JAN2021	2/2	1	Yes		NA	R (01FEB2021)	N/N
	GENRL	Chills/ chills#	4	20FEB2021	1/2	1	Yes		NA/TC	R (21FEB2021)	N/N
		Injection site pain/ pain at the injection site#	4	20FEB2021	1/2	1	Yes		NA/TC	R (21FEB2021)	N/N
	INV	Body temperature increased/ body increased temperature (37.8 C)#	4	20FEB2021	1/2	1	Yes		NA/TC	R (21FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	20FEB2021	1/2	1	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001	PSYCH	Panic reaction/ Panic syndrome	1	22AUG2020	9/1	3	No	O	NA/TC	R (22AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261203	METAB	Glucose tolerance impaired/ prediabetes	2	10SEP2020	7/C	1	No	O	NA/TC	RG	N/N
	MUSC	Arthralgia/ left knee arthralgia	2	29SEP2020	26/C	1	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	1/3	1	Yes		NA	R (01FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	21FEB2021	2/1	2	Yes		NA/TC	R (21FEB2021)	N/N
		Injection site pain/ pain at injection site#	4	21FEB2021	2/1	2	Yes		NA/TC	R (21FEB2021)	N/N
		Pyrexia/ fever (38 C)#	4	21FEB2021	2/1	2	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1226 12261207	GENRL	Pyrexia/ Fever 38 C#	4	20FEB2021	1/3	1	Yes		NA/TC	R (22FEB2021)	N/N
16-55/ C4591001 1226 12261208	GASTR	Abdominal pain/ Abdominal pain	2	12SEP2020	5/2	2	Yes		NA/TC	R (13SEP2020)	N/N
		Nausea/ Nausea	2	12SEP2020	5/2	2	Yes		NA/TC	R (13SEP2020)	N/N
	GASTR	Abdominal pain/ Abdominal pain (intermittent)	2	12OCT2020	35/C	2	No	O	NA/TC	RG	N/N
		Nausea/ Nausea (intermittent)	2	12OCT2020	35/27	2	No	O	NA/TC	R (07NOV2020)	N/N
16-55/ C4591001	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	10DEC2020	94/C		No	O	NA/TC	UNK	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261210	INFEC	Ear infection/ otitis on the left	2	12SEP2020	5/5	1	No	O	NA/TC	R (16SEP2020)	N/N
1226 12261214	GENRL	Injection site erythema/ erythema at the injection site#	3	28JAN2021	2/3	1	Yes		NA/TC	R (30JAN2021)	N/N
1226 12261215		Injection site pain/ pain at the injection site#	3	28JAN2021	2/3	1	Yes		NA/TC	R (30JAN2021)	N/N
	NERV	Headache/ headache#	3	28JAN2021	2/3	1	Yes		NA/TC	R (30JAN2021)	N/N
1226 12261216	GENRL	Injection site pain/ Pain at injection site#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
	MUSC	Myalgia/ Muscle pain#	3	23JAN2021	2/1	1	Yes		NA/TC	R (23JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	12FEB2021	2/2	2	Yes		NA/TC	R (13FEB2021)	N/N
1226 12261217	GENRL	Pyrexia/ Fever 38 C	2	11SEP2020	4/1	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	31JAN2021	2/2	1	Yes		NA	R (01FEB2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	21FEB2021	2/2	2	Yes		NA	R (22FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261220	MUSC	Myalgia/ Myalgia#	4	21FEB2021	2/2	2	Yes		NA	R (22FEB2021)	N/N
	GENRL	Injection site oedema/ Edema at the injection site#	3	23JAN2021	1/3	2	Yes		NA	R (25JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	1/3	2	Yes		NA	R (25JAN2021)	N/N
16-55/ C4591001 1226 12261228	GENRL	Injection site pain/ Pain at injection site#	3	03FEB2021	1/13	2	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1226 12261230	GENRL	Pain/ body pain#	3	06FEB2021	2/4	1	Yes		NA/TC	R (09FEB2021)	N/N
16-55/ C4591001 1226 12261233	GENRL	Injection site pain/ pain at the injection site#	3	04FEB2021	1/1	1	Yes		NA/TC	R (04FEB2021)	N/Y
16-55/ C4591001 1226 12261237	NERV	Headache/ headache#	3	04FEB2021	1/1	1	Yes		NA/TC	R (04FEB2021)	N/Y
	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	1/3	2	Yes		NA	R (01FEB2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	21FEB2021	2/1	1	Yes		NA/TC	R (21FEB2021)	N/N
		Pyrexia/ Fever 38 C#	4	21FEB2021	2/1	1	Yes		NA/TC	R (21FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Myalgia#	4	21FEB2021	2/1	1	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1226 12261238	GENRL	Injection site pain/ pain at the injection site#	4	21FEB2021	2/1	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1226 12261239	GENRL	Injection site pain/ pain at the injection site#	3	31JAN2021	2/2	2	Yes		NA	R (01FEB2021)	N/N
	GENRL	Fatigue/ Tiredness#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
	INV	Body temperature increased/ Body increased temperature#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1226 12261240	NERV	Headache/ headache	2	09NOV2020	62/3	1	No	O	NA	R (11NOV2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1226 12261241	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	1/2	2	Yes		NA	R (24JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	15FEB2021	1/3	1	Yes		NA/TC	R (17FEB2021)	N/N
	BLOOD	Lymphadenopathy/ lymphadenomegaly#	4	16FEB2021	2/7	1	Yes		NA	R (22FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261244	NERV	Headache/ headache#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Pyrexia/ fever (38,3 C- 39,5 C)#	4	12FEB2021	1/3	3	Yes		NA/TC	R (14FEB2021)	N/N
	GENRL	Asthenia/ asthenia#	4	13FEB2021	2/4	1	Yes		NA	R (16FEB2021)	N/N
	NERV	Headache/ headache#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	03FEB2021	2/2	2	Yes		NA/TC	R (04FEB2021)	N/N
	GENRL	Pyrexia/ fever (38,6 C)#	3	03FEB2021	2/2	2	Yes		NA/TC	R (04FEB2021)	N/N
16-55/ C4591001 1226 12261249	GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	15SEP2020	1/3	2	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	03FEB2021	2/2	2	Yes		NA	R (04FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261250 16-55/ C4591001 1226 12261251	GASTR	Nausea/ Nausea#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	10FEB2021	1/3	1	Yes		NA/TC	R (12FEB2021)	N/N
	GASTR	Nausea/ Nausea#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1226 12261254	GASTR	Diarrhoea/ diarrhea	2	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N
	GASTR	Abdominal pain/ abdominal pain	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GASTR	Abdominal pain/ abdominal colic	2	16OCT2020	38/14	1	No	O	NA	R (29OCT2020)	N/N
16-55/ C4591001 1226 12261259	GENRL	Fatigue/ Tiredness#	3	03FEB2021	2/2	2	Yes		NA/TC	R (04FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	3	03FEB2021	2/2	2	Yes		NA/TC	R (04FEB2021)	N/N
16-55/ C4591001 1226 12261262	GENRL	Injection site pain/ pain at the injection site#	3	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261263	GENRL	Fatigue/ fatigue#	3	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
	NERV	Headache/ headache#	3	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1226 12261264	GENRL	Fatigue/ fatigue	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
		Pyrexia/ FEVER (38,8 C)	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1226 12261266	GENRL	Injection site pain/ Pain at the injection site#	3	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1226 12261269	MUSC	Myalgia/ Myalgia#	3	04FEB2021	2/2	2	Yes		NA/TC	R (05FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	23FEB2021	2/1	2	Yes		NA/TC	R (23FEB2021)	N/N
	NERV	Headache/ headache#	4	23FEB2021	2/1	2	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1226 12261271	GENRL	Injection site erythema/ Redness at the injection site#	3	04FEB2021	1/6	2	Yes		NA	R (09FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261273	GENRL	Injection site swelling/ Swelling at the injection site#	3	04FEB2021	1/6	2	Yes		NA	R (09FEB2021)	N/N
		Pain/ body pain	1	20AUG2020	2/2	2	Yes		NA	R (21AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1226 12261274	MUSC	Myalgia/ Myalgia	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Injection site pain/ Pain on injection site	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001 1226 12261275	GENRL	Injection site pain/ Pain at injection site	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Pyrexia/ Fever	2	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1226 12261276	GENRL	Pyrexia/ Fever (38 C)	1	19AUG2020	1/1	1	Yes		NA/TC	R (19AUG2020)	N/N
	GENRL	Injection site pain/ pain at injection site	1	20AUG2020	2/2	2	Yes		NA	R (21AUG2020)	N/N
	NERV	Headache/ headache	1	20AUG2020	2/2	1	Yes		NA/TC	R (21AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261277	SKIN	Pruritus/ Diffuse itching	2	13SEP2020	3/7	1	Yes		NA/TC	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	1/1	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1226 12261278	NERV	Headache/ Headache#	3	25JAN2021	3/1	2	Yes		NA/TC	R (25JAN2021)	N/N
	NERV	Headache/ headache#	3	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N
16-55/ C4591001 1226 12261279	GENRL	Injection site pain/ pain at the injection site#	3	26JAN2021	2/3	2	Yes		NA	R (28JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	3	26JAN2021	2/1	2	Yes		NA/TC	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	15FEB2021	1/2	1	Yes		NA/TC	R (16FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	05FEB2021	1/4	2	Yes		NA	R (08FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site	1	19AUG2020	1/2	1	Yes		NA/TC	R (20AUG2020)	N/N
	NERV	Headache/ headache	1	19AUG2020	1/2	1	Yes		NA/TC	R (20AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ pain at injection site	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	NERV	Headache/ headache	2	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	11FEB2021	2/4	2	Yes		NA/TC	R (14FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	11FEB2021	2/4	2	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1226 12261282	INFEC	Appendicitis/ Appendicitis	2	01OCT2020	22/3	3	No	O	NA/TC/TCN	R (03OCT2020)	Y/N
16-55/ C4591001 1226 12261285	INFEC	Sinusitis bacterial/ Bacterial sinusitis	2	20SEP2020	11/7	2	No	O	NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1226 12261287	GENRL	Fatigue/ Fatigue#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
		Injection site pain/ Pain at injection site#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
	MUSC	Myalgia/ Muscle pain#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
	NERV	Headache/ Headache#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	4	28FEB2021	2/C	2	Yes		NA/TC	RG	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12261291		Fatigue/ Fatigue#	4	28FEB2021	2/C	2	Yes		NA/TC	RG	N/N	
		Pyrexia/ Fever 38 C#	4	28FEB2021	2/C	2	Yes		NA/TC	RG	N/N	
16-55/ C4591001 1226 12261292	GENRL	Injection site pain/ pain at injection site	1	20AUG2020	2/3	2	Yes		NA	R (22AUG2020)	N/N	
	GENRL	Injection site pain/ pain at injection site	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N	
16-55/ C4591001 1226 12261294	GENRL	Injection site pain/ pain at the injection site#	3	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/Y	
16-55/ C4591001 1226 12261295	GENRL	Pain/ body pain#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N	
16-55/ C4591001 1226 12261299	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	2/1	2	Yes		NA	R (05FEB2021)	N/N	
	NERV	Headache/ headache#	3	05FEB2021	2/1	2	Yes		NA	R (05FEB2021)	N/N	
16-55/ C4591001 1226 12261300	RENAL	Renal colic/ Renal colic	1	29AUG2020	10/2	4	No	O	NA/TC/TCN	R (30AUG2020)	Y/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261301	INFEC	Conjunctivitis/ Conjunctivitis	1	01SEP2020	13/7	1	No	O	NA/TC	R (07SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
	MUSC	Arthralgia/ Joint pain	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1226 12261302		Myalgia/ Muscle pain	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ Headache	2	14SEP2020	1/2	3	Yes		NA	R (15SEP2020)	N/N
	GENRL	Chills/ Chills#	3	04FEB2021	1/2	2	Yes		NA/TC	R (05FEB2021)	N/N
16-55/ C4591001 1226 12261303		Pain/ Body ache#	3	04FEB2021	1/2	2	Yes		NA/TC	R (05FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site	1	21AUG2020	2/3	1	Yes		NA	R (23AUG2020)	N/N
16-55/ C4591001 1226 12261307	GENRL	Injection site pain/ Pain at injection site	1	21AUG2020	2/3	2	Yes		NA	R (23AUG2020)	N/N
		Pyrexia/ fever	1	21AUG2020	2/1	2	Yes		NA/TC	R (21AUG2020)	N/N
	MUSC	Myalgia/ myalgia	1	21AUG2020	2/1	2	Yes		NA/TC	R (21AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261308	NERV	Headache/ headache	1	21AUG2020	2/2	2	Yes		NA/TC	R (22AUG2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	14/2	1	No	O	NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	25JAN2021	1/3	2	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	17FEB2021	1/4	1	Yes		NA/TC	R (20FEB2021)	N/N
	GENRL	Pyrexia/ Fever 38.3 C#	4	18FEB2021	2/3	1	Yes		NA/TC	R (20FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	4	18FEB2021	2/3	1	Yes		NA/TC	R (20FEB2021)	N/N
	MUSC	Myalgia/ Myalgia	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N
	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	06OCT2020	26/C		No	O	NA	N	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N
16-55/ C4591001 1226 12261312	GENRL	Injection site pain/ pain at injection site	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1226 12261313	GENRL	Injection site pain/ pain at injection site	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1226 12261314	GENRL	Injection site pain/ pain at injection site	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261319	MUSC	Arthralgia/ arthralgia	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	1/3	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	15FEB2021	1/3	1	Yes		NA/TC	R (17FEB2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	15FEB2021	1/3	1	Yes		NA	R (17FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
	NERV	Headache/ headache#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/Y
	MUSC	Arthralgia/ Joint pain	1	20AUG2020	1/9	3	Yes		NA/TC	R (28AUG2020)	N/N
	NERV	Headache/ headache	2	12SEP2020	1/1	2	Yes		NA/TC	R (12SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261331	RESP	Oropharyngeal pain/ sore throat	2	12OCT2020	22/1	1	No	O	NA	R (12OCT2020)	N/N	
16-55/ C4591001 1226 12261332	GENRL	Injection site oedema/ edema at injection site	2	21SEP2020	1/6	2	Yes		NA	R (26SEP2020)	N/N	
	MUSC	Myalgia/ muscle pain	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N	
16-55/ C4591001 1226 12261336	GENRL	Injection site pain/ Pain at injection site#	3	24JAN2021	2/1	1	Yes		NA	R (24JAN2021)	N/N	
	GENRL	Injection site pain/ Pain at the injection site#	4	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N	
16-55/ C4591001 1226 12261337	MUSC	Myalgia/ muscle pain	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N	
	NERV	Headache/ headache	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N	
16-55/ C4591001 1226 12261338	GENRL	Injection site pain/ Pain at injecton site	1	22AUG2020	2/2	1	Yes		NA/TC	R (23AUG2020)	N/N	
		Pain/ Body pain	1	22AUG2020	2/2	1	Yes		NA/TC	R (23AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261341	GENRL	Pyrexia/ Fever	1	22AUG2020	2/2	1	Yes		NA/TC	R (23AUG2020)	N/N	
		Injection site pain/ Pain at injection site	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N	
	GENRL	Chills/ chills	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N	
	INFEC	Gastroenteritis/ Gastroenterocolitis	2	20NOV2020	73/10	2	No	O	NA/TC	R (29NOV2020)	Y/N	
	GENRL	Injection site pain/ Pain at injection site	2	21SEP2020	1/1	1	Yes		NA/TCN	R (21SEP2020)	N/N	
	MUSC	Myalgia/ myalgia	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N	
	MUSC	Myalgia/ Muscle pain	2	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N	
	MUSC	Back pain/ Left back pain	2	19SEP2020	10/C	1	No	O	NA/TC	RG	N/N	
	GENRL	Injection site pain/ pain at injection site	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N	
	GENRL	Pyrexia/ Fever (38,8 C)	2	12SEP2020	2/3	2	Yes		NA/TC	R (14SEP2020)	N/N	
MUSC	Myalgia/ Muscle pain	2	12SEP2020	2/3	2	Yes		NA/TC	R (14SEP2020)	N/N		
16-55/ C4591001	GENRL	Injection site pain/ pain at the injection site#	3	29JAN2021	1/3	2	Yes		NA	R (31JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261349 16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	21AUG2020	1/3	2	Yes		NA/TC	R (23AUG2020)	N/N
1226 12261351	GENRL	Injection site pain/ Pain at injection site	2	10SEP2020	1/5	2	Yes		NA/TC	R (14SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	11SEP2020	2/4	2	Yes		NA/TC	R (14SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	11SEP2020	2/4	2	Yes		NA/TC	R (14SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	22AUG2020	2/1	2	Yes		NA/TC	R (22AUG2020)	N/N
1226 12261352	NERV	Headache/ Headache	1	22AUG2020	2/1	2	Yes		NA/TC	R (22AUG2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	2/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at the injection site#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
1226 12261354 16-55/ C4591001	GENRL	Pyrexia/ Fever (38.7 C)	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
1226 12261355	MUSC	Myalgia/ Muscle pain	2	12SEP2020	2/1	2	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Investigational Vaccine Dose/ Subject	Action: Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261357	GENRL	Injection site pain/ pain at the injection site#	3	04FEB2021	1/2	2	Yes	NA/TC	R (05FEB2021)	N/N	
	NERV	Headache/ headache#	3	04FEB2021	1/2	2	Yes	NA/TC	R (05FEB2021)	N/N	
16-55/ C4591001 1226 12261358	GENRL	Injection site pain/ pain at injection site	2	11SEP2020	1/2	1	Yes	NA	R (12SEP2020)	N/N	
	GENRL	Pyrexia/ fever (37.9C)	2	12SEP2020	2/1	1	Yes	NA/TC	R (12SEP2020)	N/N	
16-55/ C4591001 1226 12261359	GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	1/4	2	Yes	NA/TC	R (26JAN2021)	N/N	
	GENRL	Injection site pain/ Pain at the injection site#	4	16FEB2021	2/2	1	Yes	NA/TC	R (17FEB2021)	N/N	
		Pain/ Body ache#	4	16FEB2021	2/2	1	Yes	NA/TC	R (17FEB2021)	N/N	
16-55/ C4591001 1226 12261360	GENRL	Pain/ Body aches#	3	07FEB2021	2/2	1	Yes	NA	R (08FEB2021)	N/N	
16-55/ C4591001 1226 12261361	GENRL	Application site reaction/ hyperemia at the application site	1	22AUG2020	2/2	1	Yes	NA	R (23AUG2020)	N/N	
		Injection site pain/ Pain at injection site	1	22AUG2020	2/2	1	Yes	NA	R (23AUG2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site erythema/ Erythema at injection site	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
		Injection site pain/ Pain at the injection site	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001 1226 12261362	GENRL	Pain/ Body pain	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1226 12261364	MUSC	Myalgia/ Muscle pain	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
	NERV	Headache/ Headache	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1226 12261365	GENRL	Injection site pain/ pain at the injection site	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N
	GENRL	Pyrexia/ fever (38.3C)	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1226 12261369	GENRL	Injection site pain/ Pain at the injection site#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1226 12261373	GENRL	Injection site pain/ Pain at the injection site#	3	04FEB2021	1/1	2	Yes		NA	R (04FEB2021)	N/N
	NERV	Somnolence/ Somnolence#	3	04FEB2021	1/1	2	Yes		NA	R (04FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261375	GENRL	Injection site pain/ Pain at injection site	1	24AUG2020	1/1	2	Yes		NA	R (24AUG2020)	N/N
16-55/ C4591001 1226 12261376	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1226 12261377	SKIN	Pruritus/ itching (arms and left hand)	2	26NOV2020	74/42	1	No	O	NA	R (06JAN2021)	N/N
16-55/ C4591001 1226 12261379	GENRL	Chills/ chills	1	25AUG2020	2/2	2	Yes		NA	R (26AUG2020)	N/N
		Pyrexia/ Fever (38,7 C)	1	25AUG2020	2/2	2	Yes		NA/TC	R (26AUG2020)	N/N
	MUSC	Myalgia/ muscle pain	1	25AUG2020	2/2	2	Yes		NA	R (26AUG2020)	N/N
16-55/ C4591001 1226 12261382	GENRL	Fatigue/ Tiredness	1	25AUG2020	2/3	2	Yes		NA/TC	R (27AUG2020)	N/N
		Injection site pain/ Pain at injection site	1	25AUG2020	2/3	2	Yes		NA/TC	R (27AUG2020)	N/N
		Pyrexia/ Fever	1	25AUG2020	2/3	2	Yes		NA/TC	R (27AUG2020)	N/N
	GENRL	Malaise/ Malaise	1	15SEP2020	23/2	2	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pain/ Body pain	2	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ Fever	2	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1226 12261383	GENRL	Injection site pain/ pain at the injection site#	3	29JAN2021	2/2	1	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
		Malaise/ malaise#	4	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	INV	Body temperature increased/ increased of body temperature#	4	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1226 12261384	GENRL	Chills/ Chills#	3	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N
		Injection site pain/ Pain at injection site#	3	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N
	INV	Body temperature increased/ Body increased temperature (37.8 C)#	3	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	3	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N
	NERV	Headache/ Headache#	3	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1226 12261387	GENRL	Injection site pain/ Pain at injection site	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261390	GENRL	Chills/ chills	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	14SEP2020	1/3	1	Yes		NA/TC	R (16SEP2020)	N/N
	MUSC	Back pain/ Backache	1	30AUG2020	7/3	2	No	O	NA/TC	R (01SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	15SEP2020	1/19	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Pyrexia/ Fever (38 C)	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Malaise/ Malaise	2	16SEP2020	2/28	2	Yes		NA	R (13OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea intermittent	2	18SEP2020	4/49	1	Yes		NA/TC	R (05NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	18SEP2020	4/26	2	Yes		NA	R (13OCT2020)	N/N
	METAB	Decreased appetite/ Inapetence	2	18SEP2020	4/26	2	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1226 12261391	GASTR	Irritable bowel syndrome/ Irritable bowel syndrome	2	05NOV2020	52/C	2	Yes		NA/TC	RG	N/N
	MUSC	Torticollis/ torticollis	1	13SEP2020	21/5	2	No	O	NA/TC	R (17SEP2020)	N/N
	GENRL	Chills/ Chills#	3	06FEB2021	1/2	2	Yes		NA	R (07FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261392 16-55/ C4591001 1226 12261395 16-55/ C4591001 1226 12261396 16-55/ C4591001 1226 12261397 16-55/ C4591001 1226 12261399 16-55/ C4591001	NERV	Injection site pain/ Pain at the injection site#	3	06FEB2021	1/2	2	Yes		NA	R (07FEB2021)	N/N	
		Headache/ Headache#	3	06FEB2021	1/2	2	Yes		NA	R (07FEB2021)	N/N	
	GENRL	Injection site pain/ Pain at injection site	1	24AUG2020	1/3	2	Yes		NA	R (26AUG2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site	1	25AUG2020	2/4	1	Yes		NA	R (28AUG2020)	N/N	
	MUSC	Pain in extremity/ Right arm pain	2	14OCT2020	31/1	1	No	O	NA	R (14OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N	
	NERV	Headache/ Headache	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N	
	GENRL	Injection site pain/ Pain at injection site	1	26AUG2020	2/2	2	Yes		NA	R (27AUG2020)	N/N	
NERV	Neuritis/ (right submammary) Intercostal neuritis	2	28DEC2020	105/19	2	No	O	NA/TC	R (15JAN2021)	N/N		

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12261400	GENRL	Injection site pain/ pain at the injection site#	3	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N	
16-55/ C4591001 1226 12261404	GENRL	Chills/ chills	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N	
16-55/ C4591001 1226 12261406	GENRL	Pyrexia/ fever	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N	
16-55/ C4591001 1226 12261408	GENRL	Injection site pain/ Pain at injection site#	3	06FEB2021	1/2	2	Yes		NA/TC	R (07FEB2021)	N/N	
16-55/ C4591001 1226 12261409	GENRL	Injection site pain/ Pain at injection site	1	25AUG2020	1/3	2	Yes		NA	R (27AUG2020)	N/N	
16-55/ C4591001 1226 12261409	MUSC	Myalgia/ Myalgia	1	31AUG2020	7/3	2	Yes		NA/TC	R (02SEP2020)	N/N	
	NERV	Headache/ Headache	1	31AUG2020	7/3	2	Yes		NA/TC	R (02SEP2020)	N/N	
	SKIN	Rash pruritic/ Pruritic Papular eruption	1	08SEP2020	15/20	1	No	O	NA/TC	R (27SEP2020)	N/N	
16-55/ C4591001 1226 12261410	GENRL	Pyrexia/ Fever (38.1 C)#	3	30JAN2021	2/1	1	Yes		NA/TC	R (30JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261411	GASTR	Vomiting/ Vomit	2	15SEP2020	1/6	1	Yes		NA	R (20SEP2020)	N/N
	INFEC	Cystitis/ cystitis	2	20SEP2020	6/6	2	No	O	NA/TC	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection site#	3	23JAN2021	1/1	1	Yes		NA/TC	R (23JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1226 12261412	GENRL	Fatigue/ Fatigue#	3	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1226 12261413	GENRL	Injection site pain/ Pain at injection site	1	25AUG2020	1/2	2	Yes		NA	R (26AUG2020)	N/N
	GENRL	Pyrexia/ Fever (39 C)	2	15SEP2020	1/2	3	Yes		NA/TC	R (16SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ headache	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1226 12261415	GENRL	Fatigue/ Fatigue#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
		Injection site pain/ Pain at the injection site#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261416		Injection site swelling/ Swelling at the injection site#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
	NERV	Headache/ Headache#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Back pain/ backache	2	27SEP2020	13/4	3	No	O	NA/TC	R (30SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	26AUG2020	2/2	1	Yes		NA/TC	R (27AUG2020)	N/N
	BLOOD	Lymphadenopathy/ left axillary lymphadenomegaly	2	16SEP2020	2/5	2	Yes		NA/TC	R (20SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	16SEP2020	2/5	2	Yes		NA/TC	R (20SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	17SEP2020	3/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Pyrexia/ Fever (38,3 C)	1	26AUG2020	1/1	1	Yes		NA/TC	R (26AUG2020)	N/N
	12261421										
16-55/ C4591001 1226 12261423	GENRL	Fatigue/ fatigue#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
		Injection site pain/ pain at the injection site#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261425	GENRL	Chills/ Chills	1	27AUG2020	2/2	2	Yes		NA	R (28AUG2020)	N/N
	NERV	Headache/ Headache	1	28AUG2020	3/7	2	Yes		NA/TC	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	1/3	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	12FEB2021	1/2	2	Yes		NA/TC	R (13FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	12FEB2021	1/2	2	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1226 12261426	GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	2/1	2	Yes		NA/TC	R (27AUG2020)	N/N
16-55/ C4591001 1226 12261427	GENRL	Injection site pain/ pain at the injection site#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1226 12261428	METAB	Vitamin D deficiency/ Hypovitaminosis D	1	27AUG2020	2/C	1	No	O	NA/TC	RG	N/N
	NERV	Headache/ Headache	1	27AUG2020	2/1	1	Yes		NA/TC	R (27AUG2020)	N/N
	GENRL	Fatigue/ fatigue#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/Y
	GENRL	Fatigue/ Fatigue#	4	24FEB2021	1/1	1	Yes		NA	R (24FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261429	NERV	Injection site pain/ Pain at the injection site#	4	24FEB2021	1/2	1	Yes		NA/TC	R (25FEB2021)	N/N	
		Headache/ Headache#	4	24FEB2021	1/1	1	Yes		NA/TC	R (24FEB2021)	N/N	
	NERV	Headache/ Headache	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001 1226 12261430	GENRL	Injection site pain/ Pain at injection site	1	26AUG2020	1/2	1	Yes		NA/TC	R (27AUG2020)	N/N	
16-55/ C4591001 1226 12261432	NERV	Headache/ Headache	1	26AUG2020	1/2	1	Yes		NA/TC	R (27AUG2020)	N/N	
	GENRL	Injection site pain/ Pain at the site of injection	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
	NERV	Headache/ Headache	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
	GASTR	Diarrhoea/ Diarrhea	1	29AUG2020	4/1	1	Yes		NA	R (29AUG2020)	N/N	
	GASTR	Diarrhoea/ Diarrhea	1	31AUG2020	6/1	1	Yes		NA	R (31AUG2020)	N/N	
	GENRL	Injection site pain/ pain at the injection site#	3	25JAN2021	1/5	1	Yes		NA	R (29JAN2021)	N/N	
	BLOOD	Lymphadenopathy/ axillary lymphadenopathy#	3	26JAN2021	2/7	1	Yes		NA	R (01FEB2021)	N/N	
GENRL	Pyrexia/ fever (38.2 C)#	3	26JAN2021	2/1	1	Yes		NA/TC	R (26JAN2021)	N/N		

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261433	GENRL	Asthenia/ Asthenia#	4	16FEB2021	1/3	2	Yes		NA/TC	R (18FEB2021)	N/N	
		Injection site pain/ Pain at the injection site#	4	16FEB2021	1/3	2	Yes		NA/TC	R (18FEB2021)	N/N	
		Pyrexia/ Fever 38.3 C#	4	16FEB2021	1/3	2	Yes		NA/TC	R (18FEB2021)	N/N	
	MUSC	Torticollis/ torticollis	2	02OCT2020	14/20	1	No	O	NA/TC	R (21OCT2020)	N/N	
		Injection site pain/ Pain at injection site#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N	
	GENRL	Injection site pain/ pain at the injection site#	2	08FEB2021	146/4	1	Yes		NA	R (11FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
	MUSC	Myalgia/ Muscle pain#	3	24JAN2021	2/1	1	Yes		NA/TC	R (24JAN2021)	N/N	
		PSYCH	Anxiety/ Anxiety#	3	01FEB2021	10/C	2	No	O	NA/TC	RG	N/N
	GENRL	Fatigue/ fatigue#	4	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N	
		Injection site pain/ Pain at the injection site#	4	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261439	GENRL	Injection site pain/ Pain at the injection site	1	27AUG2020	2/1	2	Yes		NA/TC	R (27AUG2020)	N/N	
		Pyrexia/ Fever (38 C)	1	27AUG2020	2/1	1	Yes		NA/TC	R (27AUG2020)	N/N	
16-55/ C4591001 1226 12261441	GENRL	Injection site pain/ Pain at the injection site#	2	05FEB2021	143/2	1	Yes		NA	R (06FEB2021)	N/N	
16-55/ C4591001 1226 12261442	MUSC	Myalgia/ muscle pain	1	27AUG2020	2/1	1	Yes		NA	R (27AUG2020)	N/N	
	GENRL	Pain/ Body pain	2	15SEP2020	2/4	1	Yes		NA	R (18SEP2020)	N/N	
		Pyrexia/ Fever 38.5 C	2	15SEP2020	2/4	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001 1226 12261444	GENRL	Pyrexia/ Fever 38.5 C	2	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N	
16-55/ C4591001 1226 12261447	INJ&P	Fibula fracture/ Fracture of the left fibula	2	01DEC2020	77/C	3	No	O	NA/TC/TCN	RG	N/N	
16-55/ C4591001 1226 12261448	GENRL	Injection site pain/ Pain at the injection site	2	19SEP2020	1/3	1	Yes		NA	R (21SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261449	GENRL	Fatigue/ Fatigue	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
	MUSC	Myalgia/ myalgia#	4	13FEB2021	2/1	2	Yes		NA/TC	R (13FEB2021)	N/N
	NERV	Headache/ headache#	4	13FEB2021	2/1	2	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1226 12261451	GENRL	Chills/ Chills	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
	NERV	Headache/ Headache	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1226 12261452	GENRL	Injection site pain/ pain at the injection site#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1226 12261454	GENRL	Fatigue/ fatigue	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
	INFEC	Pilonidal cyst/ Pilonidal cyst	2	01OCT2020	13/16	2	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1226 12261456	MUSC	Myalgia/ Muscle pain	2	20SEP2020	2/1	2	Yes		NA/TC	R (20SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261457	GENRL	Injection site pain/ Pain at injection site	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1226 12261460	GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	1/3	1	Yes		NA	R (25JAN2021)	N/N
	NERV	Headache/ headache#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1226 12261463	RESP	Oropharyngeal discomfort/ throat discomfort	2	22OCT2020	34/1	1	No	O	NA	R (22OCT2020)	N/N
16-55/ C4591001 1226 12261465	GENRL	Injection site pain/ Pain at injection site#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/Y
16-55/ C4591001 1226 12261466	GENRL	Fatigue/ Fatigue	2	23SEP2020	3/18	2	Yes		NA	R (10OCT2020)	N/N
	NERV	Somnolence/ Somnolence	2	23SEP2020	3/18	2	Yes		NA	R (10OCT2020)	N/N
	GASTR	Nausea/ Nausea#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261470	GASTR	Diarrhoea/ diarrhea	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	28AUG2020	2/7	2	Yes		NA/TC	R (03SEP2020)	N/N
	NERV	Headache/ headache	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	02SEP2020	7/2	3	Yes		NA/TC	R (03SEP2020)	N/N
16-55/ C4591001 1226 12261471	GENRL	Injection site pain/ Pain at injection site	1	28AUG2020	2/3	1	Yes		NA	R (30AUG2020)	N/N
		Pyrexia/ Fever	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
		Pyrexia/ fever	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
	NERV	Headache/ headache	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1226 12261472	GENRL	Injection site pain/ Pain at the injection site#	4	16FEB2021	1/3	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue	2	19SEP2020	1/1	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261475	NERV	Headache/ headache	2	19SEP2020	1/1	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261480	GENRL	Pyrexia/ fever 37.9 C	2	19SEP2020	1/1	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1226 12261482	GENRL	Fatigue/ fatigue	1	28AUG2020	2/3	2	Yes		NA/TC	R (30AUG2020)	N/N
	NERV	Headache/ headache	1	28AUG2020	2/3	2	Yes		NA/TC	R (30AUG2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1226 12261484	GENRL	Injection site pain/ Pain at injection site	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1226 12261485	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261486	GENRL	Chills/ chills	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ pain at injection site	2	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	NERV	Headache/ headache	2	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1226 12261488	GENRL	Fatigue/ fatigue	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
		Injection site pain/ Pain at injection site	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
	GASTR	Vomiting/ Vomiting	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Chills/ Chills	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N
		Fatigue/ Fatigue	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1226 12261489	GENRL	Pyrexia/ Fever (38C)#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261490	GENRL	Chills/ Chills#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1226 12261491	GENRL	Chills/ Chills	2	19SEP2020	1/2	2	Yes		NA/TC	R (20SEP2020)	N/N
		Fatigue/ Fatigue	2	19SEP2020	1/2	2	Yes		NA/TC	R (20SEP2020)	N/N
		Pyrexia/ Fever 38.5 C	2	19SEP2020	1/2	2	Yes		NA/TC	R (20SEP2020)	N/N
		MUSC Myalgia/ Muscle pain	2	19SEP2020	1/2	2	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1226 12261492	PSYCH	Insomnia/ Insomnia	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Fatigue/ fatigue	2	19SEP2020	1/2	2	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	2/1	1	Yes		NA/TC	R (23JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261495	NERV	Headache/ headache	1	28AUG2020	1/2	1	Yes		NA/TC	R (29AUG2020)	N/N
16-55/ C4591001 1226 12261497	GENRL	Injection site pain/ Pain at the injection site#	3	06FEB2021	1/3	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261500	GENRL	Injection site pain/ injection site pain	1	28AUG2020	1/1	1	Yes		NA/TC	R (28AUG2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
	GENRL	Pyrexia/ fever (38 C)	2	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1226 12261501	NERV	Headache/ Headache	1	28AUG2020	1/1	1	Yes		NA/TC	R (28AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	20SEP2020	2/2	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1226 12261502	GENRL	Fatigue/ Fatigue	1	28AUG2020	1/3	2	Yes		NA	R (30AUG2020)	N/N
	NERV	Headache/ Headache	1	28AUG2020	1/3	2	Yes		NA	R (30AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261503	GENRL	Fatigue/ Fatigue	2	21SEP2020	1/4	1	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	2/1	1	Yes		NA/TC	R (05FEB2021)	N/N	
	NERV	Headache/ headache#	3	05FEB2021	2/1	1	Yes		NA/TC	R (05FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue	1	29AUG2020	2/1	2	Yes		NA	R (29AUG2020)	N/N	
	RESP	Nasal congestion/ Nasal congestion	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
	RESP	Nasal congestion/ Nasal congestion	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
16-55/ C4591001 1226 12261504	GENRL	Injection site pain/ pain at the injection site#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N	
	INFEC	Herpes zoster/ Herpes zoster (chest)	2	29NOV2020	70/68	2	No	O	NA/TC	R (04FEB2021)	N/N	
16-55/ C4591001 1226 12261505	GENRL	Chills/ Chills	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ pain at the injection site#	4	16FEB2021	1/3	2	Yes		NA/TC	R (18FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12261508	GENRL	Injection site pain/ Pain at injection site#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N	
1226 12261509	MUSC	Myalgia/ Muscle pain	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N	
1226 12261511	GENRL	Pyrexia/ Fever 38 C#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N	
1226 12261511	GENRL	Injection site lymphadenopathy/ supraclavicular adenomegaly at injection site#	4	13FEB2021	2/7	1	Yes		NA	R (19FEB2021)	N/N	
1226 12261512	MUSC	Myalgia/ Muscle pain	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N	
1226 12261515	GENRL	Pain/ body pain#	3	07FEB2021	2/2	1	Yes		NA	R (08FEB2021)	N/N	
1226 12261516	GENRL	Fatigue/ Fatigue	1	06SEP2020	2/1	2	Yes		NA/TCN	R (06SEP2020)	N/N	
1226 12261516	GENRL	Chills/ chills	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N	
1226 12261516	GENRL	Injection site pain/ Pain at injection site	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12261517	GENRL	Chills/ chills	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N	
		Fatigue/ fatigue	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N	
	MUSC	Myalgia/ myalgia	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N	
16-55/ C4591001 1226 12261518	MUSC	Back pain/ Acute mechanical low back pain	2	14OCT2020	23/1	2	No	O	NA/TC	R (14OCT2020)	N/N	
	INV	Body temperature increased/ increased body temperature#	3	04FEB2021	1/2	1	Yes		NA/TC	R (05FEB2021)	N/N	
16-55/ C4591001 1226 12261519	NERV	Headache/ Headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
	REPRO	Testicular pain/ Testicles Pain#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N	
16-55/ C4591001 1226 12261520	GENRL	Injection site pain/ Pain at injection site*		02SEP2020	-1/4	2	Yes		NA	R (05SEP2020)	N/N	
16-55/ C4591001 1226 12261521	GENRL	Injection site pain/ Pain at the injection site#	3	21FEB2021	2/2	1	Yes		NA	R (22FEB2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261522	GENRL	Injection site pain/ Pain in the injection	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1226 12261525	GENRL	Pain/ body pain	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1226 12261526	GENRL	Injection site pain/ pain at the injection site#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/Y
16-55/ C4591001 1226 12261529	GENRL	Pyrexia/ Fever 38 C#	4	13FEB2021	2/1	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1226 12261530	GENRL	Injection site pain/ pain at the injection site#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1226 12261531	GENRL	Chills/ Chills	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1226 12261531	NERV	Headache/ Headache	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1226 12261532	GENRL	Injection site pain/ pain at the injection site#	3	06FEB2021	1/5	1	Yes		NA	R (10FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261535	GENRL	Injection site oedema/ edema at injection site	1	06SEP2020	2/3	1	Yes		NA	R (08SEP2020)	N/N
		Injection site pain/ Pain at injection site	1	06SEP2020	2/3	2	Yes		NA/TC	R (08SEP2020)	N/N
	NERV	Malaise/ Malaise	1	06SEP2020	2/6	2	Yes		NA	R (11SEP2020)	N/N
		Headache/ Headache	1	06SEP2020	2/6	2	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	08SEP2020	4/4	2	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
		Pain/ body pain	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
		Pyrexia/ fever (38.4C)	2	25SEP2020	2/2	2	Yes		NA/TC	R (26SEP2020)	N/N
		Hypotension/ Hypotension (48x32mmHg)	2	05JAN2021	104/1	3	No	O	NA/TCN	R (05JAN2021)	N/N
	16-55/ C4591001 1226 12261538	PSYCH	Panic disorder/ Panic disorder	2	17OCT2020	20/2	2	No	O	NA/TC	R (18OCT2020)
GENRL	Fatigue/ Tiredness#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N	
	Pain/ Body ache#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N	
GENRL	Injection site pain/ pain at injection site#	4	25FEB2021	2/2	2	Yes		NA	R (26FEB2021)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261540	MUSC	Myalgia/ muscle pain#	4	25FEB2021	2/2	2	Yes		NA	R (26FEB2021)	N/N
	NERV	Headache/ headache#	4	25FEB2021	2/2	2	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1226 12261540	GENRL	Injection site pain/ Pain at injection site#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1226 12261542	GASTR	Diarrhoea/ diarrhea	1	10SEP2020	6/3	2	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site erythema/ erythema at the injection site	1	12SEP2020	8/4	1	Yes		NA/TC/TCN	R (15SEP2020)	N/N
		Injection site oedema/ edema at injection site	1	12SEP2020	8/4	1	Yes		NA/TC/TCN	R (15SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
	GENRL	Chills/ Chills	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ Fever 38.5 C	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
	MUSC	Pain in extremity/ Pain in both legs	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1226 12261544	GENRL	Injection site pain/ pain at the injection site#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261545	GENRL	Injection site pain/ Pain at injection site	1	05SEP2020	1/3	2	Yes		NA	R (07SEP2020)	N/N
	NERV	Headache/ headache	1	05SEP2020	1/3	2	Yes		NA/TC	R (07SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
	NERV	Headache/ headache	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
	BLOOD	Lymphadenopathy/ enlargement of left axillary lymph node	2	25SEP2020	2/34	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Pain/ Body pain	2	26SEP2020	3/1	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1226 12261546	GENRL	Injection site pain/ Pain at the injection site#	3	06FEB2021	1/3	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261548	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1226 12261549	GENRL	Pain/ Body ache#	3	06FEB2021	1/3	1	Yes		NA/TC	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261551	GENRL	Injection site pain/ Pain at injection site	1	05SEP2020	1/2	2	Yes		NA	R (06SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261553	GENRL	Chills/ Chills	2	24SEP2020	1/1	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	1	05SEP2020	1/4	1	Yes		NA	R (08SEP2020)	N/N
		Injection site swelling/ swelling at the injection site	1	05SEP2020	1/4	1	Yes		NA	R (08SEP2020)	N/N
	GENRL	Pyrexia/ Fever	1	06SEP2020	2/2	1	Yes		NA/TC	R (07SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	25SEP2020	2/2	2	Yes		NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	25SEP2020	2/2	2	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1226 12261554	GENRL	Pyrexia/ fever (38.1 C)	2	26SEP2020	3/1	2	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1226 12261555	GENRL	Injection site pruritus/ itching at the injection site	1	05SEP2020	1/2	1	Yes		NA	R (06SEP2020)	N/N
	INJ&P	Contusion/ Knee contusion	2	26OCT2020	33/4	1	No	O	NA/TC	R (29OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site#	3	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	06SEP2020	2/1	2	Yes		NA	R (06SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261557	GENRL	Chills/ Chills	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1226 12261559	GENRL	Pyrexia/ Fever 38.5 C	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1226 12261560	GENRL	Fatigue/ fatigue	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ headache	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1226 12261561	GENRL	Injection site pain/ pain at the injection site#	3	20FEB2021	1/6	2	Yes		NA	R (25FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	3	20FEB2021	1/6	2	Yes		NA	R (25FEB2021)	N/N
	NERV	Headache/ headache#	3	20FEB2021	1/6	2	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1226 12261562	NERV	Headache/ headache	1	06SEP2020	2/2	1	Yes		NA	R (07SEP2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	1/4	1	Yes		NA	R (08FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261564	GENRL	Injection site pain/ Pain at injection site	1	05SEP2020	1/2	2	Yes		NA	R (06SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ fever (38.1C)	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Chills/ chills	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
	METAB	Decreased appetite/ inapetence	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1226 12261566	GENRL	Chills/ chills#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Chills/ Chills#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	4	17FEB2021	1/2	2	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1226 12261567	GENRL	Injection site pain/ Pain at injection site	1	05SEP2020	1/2	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1226 12261568	GENRL	Injection site swelling/ swelling at the injection site	1	05SEP2020	1/1	1	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261569	MUSC	Neck pain/ neck pain	2	30SEP2020	6/2	1	No	O	NA/TC	R (01OCT2020)	N/N	
	NERV	Headache/ Headache	2	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1226 12261570	GENRL	Injection site pain/ pain at the injection site#	3	25FEB2021	1/2	2	Yes		NA/TC	R (26FEB2021)	N/N	
		Pyrexia/ fever (38 C)#	3	25FEB2021	1/2	2	Yes		NA/TC	R (26FEB2021)	N/N	
	NERV	Headache/ headache#	3	25FEB2021	1/2	2	Yes		NA/TC	R (26FEB2021)	N/N	
	GENRL	Injection site pain/ pain at the injection site#	3	25FEB2021	1/4	1	Yes		NA/TC	R (28FEB2021)	N/N	
16-55/ C4591001 1226 12261571		Pyrexia/ fever (38 C)#	3	25FEB2021	1/4	1	Yes		NA/TC	R (28FEB2021)	N/N	
	INJ&P	Cervical vertebral fracture/ Fracture of the fourth cervical vertebra	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N	
		Contusion/ Bruises in various regions of the body	2	21OCT2020	27/10	2	No	O	NA/TC	R (30OCT2020)	N/N	
		Road traffic accident/ hit by motorcycle	2	21OCT2020	27/1	3	No	O	NA	R (21OCT2020)	Y/N	
		Skin abrasion/ Excoriations in various regions of the body	2	21OCT2020	27/10	2	No	O	NA/TC	R (30OCT2020)	N/N	
		Spinal cord injury cervical/ Cervical spinal cord contusion	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261572	NERV	Subarachnoid haemorrhage/ Subarachnoid hemorrhage	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N
	RENAL	Subcapsular renal haematoma/ Peri-renal hematoma	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N
	GENRL	Chills/ chills	1	06SEP2020	2/2	2	Yes		NA/TC	R (07SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	1	07SEP2020	3/2	1	Yes		NA	R (08SEP2020)	N/N
		Pyrexia/ fever (38.2 C)	1	07SEP2020	3/1	2	Yes		NA/TC	R (07SEP2020)	N/N
	MUSC	Myalgia/ myalgia	1	07SEP2020	3/2	1	Yes		NA	R (08SEP2020)	N/N
	INFEC	Rhinitis/ Coryza	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	GASTR	Diarrhoea/ diarrhea	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	25SEP2020	2/1	3	Yes		NA	R (25SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
	Pyrexia/ fever (38.5 C)	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N	
	MUSC	Myalgia/ muscle pain	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1226 12261574	GENRL	Injection site pain/ Pain at injection site	1	05SEP2020	1/3	1	Yes		NA	R (07SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261575	GENRL	Fatigue/ Fatigue#	3	13FEB2021	1/2	2	Yes		NA/TC	R (14FEB2021)	N/N
	NERV	Headache/ Worsening of Headache#	3	13FEB2021	1/2	2	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1226 12261577	GENRL	Chills/ chill	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N
	GASTR	Nausea/ nausea	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1226 12261578	GENRL	Fatigue/ fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	08FEB2021	4/1	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261579	GASTR	Nausea/ Nausea	1	14SEP2020	10/1	1	Yes		NA	R (14SEP2020)	N/N
	SKIN	Seborrheic dermatitis/ Seborrheic Dermatitis in the Scalp	2	06JAN2021	101/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261581	GENRL	Injection site pain/ Pain at injection site	1	07SEP2020	1/2	1	Yes		NA	R (08SEP2020)	N/N
1226 12261582	GENRL	Chills/ Chills	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
1226 12261582	MUSC	Myalgia/ Myalgia	2	28SEP2020	1/3	2	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1226 12261583	GENRL	Injection site pain/ Pain at the injection site	1	07SEP2020	1/2	2	Yes		NA	R (08SEP2020)	N/N
1226 12261583	GENRL	Injection site pain/ Pain at the injection site	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
1226 12261583	RENAL	Ureterolithiasis/ Left ureteral stone	2	13NOV2020	46/3	2	No	O	NA/TCN	R (15NOV2020)	Y/N
16-55/ C4591001 1226 12261584	GENRL	Fatigue/ discreet tiredness#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
1226 12261584	INV	Body temperature increased/ temperature increase (37,5 C)#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261585	GASTR	Diarrhoea/ diarrhea	1	08SEP2020	2/2	1	Yes		NA	R (09SEP2020)	N/N
1226 12261585	GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261586	GENRL	Injection site pain/ Pain at injection site#	4	12FEB2021	2/3	1	Yes		NA	R (14FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	13SEP2020	7/1	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1226 12261587	GENRL	Injection site pain/ Pain at the injection site#	3	24JAN2021	2/1	2	Yes		NA/TC	R (24JAN2021)	N/N
	INV	Body temperature increased/ Increased body temperature 37.2 C#	3	24JAN2021	2/1	2	Yes		NA/TC	R (24JAN2021)	N/N
16-55/ C4591001 1226 12261588	GASTR	Diarrhoea/ Diarrhea	1	09SEP2020	3/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	06FEB2021	1/3	2	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261588	GENRL	Injection site pain/ Pain at the injection site#	3	06FEB2021	1/3	2	Yes		NA	R (08FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	07SEP2020	1/2	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C4591001 1226 12261590	GENRL	Injection site pain/ pain at the injection site#	3	06FEB2021	1/3	1	Yes		NA	R (08FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain	2	02OCT2020	1/2	2	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site oedema/ Edema at injection site	1	08SEP2020	2/2	2	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12261591		Injection site pain/ Pain at site injection	1	08SEP2020	2/2	2	Yes		NA	R (09SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	29SEP2020	2/3	1	Yes		NA/TC	R (01OCT2020)	N/N	
		Injection site pain/ Pain at injection site	2	29SEP2020	2/3	1	Yes		NA/TC	R (01OCT2020)	N/N	
16-55/ C4591001 1226 12261592	GENRL	Injection site pain/ Pain at injection site	1	08SEP2020	2/2	2	Yes		NA	R (09SEP2020)	N/N	
	GENRL	Fatigue/ FATIGUE	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N	
		Injection site pain/ Pain at injection site	2	28SEP2020	1/2	1	Yes		NA/TC	R (29SEP2020)	N/N	
		Malaise/ Malaise	2	28SEP2020	1/2	1	Yes		NA/TC	R (29SEP2020)	N/N	
	NERV	Headache/ headache	2	28SEP2020	1/2	2	Yes		NA/TC	R (29SEP2020)	N/N	
	INFEC	Vulvovaginal candidiasis/ Vaginal candidiasis	2	01OCT2020	4/4	2	No	O	NA/TC	R (04OCT2020)	N/N	
16-55/ C4591001 1226 12261593	GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N	
16-55/ C4591001 1226 12261594	GENRL	Injection site pain/ Pain at the injection site#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261595	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1226 12261596		Injection site pain/ Pain at injection site	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Pyrexia/ Fever	1	08SEP2020	2/1	1	Yes		NA/TC	R (08SEP2020)	N/N
16-55/ C4591001 1226 12261597	GENRL	Pyrexia/ Fever 38 C	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
	NERV	Paraesthesia/ tingling in the left upper limb	2	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/Y
16-55/ C4591001 1226 12261598	GENRL	Injection site pain/ pain at the injection site#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1226 12261599	GENRL	Injection site pain/ pain at the injection site#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
	GENRL	Fatigue/ fatigue	1	07SEP2020	1/4	1	Yes		NA	R (10SEP2020)	N/N
	MUSC	Myalgia/ myalgia	1	07SEP2020	1/4	1	Yes		NA/TC	R (10SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261600	EYE	Ulcerative keratitis/ corneal ulcer right eye	1	20SEP2020	14/8	2	No	O	NA/TC	R (27SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	08SEP2020	2/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1226 12261601	MUSC	Myalgia/ Muscle pain	1	08SEP2020	2/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1226 12261602	NERV	Headache/ Headache	1	08SEP2020	2/2	1	Yes		NA	R (09SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	28SEP2020	1/2	2	Yes		NA/TC	R (29SEP2020)	N/N
	NERV	Headache/ Headache	2	28SEP2020	1/2	2	Yes		NA/TC	R (29SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	07SEP2020	1/3	2	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1226 12261603	NERV	Headache/ Headache	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1226 12261603	GENRL	Injection site pain/ Pain at injection site#	3	24JAN2021	2/2	2	Yes		NA/TC	R (25JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261604	GENRL	Pain/ Body ache#	4	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N	
		Injection site pain/ Pain at the injection site#	3	23JAN2021	1/3	1	Yes		NA	R (25JAN2021)	N/N	
		Chills/ Chills#	4	13FEB2021	2/3	1	Yes		NA/TC	R (15FEB2021)	N/N	
		Pyrexia/ Fever (38 C)#	4	13FEB2021	2/3	1	Yes		NA/TC	R (15FEB2021)	N/N	
		MUSC	4	13FEB2021	2/3	1	Yes		NA/TC	R (15FEB2021)	N/N	
16-55/ C4591001 1226 12261606	NERV	Headache/ Headache#	4	13FEB2021	2/3	1	Yes		NA/TC	R (15FEB2021)	N/N	
		GENRL	Asthenia/ Asthenia	2	28SEP2020	1/3	1	Yes	NA/TC	R (30SEP2020)	N/N	
16-55/ C4591001 1226 12261607	GENRL	Pyrexia/ Fever 38 C	2	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N	
		Injection site pain/ Pain at injection site	1	07SEP2020	1/2	1	Yes		NA	R (08SEP2020)	N/N	
		Fatigue/ Fatigue	1	08SEP2020	2/1	1	Yes		NA	R (08SEP2020)	N/N	
		Fatigue/ Fatigue	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N	
		Injection site erythema/ Erythema at the injection site	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Injection site pain/ Pain at the injection site	2	29SEP2020	2/2	2	Yes		NA/TC	R (30SEP2020)	N/N	
		Myalgia/ Muscle pain	2	29SEP2020	2/2	2	Yes		NA/TC	R (30SEP2020)	N/N	
16-55/ C4591001 1226 12261609	GENRL	Injection site pain/ Pain at injection site	1	08SEP2020	2/1	1	Yes		NA	R (08SEP2020)	N/N	
16-55/ C4591001 1226 12261610	GENRL	Injection site pain/ Pain at Injection Site#	3	24JAN2021	2/2	1	Yes		NA	R (25JAN2021)	N/N	
	GENRL	Malaise/ indisposition#	4	15FEB2021	1/3	2	Yes		NA	R (17FEB2021)	N/N	
		Pyrexia/ fever (38C)#	4	15FEB2021	1/3	2	Yes		NA/TC	R (17FEB2021)	N/N	
	MUSC	Myalgia/ muscle pain#	4	15FEB2021	1/3	2	Yes		NA	R (17FEB2021)	N/N	
	NERV	Headache/ headache#	4	15FEB2021	1/3	2	Yes		NA	R (17FEB2021)	N/N	
16-55/ C4591001 1226 12261612	GENRL	Injection site pain/ Pain at injection site	1	07SEP2020	1/4	1	Yes		NA	R (10SEP2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site	2	28SEP2020	1/4	1	Yes		NA	R (01OCT2020)	N/N	
	GENRL	Injection site erythema/ Erythema at the injection site	2	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N	
		Injection site swelling/ Swelling at the injection site	2	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261614	GENRL	Chills/ Chills	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N	
		Injection site pain/ Pain at the injection site	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N	
16-55/ C4591001 1226 12261616	GENRL	Pyrexia/ fever (38C)#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N	
16-55/ C4591001 1226 12261618	NERV	Headache/ Headache	2	17OCT2020	17/5	2	No	O	NA	R (21OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N	
16-55/ C4591001 1226 12261619	GENRL	Injection site pain/ Pain at the injection site	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	02OCT2020	3/2	2	Yes		NA	R (03OCT2020)	N/N	
	NERV	Headache/ Headache	2	02OCT2020	3/2	2	Yes		NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001 1226 12261621	GENRL	Chills/ chills	1	08SEP2020	2/3	2	Yes		NA	R (10SEP2020)	N/N	
		Fatigue/ fatigue	1	08SEP2020	2/3	2	Yes		NA	R (10SEP2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261623		Injection site pain/ pain at injection site	1	08SEP2020	2/3	2	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	MUSC	Arthralgia/ Joint pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	GASTR	Nausea/ Nausea	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	11SEP2020	4/2	2	Yes		NA	R (12SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	1	11SEP2020	4/5	2	Yes		NA/TC	R (15SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	06FEB2021	2/4	1	Yes		NA/TC	R (09FEB2021)	N/N
16-55/ C4591001 1226 12261624	GENRL	Chills/ Chills#	3	08FEB2021	1/1	2	Yes		NA/TC	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261625	GENRL	Injection site pain/ pain at the injection site#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1226 12261627	GENRL	Fatigue/ fatigue	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Injection site pain/ pain at injection site	1	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261628	NERV	Headache/ headache	1	08SEP2020	1/2	1	Yes		NA/TC	R (09SEP2020)	N/N
	GASTR	Nausea/ nausea	2	29SEP2020	2/1	2	Yes		NA	R (29SEP2020)	N/N
		Vomiting/ vomiting	2	29SEP2020	2/1	2	Yes		NA	R (29SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	29SEP2020	2/3	2	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	2	29SEP2020	2/1	2	Yes		NA	R (29SEP2020)	N/N
	NERV	Headache/ headache	2	26OCT2020	29/2	2	No	O	NA/TC	R (27OCT2020)	N/N
	MUSC	Myalgia/ Muscles pain	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site oedema/ Edema at injection site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	16-55/ C4591001 1226 12261630	VASC	Hypertension/ Systemic arterial hypertension	1	14SEP2020	7/C	1	Yes		NA/TC	RG
16-55/ C4591001 1226 12261631	GENRL	Injection site pain/ Pain at the injection site#	3	06FEB2021	2/3	1	Yes		NA/TC	R (08FEB2021)	N/N
	GENRL	Chills/ chills#	3	23JAN2021	1/2	2	Yes		NA/TC	R (24JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261632	NERV	Injection site pain/ pain at the injection site#	3	23JAN2021	1/2	1	Yes		NA/TC	R (24JAN2021)	N/N	
		Headache/ headache#	3	23JAN2021	1/2	2	Yes		NA/TC	R (24JAN2021)	N/N	
	GENRL	Injection site pain/ Pain at the injection site#	4	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N	
	GENRL	Injection site pain/ Pain at the injection site	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
	GENRL	Chills/ Chills	2	30SEP2020	1/1	2	Yes		NA/TC	R (30SEP2020)	N/N	
	NERV	Fatigue/ Fatigue	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N	
		Headache/ Headache	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N	
		NERV	Headache/ Headache	2	29SEP2020	1/1	1	Yes		NA/TC	R (29SEP2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site#	3	05FEB2021	1/3	2	Yes		NA/TC	R (07FEB2021)	N/N
	16-55/ C4591001 1226 12261633	NERV	Headache/ Headache#	3	05FEB2021	1/3	2	Yes		NA/TC	R (07FEB2021)	N/N
GENRL		Asthenia/ Asthenia#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N	
MUSC		Myalgia/ Myalgia#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N	
GENRL		Injection site pain/ pain at the injection site#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261634	GENRL	Injection site pain/ pain at injection site	1	09SEP2020	1/1	1	Yes	NA/TC		R (09SEP2020)	N/N
1226 12261636	GENRL	Injection site pain/ pain at the injection site	1	09SEP2020	1/3	1	Yes	NA		R (11SEP2020)	N/N
1226 12261637	GENRL	Injection site pain/ Pain at the injection site	2	29SEP2020	1/3	1	Yes	NA		R (01OCT2020)	N/N
1226 12261641	GENRL	Injection site pain/ pain at injection site	1	09SEP2020	1/3	2	Yes	NA		R (11SEP2020)	N/N
	GASTR	Diarrhoea/ diarrhea	1	10SEP2020	2/1	1	Yes	NA		R (10SEP2020)	N/N
		Nausea/ nausea	1	10SEP2020	2/2	2	Yes	NA		R (11SEP2020)	N/N
	MUSC	Arthralgia/ joint pain	1	10SEP2020	2/2	2	Yes	NA		R (11SEP2020)	N/N
		Myalgia/ muscle pain	1	10SEP2020	2/2	2	Yes	NA/TC		R (11SEP2020)	N/N
	NERV	Headache/ headache	1	10SEP2020	2/2	2	Yes	NA		R (11SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	30SEP2020	1/2	1	Yes	NA		R (01OCT2020)	N/N
		Nausea/ Nauseas	2	30SEP2020	1/2	1	Yes	NA		R (01OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Arthralgia/ Joint pain	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
		Myalgia/ Muscle pain	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1226 12261643	GENRL	Injection site pain/ Pain at injection site#	3	07FEB2021	2/4	2	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1226 12261644	GENRL	Injection site pain/ Pain at injection site	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
		Pyrexia/ Fever (39 C)	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1226 12261647	MUSC	Myalgia/ muscle pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1226 12261649	GASTR	Nausea/ nausea	1	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
		Pyrexia/ fever	1	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261650	INFEC	Urinary tract infection/ urinary tract infection	2	11OCT2020	12/7	1	No	O	NA/TC	R (17OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	
16-55/ C4591001 1226 12261651	GENRL	Fatigue/ Fatigue	1	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N	
16-55/ C4591001 1226 12261653	NERV	Headache/ headache	1	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/4	1	Yes		NA	R (04OCT2020)	N/N	
	NERV	Headache/ headache	2	01OCT2020	2/4	1	Yes		NA	R (04OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N	
	NERV	Headache/ Headache	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N	
	GENRL	Pyrexia/ Fever (38.7 C)	2	29SEP2020	1/2	2	Yes		NA/TC	R (30SEP2020)	N/N	
16-55/ C4591001 1226 12261654	GENRL	Injection site pain/ Pain at the injection site#	3	06FEB2021	1/2	1	Yes		NA	R (07FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12261655	GENRL	Injection site pain/ Pain at the injection site#	3	24JAN2021	2/2	1	Yes		NA	R (25JAN2021)	N/N	
1226 12261656	GENRL	Injection site pain/ Pain at injection site	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N	
1226 12261657	GENRL	Injection site pain/ pain at the injection site#	3	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N	
1226 12261659	GENRL	Fatigue/ fatigue#	3	09FEB2021	2/1	1	Yes		NA/TC	R (09FEB2021)	N/N	
1226 12261660	MUSC	Myalgia/ Muscle pain#	3	28JAN2021	2/1	2	Yes		NA/TC	R (28JAN2021)	N/N	
1226 12261660	GENRL	Pain/ body pain#	4	17FEB2021	1/2	2	Yes		NA/TC	R (18FEB2021)	N/N	
1226 12261660	GENRL	Pyrexia/ fever#	4	17FEB2021	1/2	2	Yes		NA/TC	R (18FEB2021)	N/N	
1226 12261661	GENRL	Injection site erythema/ erythema at the injection site	1	11SEP2020	1/5	1	Yes		NA	R (15SEP2020)	N/N	
1226 12261661	GENRL	Injection site pain/ pain at injection site	1	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue	1	14SEP2020	4/3	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Fatigue/ Tiredness	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N
	MUSC	Pain in extremity/ Right arm pain	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1226 12261664	GENRL	Injection site pain/ pain at the injection site#	3	07FEB2021	2/2	2	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261665	GENRL	Fatigue/ Fatigue	1	12SEP2020	1/1	2	Yes		NA	R (12SEP2020)	N/N
		Injection site pain/ Pain at the injection site	1	12SEP2020	1/2	2	Yes		NA	R (13SEP2020)	N/N
	GENRL	Asthenia/ Asthenia	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		Pyrexia/ Fever	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
	NERV	Headache/ Headache	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1226 12261666	INV	Body temperature increased/ elevated body temperature (37.8 C)	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1226 12261667	GENRL	Injection site pain/ Injection site pain	1	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261668	MUSC	Myalgia/ muscle pain	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	06FEB2021	1/2	2	Yes		NA/TC	R (07FEB2021)	N/N
	GENRL	Chills/ chills#	3	07FEB2021	2/2	2	Yes		NA/TC	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261669		Malaise/ malaise#	3	07FEB2021	2/2	2	Yes		NA/TC	R (08FEB2021)	N/N
	NERV	Headache/ headache#	3	07FEB2021	2/2	2	Yes		NA/TC	R (08FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	06FEB2021	1/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261670	NERV	Headache/ Headache#	3	06FEB2021	1/2	1	Yes		NA	R (07FEB2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N
	INV	Body temperature increased/ Increased body temperature 37.9	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N
	NERV	Headache/ Headache	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N
		Headache/ headache	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N
	RESP	Sneezing/ Sneezing	2	02NOV2020	32/2	1	No	O	NA/TC	R (03NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261672	GENRL	Injection site pain/ Pain at injection site#	3	06FEB2021	1/3	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261673	GENRL	Fatigue/ fatigue	1	12SEP2020	1/5	2	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ pain at injection site	1	12SEP2020	1/5	2	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Pyrexia/ Fever 38.2 C	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N
16-55/ C4591001 1226 12261674	GENRL	Injection site pain/ Pain at injection site#	3	07FEB2021	2/2	2	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261675	VASC	Hypertension/ Systemic arterial hypertension	1	19SEP2020	8/C	1	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261676	GENRL	Injection site pain/ Pain at the injection site#	3	05FEB2021	1/6	2	Yes		NA	R (10FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261677	GENRL	Fatigue/ Fatigue	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	02OCT2020	1/3	2	Yes		NA	R (04OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1226 12261679	GENRL	Fatigue/ Fatigue	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Chills/ Chills	2	03OCT2020	2/2	3	Yes		NA/TC	R (04OCT2020)	N/N
		Injection site pain/ Pain at injection site	2	03OCT2020	2/2	3	Yes		NA/TC	R (04OCT2020)	N/N
16-55/ C4591001 1226 12261680	NERV	Headache/ headache	1	13SEP2020	2/1	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Asthenia/ Asthenia	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		Injection site pain/ Pain at the injection site	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at injection site	1	14SEP2020	3/2	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12261681	SURG	Vasectomy/ Vasectomy	2	23OCT2020	22/1	1	No	O	NA/TC	R (23OCT2020)	N/N	
	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	1/3	1	Yes		NA/TC	R (07FEB2021)	N/N	
	NERV	Headache/ mild headache#	3	05FEB2021	1/3	1	Yes		NA/TC	R (07FEB2021)	N/N	
16-55/ C4591001 1226 12261682	GENRL	Injection site pain/ pain at the injection site#	3	19FEB2021	1/2	1	Yes		NA/TC	R (20FEB2021)	N/N	
	INV	Body temperature increased/ increased body temperature (37,5 C)#	3	19FEB2021	1/2	1	Yes		NA/TC	R (20FEB2021)	N/N	
16-55/ C4591001 1226 12261683	GENRL	Injection site pain/ pain at injection site	1	12SEP2020	1/2	1	Yes		NA/TC	R (13SEP2020)	N/N	
	MUSC	Myalgia/ myalgia	1	12SEP2020	1/2	1	Yes		NA/TC	R (13SEP2020)	N/N	
	GENRL	Pyrexia/ Fever 38 C	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N	
	MUSC	Myalgia/ Muscle pain	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001 1226 12261685	GENRL	Injection site pain/ pain at the injection site#	3	13FEB2021	2/3	1	Yes		NA	R (15FEB2021)	N/N	
16-55/ C4591001	MUSC	Myalgia/ Muscle pain	1	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261686	MUSC	Myalgia/ Muscle pain	2	06OCT2020	2/1	1	Yes	NA/TC		R (06OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	08FEB2021	1/3	2	Yes	NA/TC		R (10FEB2021)	N/N
16-55/ C4591001 1226 12261687	MUSC	Myalgia/ myalgia#	3	17FEB2021	1/2	1	Yes	NA/TC		R (18FEB2021)	N/N
16-55/ C4591001 1226 12261688	GENRL	Injection site pain/ pain at injection site	1	12SEP2020	1/3	1	Yes	NA		R (14SEP2020)	N/N
	MUSC	Pain in extremity/ Left arm pain	2	02OCT2020	1/3	1	Yes	NA		R (04OCT2020)	N/N
16-55/ C4591001 1226 12261689	GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	1/3	1	Yes	NA		R (25JAN2021)	N/N
	GENRL	Pyrexia/ fever (38C)#	4	14FEB2021	2/1	1	Yes	NA/TC		R (14FEB2021)	N/N
16-55/ C4591001 1226 12261690	GENRL	Injection site pain/ pain at injection site	1	12SEP2020	1/3	2	Yes	NA		R (14SEP2020)	N/N
	GENRL	Chills/ chills	2	02OCT2020	1/2	1	Yes	NA/TC		R (03OCT2020)	N/N
		Pyrexia/ fever (38 C)	2	02OCT2020	1/2	1	Yes	NA/TC		R (03OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261691	MUSC	Myalgia/ muscle pain	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
	NERV	Headache/ headache	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Pyrexia/ Fever 38.2 C	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1226 12261693	GENRL	Injection site pain/ pain at the injection site#	3	08FEB2021	1/4	2	Yes		NA	R (11FEB2021)	N/N
		Pyrexia/ Fever 38.6 C#	3	08FEB2021	1/2	2	Yes		NA/TC	R (09FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	08FEB2021	1/2	2	Yes		NA/TC	R (09FEB2021)	N/N
	NERV	Headache/ headache#	3	08FEB2021	1/C	3	Yes		NA/TC	RG	N/N
	GENRL	Chills/ Chills#	3	07FEB2021	2/2	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261694		Fatigue/ Tiredness#	3	07FEB2021	2/2	1	Yes		NA	R (08FEB2021)	N/N
		Injection site pain/ Pain at injection site#	3	07FEB2021	2/2	1	Yes		NA	R (08FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261695	INV	Body temperature increased/ Increased oral temperature 37,8 C	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
	GASTR	Abdominal pain/ Abdominal pain	2	05OCT2020	4/7	1	No	O	NA/TC	R (11OCT2020)	N/N
	RESP	Nasal congestion/ Nasal congestion	2	04JAN2021	95/6	1	No	O	NA/TC	R (09JAN2021)	N/N
16-55/ C4591001 1226 12261696	GENRL	Injection site pain/ pain at injection site	1	12SEP2020	1/2	2	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1226 12261697	GENRL	Injection site pain/ Pain at injection site	1	12SEP2020	1/2	3	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ Headache	1	12SEP2020	1/2	3	Yes		NA/TC	R (13SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	13SEP2020	2/1	2	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1226 12261698	GENRL	Pain/ Body ache#	3	06FEB2021	1/2	1	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ Diarrhea	2	06OCT2020	2/1	2	Yes		NA	R (06OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12261699	NERV	Headache/ Headache	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N	
16-55/ C4591001	GENRL	Chills/ Chills	2	06OCT2020	2/1	2	Yes		NA	R (06OCT2020)	N/N	
1226 12261703	MUSC	Myalgia/ Muscle pain	2	06OCT2020	2/1	2	Yes		NA/TC	R (06OCT2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ pain at the injection site#	3	25JAN2021	1/4	1	Yes		NA	R (28JAN2021)	N/N	
1226 12261704	GENRL	Injection site pain/ pain at the injection site#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N	
	INV	Body temperature increased/ Increased body temperature (37.5C)#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N	
	MUSC	Myalgia/ myalgia#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N	
16-55/ C4591001	GASTR	Abdominal pain/ Colic abdominal pain	1	16SEP2020	3/2	1	Yes		NA/TC	R (17SEP2020)	N/N	
1226 12261705		Diarrhoea/ Diarrhea	1	16SEP2020	3/2	1	Yes		NA/TC	R (17SEP2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	1/3	1	Yes		NA	R (25JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	14FEB2021	2/1	1	Yes		NA/TC	R (14FEB2021)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261706	INV	Body temperature increased/ Increased body temperature 37.9 C#	4	14FEB2021	2/1	1	Yes		NA/TC	R (14FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
	NERV	Headache/ Headache	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1226 12261707	RESP	Oropharyngeal pain/ Sore throat	2	06OCT2020	2/2	1	No	O	NA/TC	R (07OCT2020)	N/N
	GENRL	Pyrexia/ fever (37,8 C)	2	05OCT2020	1/1	1	Yes		NA/TC	R (05OCT2020)	N/N
	BLOOD	Lymphadenopathy/ axillary lymphadenopathy in the left arm	2	06OCT2020	2/3	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1226 12261710	INFEC	Cystitis/ cystitis	1	18SEP2020	5/2	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1226 12261711	MUSC	Myalgia/ muscle pain	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
	NERV	Headache/ headache#	3	09FEB2021	1/5	1	Yes		NA/TC	R (13FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	06FEB2021	2/5	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	14SEP2020	1/3	2	Yes		NA	R (16SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261712	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	01FEB2021	120/C		No	O	NA	UNK	N/N
16-55/ C4591001 1226 12261713	GENRL	Injection site pain/ Pain at injection site#	3	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1226 12261714	BLOOD	Lymphadenopathy/ Axillary adenomegaly	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ Headache	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1226 12261715	GENRL	Injection site pain/ Pain at injection site	1	14SEP2020	1/3	2	Yes		NA/TCN	R (16SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
		Pyrexia/ Fever (38.5 C)	2	05OCT2020	1/2	2	Yes		NA/TC	R (06OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	05OCT2020	1/3	2	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ Headache	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	14SEP2020	1/1	1	Yes		NA	R (14SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12261716	MUSC	Myalgia/ muscle pain	1	14SEP2020	1/1	1	Yes		NA/TC	R (14SEP2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N	
	MUSC	Myalgia/ Muscle pain	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N	
	GENRL	Injection site erythema/ Erythema at the injection site	2	07OCT2020	3/4	1	Yes		NA	R (10OCT2020)	N/N	
16-55/ C4591001 1226 12261717	GENRL	Injection site pain/ pain at the injection site#	3	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N	
16-55/ C4591001 1226 12261718	NERV	Headache/ Headache	1	23SEP2020	10/1	1	No	O	NA/TC	R (23SEP2020)	N/N	
16-55/ C4591001 1226 12261719	GENRL	Injection site pain/ Pain at injection site#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N	
16-55/ C4591001 1226 12261720	INV	Body temperature increased/ Body temperature elevated 37.8 C	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N	
	MUSC	Myalgia/ Muscle pain	2	05OCT2020	1/3	1	Yes		NA/TC	R (07OCT2020)	N/N	
16-55/ C4591001	GENRL	Injection site erythema/ Hyperemia at injection site	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12261721		Injection site pain/ Pain at injection site	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N	
	GENRL	Injection site pain/ pain at injection site	2	05OCT2020	1/4	1	Yes		NA/TC	R (08OCT2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ pain at injection site	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N	
1226 12261724		Injection site pain/ pain at the injection site#	3	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N	
16-55/ C4591001	GENRL	Chills/ Chills#	3	06FEB2021	1/3	1	Yes		NA	R (08FEB2021)	N/N	
1226 12261725		Paraesthesia/ Paresthesia in lower limbs#	3	06FEB2021	1/3	1	Yes		NA	R (08FEB2021)	N/N	
16-55/ C4591001	GENRL	Injection site erythema/ Erythema at injection site	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N	
1226 12261726												
16-55/ C4591001	GENRL	Chills/ chills	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N	
1226 12261729		Headache/ headache	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site	1	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12261730	MUSC	Myalgia/ Muscle pain	1	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N	
	PSYCH	Insomnia/ Insomnia	1	16SEP2020	2/4	2	Yes		NA/TC	R (19SEP2020)	N/N	
	MUSC	Arthralgia/ Joint pain	2	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N	
		Myalgia/ Muscle pain	2	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N	
16-55/ C4591001 1226 12261731	GASTR	Diarrhoea/ diarrhea	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site#	3	12FEB2021	1/4	1	Yes		NA/TC	R (15FEB2021)	N/N	
16-55/ C4591001 1226 12261733	GENRL	Pyrexia/ Fever 38.2 C	2	07OCT2020	2/1	2	Yes		NA/TC	R (07OCT2020)	N/N	
	NERV	Headache/ Headache	2	08OCT2020	3/2	2	Yes		NA/TC	R (09OCT2020)	N/N	
	GASTR	Dysphagia/ SWALLOWING DIFFICULT	2	23OCT2020	18/2	1	No	O	NA/TC	R (24OCT2020)	N/N	
16-55/ C4591001 1226 12261737	GENRL	Injection site pain/ pain at injection site*		15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
	NERV	Headache/ headache	1	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261740	GENRL	Chills/ Chills#	4	17FEB2021	1/3	1	Yes		NA/TC	R (19FEB2021)	N/N	
		Pyrexia/ Fever 38 C#	4	17FEB2021	1/3	1	Yes		NA/TC	R (19FEB2021)	N/N	
	NERV	Headache/ Headache#	4	17FEB2021	1/3	1	Yes		NA/TC	R (19FEB2021)	N/N	
	GASTR	Diarrhoea/ diarrhea#	3	27FEB2021	4/2	1	Yes		NA	R (28FEB2021)	N/N	
	MUSC	Myalgia/ muscle pain#	3	27FEB2021	4/2	1	Yes		NA	R (28FEB2021)	N/N	
	GENRL	Chills/ Chills	1	16SEP2020	1/1	2	Yes		NA	R (16SEP2020)	N/N	
		Pyrexia/ Fever (38,5 C)	1	16SEP2020	1/1	2	Yes		NA/TC	R (16SEP2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site	1	17SEP2020	2/3	2	Yes		NA	R (19SEP2020)	N/N	
	NERV	Headache/ Headache	1	17SEP2020	2/1	2	Yes		NA	R (17SEP2020)	N/N	
	SKIN	Urticaria/ Urticaria localised (neck and forearm plaques, 1 plaque in each of these locations)	1	19SEP2020	4/11	1	No	O	NA	R (29SEP2020)	N/N	
GENRL	Chills/ Chills	2	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/N		
	Injection site pain/ Pain at the injection site	2	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/N		

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261742	GENRL	Pyrexia/ fever (39.5 C)	2	07OCT2020	2/1	3	Yes		NA/TC	R (07OCT2020)	N/N	
	MUSC	Myalgia/ muscle pain	2	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N	
16-55/ C4591001 1226 12261743	GENRL	Injection site pain/ pain at the injection site#	3	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N	
16-55/ C4591001 1226 12261745	NEOPL	Leydig cell tumour of the testis/ Leydig cell tumor in left testicle	1	23SEP2020	8/15	2	No	O	NA	R (07OCT2020)	Y/N	
16-55/ C4591001 1226 12261746	GENRL	Injection site pain/ Pain at injection site	1	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	07OCT2020	2/1	2	Yes		NA/TC	R (07OCT2020)	N/N	
	GENRL	Pyrexia/ Fever 38.5	2	07OCT2020	2/1	2	Yes		NA/TC	R (07OCT2020)	N/N	
16-55/ C4591001 1226 12261747	GENRL	Injection site erythema/ erythema at injection site	1	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N	
	GENRL	Injection site pain/ pain at injection site	1	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261748	GENRL	Chills/ Chills#	3	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	3	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1226 12261751	GENRL	Injection site erythema/ Erythema at injection site	1	18SEP2020	3/2	1	Yes		NA	R (19SEP2020)	N/N
		Injection site oedema/ edema at injection site	1	18SEP2020	3/2	1	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Pain at injection site	1	18SEP2020	3/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	2	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N
	MUSC	Arthralgia/ joint pain in hands	2	07OCT2020	2/2	2	Yes		NA/TC	R (08OCT2020)	N/N
		Joint swelling/ joint swelling in hands	2	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1226 12261752	GENRL	Injection site swelling/ Swelling at the injection site#	3	06FEB2021	1/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261753	NERV	Headache/ Headache	1	16SEP2020	1/1	1	Yes		NA/TC	R (16SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261754	GENRL	Injection site pain/ pain at the injection site#	3	06FEB2021	1/2	1	Yes		NA	R (07FEB2021)	N/N
	GENRL	Fatigue/ tiredness#	4	17FEB2021	1/4	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1226 12261756		Pyrexia/ fever (38.2C)#	4	17FEB2021	1/4	1	Yes		NA/TC	R (20FEB2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	07FEB2021	2/4	2	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1226 12261759	GASTR	Diarrhoea/ diarrhea	1	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1226 12261760	GENRL	Fatigue/ fatigue	1	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ pain at injection site	1	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1226 12261761	GENRL	Injection site oedema/ edema at injection site#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1226 12261761	GENRL	Injection site pain/ pain at the injection site#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261763	GENRL	Injection site pain/ Pain at the injection site	2	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1226 12261764	GENRL	Injection site pain/ Pain at the injection site	2	09OCT2020	1/2	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1226 12261765	NERV	Headache/ Headache	1	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1226 12261766	GENRL	Fatigue/ Fatigue	2	08OCT2020	2/2	2	Yes		NA/TC	R (09OCT2020)	N/N
		Pyrexia/ Fever 38.7 C	2	08OCT2020	2/2	2	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1226 12261767	GENRL	Fatigue/ Fatigue	1	19SEP2020	3/3	2	Yes		NA	R (21SEP2020)	N/N
	NERV	Headache/ Headache	1	19SEP2020	3/3	2	Yes		NA	R (21SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	24JAN2021	2/3	1	Yes		NA	R (26JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261768	GENRL	Fatigue/ tiredness#	4	16FEB2021	2/2	2	Yes		NA	R (17FEB2021)	N/N
		Injection site pain/ pain at the injection site#	4	16FEB2021	2/2	2	Yes		NA/TC	R (17FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	16FEB2021	2/2	2	Yes		NA/TC	R (17FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1226 12261769	GENRL	Chills/ Chills	1	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	06FEB2021	1/3	2	Yes		NA	R (08FEB2021)	N/N
	GENRL	Injection site pruritus/ Pruritus at the injection site	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Pyrexia/ Fever 38.2 C	2	07OCT2020	1/3	2	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1226 12261770	MUSC	Myalgia/ Muscle pain	2	07OCT2020	1/3	2	Yes		NA/TC	R (09OCT2020)	N/N
	NERV	Idiopathic intracranial hypertension/ idiopathic intracranial hypertension	2	22OCT2020	16/9	3	No	O	NA/TC/TCN	R (30OCT2020)	Y/N
	INFEC	Postoperative wound infection/ surgical site infection (Flank)	2	03NOV2020	28/39	3	No	O	NA/TC	R (11DEC2020)	Y/N
	GENRL	Injection site pain/ Pain at the injection site	1	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261771	GENRL	Fatigue/ Tiredness	1	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1226 12261773	GENRL	Injection site pain/ pain at the injection site#	3	25JAN2021	1/4	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	15FEB2021	1/2	2	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1226 12261775	GENRL	Injection site pain/ Pain at the injection site#	3	13FEB2021	1/2	2	Yes		NA/TC	R (14FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Ipsilateral axillary lymph node enlargement#	3	15FEB2021	3/3	2	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1226 12261776	GENRL	Injection site pain/ Pain at the injection site#	3	09FEB2021	1/4	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1226 12261778	GENRL	Pyrexia/ Fever (38.5 C)	1	17SEP2020	1/1	2	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1226 12261779	NERV	Headache/ Headache	1	19SEP2020	3/2	1	Yes		NA/TC	R (20SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	17OCT2020	11/2	1	Yes		NA	R (18OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261780	GENRL	Injection site pain/ Pain at the injection site#	3	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1226 12261781	GENRL	Injection site pain/ pain at the injection site#	3	03MAR2021	1/5	1	Yes		NA	R (07MAR2021)	N/N
	GENRL	Fatigue/ fatigue#	3	04MAR2021	2/4	1	Yes		NA	R (07MAR2021)	N/N
	METAB	Decreased appetite/ loss of appetite#	3	04MAR2021	2/4	1	Yes		NA	R (07MAR2021)	N/N
16-55/ C4591001 1226 12261784	GENRL	Injection site pain/ Pain at injection site	1	18SEP2020	2/8	2	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	08OCT2020	2/1	2	Yes		NA/TC	R (08OCT2020)	N/N
		Pyrexia/ fever (38.4C)	2	08OCT2020	2/1	2	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1226 12261790	GENRL	Injection site erythema/ erythema at injection site	1	17SEP2020	1/12	2	Yes		NA	R (28SEP2020)	N/N
		Injection site pain/ pain at injection site	1	17SEP2020	1/12	2	Yes		NA	R (28SEP2020)	N/N
	GENRL	Pyrexia/ Fever 38.2	2	08OCT2020	2/3	1	Yes		NA	R (10OCT2020)	N/N
	METAB	Decreased appetite/ inapetence	2	08OCT2020	2/3	1	Yes		NA	R (10OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261791	GENRL	Injection site pain/ Pain at injection site	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N
		Pyrexia/ fever (38 C)	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1226 12261792	GENRL	Injection site pain/ Pain at injection site	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ Chills#	3	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
		Fatigue/ Fatigue#	3	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
	BLOOD	Lymphadenopathy/ (left) axillary lymph node enlargement#	4	17FEB2021	2/3	2	Yes		NA/TC	R (19FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	17FEB2021	2/3	2	Yes		NA/TC	R (19FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	17FEB2021	2/3	2	Yes		NA/TC	R (19FEB2021)	N/N
	GENRL	Pain/ body pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1226 12261794	GASTR	Nausea/ nausea#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261795	GENRL	Fatigue/ tiredness#	4	18FEB2021	2/1	2	Yes		NA	R (18FEB2021)	N/N
		Pain/ body pain#	4	18FEB2021	2/1	2	Yes		NA	R (18FEB2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1226 12261796	GENRL	Injection site pain/ Pain at injection site	2	07OCT2020	1/5	2	Yes		NA	R (11OCT2020)	N/N
	GENRL	Pyrexia/ Fever 38.1 C	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Asthenia/ Weakness	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N
	INV	Body temperature increased/ Increased body temperature 37.5 C#	3	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N
	INJ&P	Contusion/ BRUISING ON THE FOREHEAD#	3	14FEB2021	20/C	2	No	O	NA/TC	RG	N/N
		Facial bones fracture/ Nose fracture#	3	14FEB2021	20/C	2	No	O	NA/TC	RG	N/N
		Skin laceration/ Cut on the forehead#	3	14FEB2021	20/C	2	No	O	NA/TC	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Pain at the injection site#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1226 12261797	GENRL	Injection site pain/ Pain at the injection site	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1226 12261800	GENRL	Chills/ chills	1	17SEP2020	1/6	1	Yes		NA	R (22SEP2020)	N/N
		Injection site erythema/ erythema at injection site	1	17SEP2020	1/6	1	Yes		NA	R (22SEP2020)	N/N
		Injection site pain/ pain at injection site	1	17SEP2020	1/6	1	Yes		NA	R (22SEP2020)	N/N
		Pyrexia/ fever	1	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	1	17SEP2020	1/6	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1226 12261801	GENRL	Injection site pain/ Pain at the injection site#	3	06FEB2021	1/3	1	Yes		NA	R (08FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	06FEB2021	1/4	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1226 12261802	GENRL	Fatigue/ Fatigue	1	21SEP2020	5/1	2	Yes		NA	R (21SEP2020)	N/N
	NERV	Headache/ Headache	1	21SEP2020	5/1	2	Yes		NA	R (21SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261803	GENRL	Injection site pain/ Pain at injection site#	3	24JAN2021	2/1	2	Yes		NA/TC	R (24JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	13FEB2021	2/2	1	Yes		NA/TC	R (14FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1226 12261806	GENRL	Chills/ chills#	3	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Chills/ Chills	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1226 12261807	GENRL	Fatigue/ Fatigue	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	METAB	Decreased appetite/ Inapetence	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ Muscular pain	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ Headache	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Pyrexia/ Fever 38.2 C	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1226 12261807	GENRL	Injection site pain/ Pain at injection site#	3	20FEB2021	1/3	1	Yes		NA	R (22FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INFEC	Cystitis/ Cystitis#	3	09MAR2021	18/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1226 12261809	GENRL	Pyrexia/ Fever (38.1 C)	1	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1226 12261810	GENRL	Injection site pain/ Pain at injection site#	3	25JAN2021	3/3	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	19FEB2021	7/3	2	Yes		NA	R (21FEB2021)	N/N
		Pyrexia/ Fever 39 C#	4	19FEB2021	7/3	2	Yes		NA	R (21FEB2021)	N/N
	MUSC	Arthralgia/ Joint Pain#	4	19FEB2021	7/3	2	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1226 12261812	GENRL	Injection site pain/ pain at the injection site#	3	09FEB2021	2/3	2	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1226 12261813	GENRL	Fatigue/ Fatigue#	3	24JAN2021	2/1	1	Yes		NA	R (24JAN2021)	N/N
		Injection site pain/ Pain at injection site#	3	24JAN2021	2/1	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	14FEB2021	2/1	1	Yes		NA	R (14FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261815	GENRL	Injection site pain/ Pain at injection site	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
		Pyrexia/ Fever (38 C)	2	08OCT2020	1/3	1	Yes		NA/TC	R (10OCT2020)	N/N
	GASTR	Abdominal pain upper/ epigastric pain	2	09OCT2020	2/4	2	Yes		NA	R (12OCT2020)	N/N
		Diarrhoea/ diarrhea	2	09OCT2020	2/4	2	Yes		NA	R (12OCT2020)	N/N
	NERV	Headache/ headache	2	09OCT2020	2/6	2	Yes		NA/TC	R (14OCT2020)	N/N
	SKIN	Skin lesion/ pruritic erimatus lesions on the face	2	13OCT2020	6/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1226 12261819	INV	Body temperature increased/ Body temperature increased 37.3 C	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1226 12261820	GENRL	Fatigue/ Fatigue	2	08OCT2020	1/1	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1226 12261821	GENRL	Injection site pain/ Pain at the injection site#	3	24JAN2021	2/1	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1226 12261823	RESP	Rhinorrhoea/ runny nose	1	28SEP2020	11/1	1	No	O	NA	R (28SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261824	GENRL	Pain/ body pain#	3	06FEB2021	1/4	2	Yes		NA/TC	R (09FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	28FEB2021	2/3	1	Yes		NA/TC	R (02MAR2021)	N/N
	MUSC	Arthralgia/ joint pain#	4	28FEB2021	2/3	1	Yes		NA/TC	R (02MAR2021)	N/N
		Myalgia/ muscle pain#	4	28FEB2021	2/3	1	Yes		NA/TC	R (02MAR2021)	N/N
	GENRL	Injection site pain/ pain at injection site	1	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
	GENRL	Chills/ chills	2	08OCT2020	1/1	1	Yes		NA/TC	R (08OCT2020)	N/N
		Injection site pain/ pain at injection site	2	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1226 12261826	GENRL	Fatigue/ fatigue	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
		Pyrexia/ Fever 38 C	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1226 12261827	MUSC	Myalgia/ muscle pain	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
	NERV	Headache/ headache	1	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261828	NERV	Headache/ Headache	2	09OCT2020	2/1	2	Yes		NA/TC	R (09OCT2020)	N/N	
	SKIN	Pityriasis rosea/ Pityriasis rosea	2	20NOV2020	44/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1226 12261830	GENRL	Injection site pain/ pain at the injection site#	3	11FEB2021	1/3	2	Yes		NA/TC	R (13FEB2021)	N/N	
	GENRL	Injection site pain/ pain at the injection site#	3	07FEB2021	2/2	1	Yes		NA	R (08FEB2021)	N/N	
16-55/ C4591001 1226 12261831	GENRL	Injection site pain/ pain at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N	
16-55/ C4591001 1226 12261833	GENRL	Injection site pain/ Pain at the injection site#	3	06FEB2021	1/3	2	Yes		NA/TC	R (08FEB2021)	N/N	
	NERV	Headache/ Headache#	3	06FEB2021	1/3	2	Yes		NA/TC	R (08FEB2021)	N/N	
16-55/ C4591001 1226 12261835	GENRL	Chills/ Chills	2	08OCT2020	1/2	2	Yes		NA	R (09OCT2020)	N/N	
	MUSC	Myalgia/ Muscle pain	2	08OCT2020	1/2	2	Yes		NA	R (09OCT2020)	N/N	
16-55/ C4591001 1226 12261835	MUSC	Arthralgia/ Joint pain	1	19SEP2020	2/4	1	Yes		NA	R (22SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261836		Myalgia/ Myalgia	1	19SEP2020	2/4	1	Yes		NA	R (22SEP2020)	N/N
	GASTR	Gastroesophageal reflux disease/ gastroesophageal reflux	2	NOV2020	24/C	1	No	O	NA/TC	RG	N/N
	PSYCH	Anxiety/ Anxiety	2	10NOV2020	33/C	2	No	O	NA/TC	RG	N/N
	GENRL	Fatigue/ Fatigue#	3	24JAN2021	2/2	1	Yes		NA	R (25JAN2021)	N/N
	CARD	Supraventricular tachycardia/ Supraventricular tachycardia#	3	11FEB2021	20/1	2	No	O	NA/TC	R (11FEB2021)	N/N
	INJ&P	Road traffic accident/ automobile accident (driver)#	3	11FEB2021	20/1	2	No	O	NA	R (11FEB2021)	N/N
	NERV	Loss of consciousness/ Loss of consciousness#	3	11FEB2021	20/1	3	No	O	NA	R (11FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	3	12FEB2021	21/2	3	No	O	NA/TC	R (13FEB2021)	Y/N
	GENRL	Injection site pain/ pain at the injection site#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Pyrexia/ fever (37,8 C)#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1226 12261838	GENRL	Pyrexia/ Fever(39 C)	2	08OCT2020	1/3	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1226 12261839	GENRL	Fatigue/ fatigue	1	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261840		Injection site erythema/ erythema at the injection site	1	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	19SEP2020	2/3	2	Yes		NA/TC	R (21SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	07OCT2020	1/3	2	Yes		NA/TC	R (09OCT2020)	N/Y
	MUSC	Myalgia/ myalgia	2	07OCT2020	1/3	2	Yes		NA/TC	R (09OCT2020)	N/Y
	GASTR	Abdominal pain/ Intermittent abdominal colic	2	24OCT2020	17/7	1	No	O	NA	R (30OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	10FEB2021	2/2	2	Yes		NA/TC	R (11FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	10OCT2020	3/1	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	06FEB2021	1/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261843	GENRL	Injection site pain/ pain at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261845	GENRL	Injection site pain/ pain at injection site	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
	GENRL	Asthenia/ asthenia	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1226 12261846	GENRL	Injection site pain/ Pain at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GASTR	Diarrhoea/ diarrhea	1	24SEP2020	7/1	2	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1226 12261847	GENRL	Injection site pain/ pain at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1226 12261848	GENRL	Chills/ Chills#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ pain at the injection site#	3	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	NERV	Headache/ headache#	3	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Pain/ Body ache#	4	17FEB2021	1/3	2	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at injection site	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12261850 16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N	
1226 12261852 16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N	
1226 12261853		Injection site pain/ Pain at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N	
	NERV	Headache/ Headache	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N	
	GENRL	Chills/ Chills	2	09OCT2020	1/3	2	Yes		NA/TC	R (11OCT2020)	N/N	
		Pyrexia/ Fever 38 C	2	09OCT2020	1/3	2	Yes		NA/TC	R (11OCT2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site	2	10OCT2020	2/5	1	Yes		NA/TC	R (14OCT2020)	N/N	
1226 12261854		Malaise/ Malaise	2	10OCT2020	2/5	1	Yes		NA/TC	R (14OCT2020)	N/N	
	MUSC	Myalgia/ Muscle pain	2	10OCT2020	2/5	1	Yes		NA/TC	R (14OCT2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site#	3	06FEB2021	1/3	1	Yes		NA	R (08FEB2021)	N/N	
1226 12261857												

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261858	GENRL	Fatigue/ fatigue	1	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
		Injection site pain/ pain at injection site	1	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ myalgia	1	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
	INV	Body temperature increased/ Increased body temperature (37.5)	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1226 12261859	GENRL	Chills/ Chills#	3	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1226 12261860	GENRL	Injection site erythema/ erythema at site injection	1	20SEP2020	2/2	1	Yes		NA	R (21SEP2020)	N/N
		Injection site pain/ pain at injection site	1	20SEP2020	2/2	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1226 12261863	GASTR	Abdominal pain upper/ Epigastric pain	1	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1226 12261864	BLOOD	Lymphadenopathy/ Left axillary lymph node enlargement	2	10OCT2020	2/6	2	Yes		NA/TC	R (15OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261865	MUSC	Myalgia/ Muscle pain	2	10OCT2020	2/2	2	Yes		NA/TC	R (11OCT2020)	N/N	
	NERV	Headache/ Headache	1	20SEP2020	2/4	2	Yes		NA/TC	R (23SEP2020)	N/N	
	NERV	Headache/ Headache	2	10OCT2020	2/5	2	Yes		NA	R (14OCT2020)	N/N	
	GASTR	Diarrhoea/ Diarrhea		2	12OCT2020	4/3	2	Yes		NA/TC	R (14OCT2020)	N/N
				2	12OCT2020	4/3	2	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1226 12261866	MUSC	Arthralgia/ Generalized joint pain	2	12OCT2020	4/3	2	Yes		NA/TC	R (14OCT2020)	N/N	
		Myalgia/ Muscle pain	2	12OCT2020	4/3	2	Yes		NA/TC	R (14OCT2020)	N/N	
	GENRL	Injection site pain/ pain at the injection site#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	
16-55/ C4591001 1226 12261867	GENRL	Fatigue/ fatigue#	3	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N	
	GENRL	Injection site pain/ Pain at injection site	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N	
	GENRL	Pyrexia/ Fever (39 C)	2	10OCT2020	2/1	2	Yes		NA/TC	R (10OCT2020)	N/N	
	MUSC	Myalgia/ Muscle pain	2	10OCT2020	2/1	2	Yes		NA/TC	R (10OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261868	NERV	Headache/ Headache	2	10OCT2020	2/1	2	Yes		NA/TC	R (10OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site	1	19SEP2020	1/2	1	Yes		NA	R (20SEP2020)	N/N	
16-55/ C4591001 1226 12261869	GENRL	Fatigue/ Fatigue	1	19SEP2020	1/1	1	Yes		NA	R (19SEP2020)	N/N	
16-55/ C4591001 1226 12261871	MUSC	Myalgia/ Muscle pain	1	19SEP2020	1/1	1	Yes		NA	R (19SEP2020)	N/N	
	MUSC	Neck pain/ Cervicalgia	1	08OCT2020	20/4	2	No	O	NA/TC	R (11OCT2020)	N/N	
	GENRL	Pain/ Body ache	2	14OCT2020	2/3	1	Yes		NA/TC	R (16OCT2020)	N/N	
	NERV	Headache/ Headache	2	14OCT2020	2/3	1	Yes		NA/TC	R (16OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue#	3	27JAN2021	2/1	2	Yes		NA	R (27JAN2021)	N/N	
			Injection site pain/ Pain at the injection site#	3	27JAN2021	2/1	2	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N	
16-55/ C4591001	NERV	Headache/ headache#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261873		Injection site pain/ Pain at injection site	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
		Pyrexia/ Fever 38.1 C	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1226 12261874	GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	1/4	2	Yes		NA	R (26JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	24JAN2021	2/2	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Fatigue/ Tiredness#	4	16FEB2021	2/3	1	Yes		NA/TC	R (18FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	4	16FEB2021	2/3	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1226 12261875	GENRL	Fatigue/ Fatigue	1	20SEP2020	2/2	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Chills/ chills	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
		Fatigue/ fatigue	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
		Injection site pain/ pain at injection site	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1226 12261876	NERV	Headache/ Headache	1	19SEP2020	1/2	1	Yes		NA	R (20SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ pain at the injection site#	3	12FEB2021	1/3	2	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1226 12261877	NERV	Headache/ Headache	2	08NOV2020	31/1	1	No	O	NA/TC	R (08NOV2020)	N/N
	GASTR	Diarrhoea/ diarrhea#	3	11FEB2021	2/3	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1226 12261878	GENRL	Injection site pain/ pain at injection site	1	19SEP2020	1/3	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Chills/ Chills	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
		Injection site pain/ Pain at injection site	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
		Pyrexia/ Fever (38 C)	2	08OCT2020	1/2	2	Yes		NA/TC/TCN	R (09OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1226 12261880	GENRL	Pyrexia/ fever (38.4C)	2	14OCT2020	1/1	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1226 12261881	GENRL	Injection site pain/ Pain at injection site	1	26SEP2020	2/1	2	Yes		NA/TC	R (26SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261882	GASTR	Diarrhoea/ diarrhea	1	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	1	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C4591001 1226 12261884	GASTR	Abdominal pain/ abdominal colic	1	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Chills/ Chills	1	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ headache	1	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
	NERV	Headache/ Headache	2	19DEC2020	66/1	3	No	O	NA/TC	R (19DEC2020)	N/N
		Hemiparaesthesia/ Left hemiparesthesia	2	19DEC2020	66/1	3	No	O	NA/TC	R (19DEC2020)	N/N
16-55/ C4591001 1226 12261886	GENRL	Injection site pain/ pain at the injection site#	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1226 12261887	GENRL	Pyrexia/ Fever	1	25SEP2020	1/3	1	Yes		NA/TC	R (27SEP2020)	N/N
	INV	Body temperature increased/ Body temperature increased 37.5 C	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261888	GENRL	Chills/ Chills	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
	NERV	Headache/ Headache	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1226 12261889	GENRL	Injection site pain/ pain at the injection site#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Chills/ chills#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
		Injection site pain/ pain at injection site#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
		Pyrexia/ fever (38 C)#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1226 12261892	GENRL	Injection site pain/ pain at the injection site#	3	11FEB2021	1/2	2	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1226 12261895	GENRL	Chills/ Chills	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1226 12261896	GENRL	Injection site pain/ Pain at the injection site#	3	10FEB2021	2/3	2	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever (39 C)#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261897	NERV	Headache/ Headache#	4	18FEB2021	2/3	1	Yes	NA		R (20FEB2021)	N/N
16-55/ C4591001 1226 12261898	MUSC	Myalgia/ Muscle pain	2	16OCT2020	3/4	1	Yes	NA		R (19OCT2020)	N/N
16-55/ C4591001 1226 12261899	GENRL	Chills/ chills#	3	09FEB2021	2/2	1	Yes	NA/TC		R (10FEB2021)	N/N
		Injection site pain/ pain at the injection site#	3	09FEB2021	2/2	1	Yes	NA/TC		R (10FEB2021)	N/N
		Malaise/ Malaise#	3	09FEB2021	2/2	1	Yes	NA/TC		R (10FEB2021)	N/N
	INV	Body temperature increased/ increased body temperature#	3	09FEB2021	2/2	1	Yes	NA/TC		R (10FEB2021)	N/N
	NERV	Headache/ Headache#	3	09FEB2021	2/2	1	Yes	NA/TC		R (10FEB2021)	N/N
16-55/ C4591001 1226 12261900	GENRL	Injection site pain/ Pain at injection site	1	25SEP2020	1/4	2	Yes	NA/TC		R (28SEP2020)	N/N
	GENRL	Chills/ Chills	2	16OCT2020	1/2	1	Yes	NA		R (17OCT2020)	N/N
		Fatigue/ Fatigue	2	16OCT2020	1/2	1	Yes	NA		R (17OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	2	21OCT2020	1/3	1	Yes	NA		R (23OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261901	GENRL	Injection site pain/ Pain at the injection site	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
1226 12261902	GENRL	Injection site pain/ Pain at the injection site#	3	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
1226 12261904	MUSC	Arthralgia/ Arthralgia in hands	2	15DEC2020	63/C	1	No	O	NA	RG	N/N
1226 12261905	GENRL	Injection site pain/ Pain at the injection site	1	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
1226 12261908	GENRL	Injection site pain/ Pain at injection site	1	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N
1226 12261912	NERV	Headache/ Headache	1	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	19OCT2020	22/4	1	Yes		NA	R (22OCT2020)	N/N
1226 12261914	GENRL	Injection site pain/ pain at the injection site#	3	11FEB2021	1/1	1	Yes		NA	R (11FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261917	GENRL	Injection site pain/ pain at the injection site#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N	
16-55/ C4591001 1226 12261918	EYE	Keratitis/ Ocular keratitis	1	04OCT2020	7/8	1	No	O	NA/TC	R (11OCT2020)	N/N	
	GENRL	Injection site pain/ pain at injection site#	3	24FEB2021	1/4	1	Yes		NA	R (27FEB2021)	N/N	
	GENRL	Fatigue/ fatigue#	3	25FEB2021	2/3	1	Yes		NA	R (27FEB2021)	N/N	
	METAB	Decreased appetite/ loss of appetite#	3	25FEB2021	2/3	1	Yes		NA	R (27FEB2021)	N/N	
	NERV	Headache/ headache#	3	25FEB2021	2/3	1	Yes		NA	R (27FEB2021)	N/N	
16-55/ C4591001 1226 12261919	GENRL	Injection site pain/ Pain at the injection site	2	19OCT2020	1/3	1	Yes		NA	R (21OCT2020)	N/N	
	GENRL	Pain/ Body pain	2	20OCT2020	2/2	2	Yes		NA/TC	R (21OCT2020)	N/N	
		Pyrexia/ Fever	2	20OCT2020	2/2	2	Yes		NA/TC	R (21OCT2020)	N/N	
	NERV	Headache/ Headache	2	20OCT2020	2/2	2	Yes		NA/TC	R (21OCT2020)	N/N	
16-55/ C4591001 1226 12261920	GASTR	Nausea/ Nausea	2	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261922	GASTR	Diarrhoea/ Diarrhea	1	11OCT2020	14/2	1	No	O	NA	R (12OCT2020)	N/N	
	GENRL	Fatigue/ fatigue	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N	
	NERV	Headache/ headache	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N	
16-55/ C4591001 1226 12261923	GASTR	Diarrhoea/ Diarrhea	2	23OCT2020	3/3	2	Yes		NA	R (25OCT2020)	N/N	
16-55/ C4591001 1226 12261925	MUSC	Myalgia/ Muscle pain#	3	14FEB2021	2/3	1	Yes		NA	R (16FEB2021)	N/N	
16-55/ C4591001 1226 12261926	INFEC	Ear infection/ Left otitis#	4	09MAR2021	25/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1226 12261928	GENRL	Injection site pain/ Pain at injection site	1	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N	
		Malaise/ Malaise	1	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site	2	21OCT2020	2/3	2	Yes		NA/TC	R (23OCT2020)	N/N	
16-55/ C4591001	NERV	Headache/ Headache	2	21OCT2020	2/1	1	Yes		NA/TC	R (21OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine Subject	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261929	GENRL	Fatigue/ Fatigue	1	29SEP2020	1/2	1	Yes	NA		R (30SEP2020)	N/N
16-55/ C4591001 1226 12261930	GENRL	Injection site pain/ Pain at the injection site	1	29SEP2020	1/2	1	Yes	NA		R (30SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	22OCT2020	1/3	1	Yes	NA		R (24OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23OCT2020	2/2	1	Yes	NA		R (24OCT2020)	N/N
16-55/ C4591001 1226 12261931	GENRL	Injection site pain/ Pain at the injection site#	3	10FEB2021	1/2	2	Yes	NA/TC		R (11FEB2021)	N/N
16-55/ C4591001 1226 12261932	GENRL	Injection site pain/ Pain at injection site#	3	12FEB2021	1/2	2	Yes	NA/TC		R (13FEB2021)	N/N
16-55/ C4591001 1226 12261933	GENRL	Injection site pain/ pain at the injection site#	3	25JAN2021	1/2	1	Yes	NA		R (26JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	16FEB2021	1/3	1	Yes	NA/TC		R (18FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	17FEB2021	2/2	1	Yes	NA/TC		R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/2	1	Yes	NA/TC		R (18FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261934	GENRL	Injection site pain/ Pain at injection site	1	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	20OCT2020	1/3	2	Yes		NA	R (22OCT2020)	N/N
			2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1226 12261935	NERV	Headache/ Headache	1	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
	GENRL	Pain/ Body pain	2	21OCT2020	2/1	1	Yes		NA/TC	R (21OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ fatigue#  Pyrexia/ fever (38.2C)#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
			4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
16-55/ C4591001 1226 12261936	GENRL	Injection site pain/ pain at injection site	1	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	21OCT2020	2/1	2	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C4591001 1226 12261937	GENRL	Fatigue/ Fatigue	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261938	MUSC	Injection site pain/ Pain at the injection site	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
		Myalgia/ Muscle pain	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
	NERV	Headache/ Headache	1	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1226 12261939	GENRL	Injection site erythema/ redness at the injection site	2	05FEB2021	108/3	1	Yes		NA/TC	R (07FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site	2	05FEB2021	108/3	1	Yes		NA/TC	R (07FEB2021)	N/N
		Chills/ chills	1	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1226 12261940	GENRL	Injection site pain/ pain at injection site	1	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
		Malaise/ malaise	1	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
	Chills/ Chills	2	20OCT2020	1/1	1	Yes		NA/TC	R (20OCT2020)	N/N	
	Pyrexia/ Fever 39.5 C	2	20OCT2020	1/1	1	Yes		NA/TC	R (20OCT2020)	N/N	
GENRL	Injection site pain/ Pain at injection site#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N	
GENRL	Injection site pain/ pain at injection site	2	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261941	GENRL	Injection site pain/ pain at the injection site#	3	10FEB2021	1/2	2	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1226 12261942	MUSC	Myalgia/ Muscle pain	1	30SEP2020	2/2	2	Yes		NA/TC	R (01OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	20OCT2020	1/5	2	Yes		NA/TC	R (24OCT2020)	N/N
	NERV	Headache/ Headache	2	20OCT2020	1/5	2	Yes		NA/TC	R (24OCT2020)	N/N
16-55/ C4591001 1226 12261944	GENRL	Injection site pain/ pain at the injection site#	3	13FEB2021	2/2	2	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1226 12261945	GENRL	Fatigue/ fatigue	1	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Myalgia/ myalgia	1	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1226 12261946	GENRL	Pyrexia/ Fever	2	21OCT2020	2/1	1	Yes		NA/TC	R (21OCT2020)	N/N
	NERV	Headache/ Headache	2	21OCT2020	2/1	1	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261947		Malaise/ malaise	1	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N
	INV	Body temperature increased/ increased body temperature 37,8C	2	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1226 12261950	GENRL	Injection site pain/ Pain at injection site	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1226 12261951	GENRL	Injection site pain/ pain at the injection site#	3	10FEB2021	1/5	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1226 12261952	GENRL	Injection site pain/ pain at injection site	1	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ Fever (38 C)	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
	NERV	Headache/ headache	1	01OCT2020	2/63	1	Yes		NA	R (02DEC2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	11NOV2020	1/3	1	Yes		NA/TC	R (13NOV2020)	N/N
	INV	Body temperature increased/ Increased body temperature (37.8 C)	2	11NOV2020	1/2	2	Yes		NA/TC	R (12NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261953	NERV	Headache/ Headache	2	21OCT2020	1/1	1	Yes		NA	R (21OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain#	3	12FEB2021	2/1	2	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1226 12261954	GASTR	Diarrhoea/ Diarrhea	1	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Asthenia/ weakness	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
		Fatigue/ fatigue	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1226 12261956	NERV	Headache/ Headache	1	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
	GENRL	Chills/ chills	2	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
		Pyrexia/ fever (38 C)	2	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	2	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1226 12261957	GENRL	Injection site pain/ Pain at the injection site#	3	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261958	GENRL	Injection site pain/ Pain at the injection site	2	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	NERV	Headache/ Headache	2	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1226 12261959	GENRL	Injection site pain/ pain at the injection site#	3	10FEB2021	1/3	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1226 12261960	NERV	Headache/ Headache	1	03OCT2020	4/2	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Chills/ Chills#	4	12MAR2021	1/2	1	Yes		NA	R (13MAR2021)	N/N
16-55/ C4591001 1226 12261961	GASTR	Nausea/ Nauseas	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Fatigue/ Tiredness	2	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1226 12261962	MUSC	Arthralgia/ joint pain	2	21OCT2020	1/2	2	Yes		NA/TC	R (22OCT2020)	N/N
		Myalgia/ Myalgia	2	21OCT2020	1/2	2	Yes		NA/TC	R (22OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261963	NERV	Myalgia/ muscle pain	2	21OCT2020	1/2	2	Yes		NA/TC	R (22OCT2020)	N/N
		Headache/ headache	2	21OCT2020	1/2	2	Yes		NA/TC	R (22OCT2020)	N/N
	SKIN	Linear erythematous lesions in the anterior thoracic region	2	22OCT2020	2/4	1	No	O	NA	R (25OCT2020)	N/N
	INFEC	Rhinitis/ Coryza	2	25OCT2020	5/1	1	No	O	NA	R (25OCT2020)	N/N
	RESP	Nasal congestion/ Nasal congestion	2	25OCT2020	5/1	1	No	O	NA	R (25OCT2020)	N/N
16-55/ C4591001 1226 12261964	GENRL	Fatigue/ fatigue	2	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1226 12261966	NERV	Headache/ headache	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	10FEB2021	1/3	1	Yes		NA/TC	R (12FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	3	10FEB2021	1/3	1	Yes		NA/TC	R (12FEB2021)	N/N
	NERV	Headache/ Headache#	3	10FEB2021	1/3	1	Yes		NA/TC	R (12FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain	2	24OCT2020	2/2	1	Yes		NA/TC	R (25OCT2020)	N/N
	NERV	Headache/ Headache	2	24OCT2020	2/2	1	Yes		NA/TC	R (25OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261967	GENRL	Injection site pain/ Pain at injection site#	3	15FEB2021	1/3	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1226 12261968	GENRL	Injection site pain/ pain at injection site	1	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
	NERV	Headache/ headache	1	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
	NERV	Headache/ Headache	2	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1226 12261970	GENRL	Fatigue/ Fatigue	2	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
		Injection site pain/ Pain at the injection site	2	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1226 12261971	GENRL	Fatigue/ fatigue#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	NERV	Headache/ headache#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
	NERV	Headache/ headache#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261972	GENRL	Capsular contracture associated with breast implant/ Capsular contracture in breast implants	1	08OCT2020	9/C	2	No	O	NA	RG	N/N	
		Medical device site granuloma/ Granuloma in breast implants	1	08OCT2020	9/C	2	No	O	NA	RG	N/N	
16-55/ C4591001 1226 12261973	GENRL	Injection site pain/ pain at the injection site#	3	13FEB2021	1/3	1	Yes		NA	R (15FEB2021)	N/N	
	MUSC	Myalgia/ myalgia#	3	13FEB2021	1/3	1	Yes		NA	R (15FEB2021)	N/N	
16-55/ C4591001 1226 12261974	GENRL	Injection site pain/ pain at the injection site#	3	13FEB2021	1/3	1	Yes		NA	R (15FEB2021)	N/N	
16-55/ C4591001 1226 12261975	GENRL	Pyrexia/ Fever 38.5 C	2	24OCT2020	2/1	1	Yes		NA/TC	R (24OCT2020)	N/N	
16-55/ C4591001 1226 12261976	GENRL	Chills/ chills	2	22OCT2020	1/1	2	Yes		NA/TC	R (22OCT2020)	N/N	
		Injection site pain/ pain at injection site	2	22OCT2020	1/2	2	Yes		NA/TC	R (23OCT2020)	N/N	
16-55/ C4591001 1226 12261978	GENRL	Injection site pain/ Pain at injection site	1	01OCT2020	1/1	1	Yes		NA	R (01OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Pain at injection site	2	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
		Pyrexia/ Fever (38.5 C)	2	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1226 12261980	GENRL	Injection site pain/ pain at the injection site#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1226 12261981	GENRL	Fatigue/ Fatigue	1	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Injection site pain/ Pain at the injection site	1	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	NERV	Headache/ Headache	1	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1226 12261983	GENRL	Injection site pain/ Pain at the injection site	1	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1226 12261985	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	1/3	1	Yes		NA	R (25JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	23JAN2021	1/3	1	Yes		NA	R (25JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261987	GENRL	Injection site pain/ Pain at the injection site#	4	12FEB2021	1/7	1	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	25JAN2021	1/1	2	Yes		NA/TC	R (25JAN2021)	N/N
16-55/ C4591001 1226 12261988	GENRL	Injection site pain/ pain at the injection site#	3	25JAN2021	1/3	2	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	16FEB2021	1/4	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1226 12261988	GENRL	Injection site pain/ Pain at the injection site	1	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1226 12261989	GENRL	Injection site pain/ Pain at the injection site	2	26OCT2020	1/2	2	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001 1226 12261992	GENRL	Injection site pain/ Pain at the injection site#	3	24JAN2021	2/2	1	Yes		NA/TC	R (25JAN2021)	N/N
16-55/ C4591001	NERV	Headache/ Headache#	3	24JAN2021	2/2	1	Yes		NA/TC	R (25JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain	1	02OCT2020	2/2	2	Yes		NA	R (03OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261995 16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site#	3	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
1226 12261997 16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site	1	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
1226 12261998	GENRL	Malaise/ Malaise	1	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
	NERV	Headache/ Headache	1	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24OCT2020	2/1	1	Yes		NA/TC	R (24OCT2020)	N/N
	NERV	Headache/ Headache	2	24OCT2020	2/1	1	Yes		NA/TC	R (24OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at injection site	1	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
1226 12261999		Pyrexia/ Fever (38C)	1	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
	GENRL	Pyrexia/ Fever 38 C	2	23OCT2020	1/3	1	Yes		NA/TC	R (25OCT2020)	N/N
16-55/ C4591001	CARD	Arrhythmia/ Arrhythmia	2	19NOV2020	29/3	1	No	O	NA	R (21NOV2020)	N/N
1226 12262000											

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262001	GENRL	Chest pain/ Chest pain	2	19NOV2020	29/3	1	No	O	NA	R (21NOV2020)	N/N
	INFEC	COVID-19/ COVID-19	2	20DEC2020	60/26	4	No	O	NA/TC/TCN	RS (14JAN2021)	Y/N
	RENAL	Dysuria/ Dysuria	2	16FEB2021	118/C	1	No	O	NA/TC	RG	N/N
	GENRL	Malaise/ Malaise	1	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
			Pain/ Body pain	1	02OCT2020	2/1	1	Yes	NA	R (02OCT2020)	N/N
			Pyrexia/ Fever 38.5 C	1	02OCT2020	2/1	1	Yes	NA/TC	R (02OCT2020)	N/N
	NERV	Headache/ Headache	2	23OCT2020	1/1	1	Yes		NA/TC	R (23OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site	1	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
			Malaise/ malaise	1	01OCT2020	1/3	1	Yes	NA	R (03OCT2020)	N/N
	NERV	Headache/ headache	1	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1226 12262002	GENRL	Injection site pain/ Pain at the injection site	2	23OCT2020	1/3	1	Yes		NA/TC	R (25OCT2020)	N/N
		Pain/ Body generalized pain	2	23OCT2020	1/3	1	Yes		NA/TC	R (25OCT2020)	N/N
	NERV	Headache/ Headache	2	23OCT2020	1/3	1	Yes		NA/TC	R (25OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262003	GENRL	Injection site pain/ pain at the injection site#	3	11FEB2021	1/3	2	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1226 12262007	GENRL	Fatigue/ Fatigue	2	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1226 12262008	MUSC	Myalgia/ muscle pain#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1226 12262010	GENRL	Injection site pain/ Pain at injection site#	3	25JAN2021	1/1	2	Yes		NA/TC	R (25JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1226 12262011	GENRL	Asthenia/ Asthenia#	3	21FEB2021	2/4	2	Yes		NA/TC	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	3	21FEB2021	2/2	2	Yes		NA/TC	R (22FEB2021)	N/N
16-55/ C4591001 1226 12262012	GENRL	Injection site pain/ pain at injection site	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12262013	GENRL	Fatigue/ fatigue	1	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N	
	MUSC	Myalgia/ Muscle pain	2	22OCT2020	2/2	2	Yes		NA/TC	R (23OCT2020)	N/N	
	NERV	Headache/ Headache	2	22OCT2020	2/2	2	Yes		NA/TC	R (23OCT2020)	N/N	
	GENRL	Chills/ Chills	2	05NOV2020	1/2	2	Yes		NA	R (06NOV2020)	N/N	
16-55/ C4591001 1226 12262014	MUSC	Myalgia/ Myalgia	2	05NOV2020	1/2	2	Yes		NA	R (06NOV2020)	N/N	
	GENRL	Fatigue/ fatigue	2	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N	
16-55/ C4591001 1226 12262015		Injection site pain/ pain at injection site	2	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N	
	GENRL	Injection site pain/ pain at injection site#	3	14FEB2021	2/2	1	Yes		NA	R (15FEB2021)	N/N	
	GENRL	Injection site pain/ Paim at injection site	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site	2	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N	
16-55/ C4591001	MUSC	Myalgia/ Myalgia	2	24OCT2020	2/1	1	Yes		NA	R (24OCT2020)	N/N	
	GASTR	Toothache/ toothache	2	27OCT2020	7/7	2	No	O	NA/TC	R (02NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12262016	NERV	Headache/ headache#	3	13FEB2021	1/2	1	Yes		NA	R (14FEB2021)	N/N	
16-55/ C4591001 1226 12262017	GENRL	Injection site pain/ Pain at the injection site	2	21OCT2020	1/5	2	Yes		NA/TC	R (25OCT2020)	N/N	
			2	21OCT2020	1/1	1	Yes		NA/TC	R (21OCT2020)	N/N	
	GENRL	Injection site erythema/ Erythema at the injection site	2	22OCT2020	2/4	2	Yes		NA/TC	R (25OCT2020)	N/N	
		Injection site oedema/ Edema at the injection site	2	22OCT2020	2/4	2	Yes		NA/TC	R (25OCT2020)	N/N	
		Pyrexia/ Fever 38.7 C	2	22OCT2020	2/1	2	Yes		NA/TC	R (22OCT2020)	N/N	
16-55/ C4591001 1226 12262018	GENRL	Pyrexia/ fever (38 C)	2	24OCT2020	2/1	1	Yes		NA/TC	R (24OCT2020)	N/N	
	MUSC	Myalgia/ muscle pain	2	24OCT2020	2/1	1	Yes		NA	R (24OCT2020)	N/N	
16-55/ C4591001 1226 12262019	MUSC	Arthralgia/ Joint pain in the right knee	1	04OCT2020	3/31	1	Yes		NA	R (03NOV2020)	N/N	
	GENRL	Injection site pain/ pain at the injection site#	3	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N	
16-55/ C4591001	GENRL	Chills/ chills	1	02OCT2020	1/1	2	Yes		NA	R (02OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262021	NERV	Headache/ headache	1	02OCT2020	1/3	2	Yes		NA	R (04OCT2020)	N/N
	MUSC	Arthralgia/ joint pain	1	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	14FEB2021	2/2	2	Yes		NA	R (15FEB2021)	N/N
	GASTR	Dyspepsia/ dyspepsia#	3	22FEB2021	10/C	2	Yes		NA/TC	RG	N/N
16-55/ C4591001 1226 12262023	GENRL	Fatigue/ Fatigue	1	02OCT2020	1/5	2	Yes		NA	R (06OCT2020)	N/N
	MUSC	Arthralgia/ Arthralgia	1	02OCT2020	1/5	2	Yes		NA	R (06OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	01FEB2021	1/2	2	Yes		NA	R (02FEB2021)	N/N
	NERV	Headache/ headache#	3	01FEB2021	1/2	2	Yes		NA	R (02FEB2021)	N/N
	GENRL	Chills/ chills#	3	02FEB2021	2/1	2	Yes		NA	R (02FEB2021)	N/N
	INV	Body temperature increased/ increased body temperature#	3	02FEB2021	2/1	2	Yes		NA	R (02FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	3	02FEB2021	2/1	2	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1226 12262024	GENRL	Chills/ chills#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262026	GENRL	Injection site pain/ Pain at the injection site	1	03OCT2020	1/2	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Chills/ Chills	1	04OCT2020	2/1	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Pyrexia/ Fever 39 C	2	23OCT2020	2/1	3	Yes		NA/TC	R (23OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	23OCT2020	2/1	2	Yes		NA/TC	R (23OCT2020)	N/N
	NERV	Headache/ Headache	2	23OCT2020	2/1	2	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1226 12262029	GASTR	Diarrhoea/ Diarrhea	1	04OCT2020	2/3	2	Yes		NA	R (06OCT2020)	N/N
		Nausea/ Nausea	1	04OCT2020	2/3	2	Yes		NA/TC	R (06OCT2020)	N/N
	NERV	Headache/ Headache	1	04OCT2020	2/3	2	Yes		NA/TC	R (06OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23OCT2020	2/2	2	Yes		NA/TC	R (24OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	23OCT2020	2/2	2	Yes		NA/TC	R (24OCT2020)	N/N
16-55/ C4591001 1226 12262030	GASTR	Diarrhoea/ diarrhea#	3	16FEB2021	4/8	2	Yes		NA/TC	R (23FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	16FEB2021	4/5	2	Yes		NA/TC	R (20FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12262034	INV	Malaise/ unwell#	3	16FEB2021	4/5	2	Yes		NA/TC	R (20FEB2021)	N/N	
		Body temperature increased/ increased body temperature (37,2 C)#	3	16FEB2021	4/5	2	Yes		NA/TC	R (20FEB2021)	N/N	
	GENRL	Fatigue/ fatigue	1	03OCT2020	1/3	1	Yes		NA	R (05OCT2020)	N/N	
	MUSC	Malaise/ malaise	1	03OCT2020	1/3	1	Yes		NA	R (05OCT2020)	N/N	
		Myalgia/ muscle pain	1	03OCT2020	1/3	1	Yes		NA	R (05OCT2020)	N/N	
		NERV	Headache/ headache	1	04OCT2020	2/2	1	Yes		NA	R (05OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N	
	MUSC	Injection site pain/ Pain at the injection site	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N	
		Pyrexia/ Fever 38.4 C	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N	
		Myalgia/ Muscle pain	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N	
GENRL		Injection site pain/ pain at the injection site#	3	13FEB2021	1/3	1	Yes		NA/TC	R (15FEB2021)	N/N	
16-55/ C4591001 1226 12262036	GENRL	Asthenia/ Asthenia	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262037	BLOOD	Injection site pain/ Pain at injection site	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
		Lymphadenopathy/ Left axillary adenomegaly	2	29OCT2020	4/6	1	Yes		NA	R (03NOV2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
	INV	Body temperature increased/ Body temperature increased 37.6 C	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001 1226 12262038	MUSC	Myalgia/ Myalgia	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	26JAN2021	2/1	2	Yes		NA	R (26JAN2021)	N/N
	MUSC	Myalgia/ muscle pain#	3	26JAN2021	2/1	2	Yes		NA	R (26JAN2021)	N/N
	GENRL	Chills/ chills#	4	17FEB2021	2/2	2	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1226 12262039	MUSC	Myalgia/ myalgia#	4	17FEB2021	2/2	2	Yes		NA/TC	R (18FEB2021)	N/N
	NERV	Headache/ headache#	4	17FEB2021	2/2	2	Yes		NA	R (18FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	1	04OCT2020	2/8	1	Yes		NA	R (11OCT2020)	N/N
	NERV	Headache/ Headache	1	04OCT2020	2/1	1	Yes		NA	R (04OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue	2	23OCT2020	2/8	1	Yes		NA	R (30OCT2020)	N/N
	NERV	Headache/ headache	2	23OCT2020	2/8	1	Yes		NA	R (30OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	12FEB2021	1/5	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1226 12262040	GENRL	Injection site pain/ Pain at injection site	1	03OCT2020	1/8	2	Yes		NA	R (10OCT2020)	N/N
	GENRL	Chills/ Chills	2	24OCT2020	2/7	2	Yes		NA/TC	R (30OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	24OCT2020	2/7	2	Yes		NA	R (30OCT2020)	N/N
	NERV	Headache/ Headache	2	24OCT2020	2/7	2	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1226 12262041	MUSC	Myalgia/ Muscle pain#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1226 12262042	GENRL	Injection site pain/ Pain at injection site	1	03OCT2020	1/4	1	Yes		NA	R (06OCT2020)	N/N
	NERV	Headache/ Headache	1	04OCT2020	2/2	1	Yes		NA/TC	R (05OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Tiredness	1	04OCT2020	2/3	2	Yes		NA	R (06OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12262044		Injection site pain/ Pain at injection site	1	04OCT2020	2/3	2	Yes		NA	R (06OCT2020)	N/N	
		Malaise/ Malaise	1	04OCT2020	2/3	2	Yes		NA	R (06OCT2020)	N/N	
	NERV	Headache/ Headache	1	04OCT2020	2/3	2	Yes		NA	R (06OCT2020)	N/N	
	GENRL	Chills/ Chills	2	26OCT2020	1/3	1	Yes		NA/TC	R (28OCT2020)	N/N	
		Injection site pain/ Pain at the injection site	2	26OCT2020	1/3	1	Yes		NA/TC	R (28OCT2020)	N/N	
16-55/ C4591001 1226 12262045	NERV	Headache/ Headache	1	04OCT2020	2/4	1	Yes		NA	R (07OCT2020)	N/N	
	GENRL	Injection site pain/ pain at the injection site#	3	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N	
16-55/ C4591001 1226 12262046	GENRL	Pyrexia/ Fever (38,9 C)	2	26OCT2020	1/1	2	Yes		NA/TC	R (26OCT2020)	N/N	
16-55/ C4591001 1226 12262048	GASTR	Nausea/ nausea	1	04OCT2020	2/2	1	Yes		NA	R (05OCT2020)	N/N	
	MUSC	Neck pain/ Cervicalgia	2	26NOV2020	32/2	2	No	O	NA/TC	R (27NOV2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site#	3	25JAN2021	1/2	1	Yes		NA/TC	R (26JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262049	GENRL	Injection site pain/ Pain at the injection site#	4	15FEB2021	1/2	2	Yes		NA/TC	R (16FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/1	2	Yes		NA/TC	R (16FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
	GENRL	Pain/ Body ache	2	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	INV	Body temperature increased/ increased body temperature (37 C)	2	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	INV	Body temperature increased/ Increased body temperature (37.7 C)	2	23OCT2020	1/2	1	Yes		NA/TC	R (24OCT2020)	N/N
	NERV	Headache/ Headache	2	24OCT2020	2/3	1	Yes		NA	R (26OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
	MUSC	Myalgia/ muscle pain	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1226 12262052	VASC	Deep vein thrombosis/ Deep vein thrombosis in right lower limb	2	05JAN2021	72/9	2	No	O	NA/TC/TCN	R (13JAN2021)	Y/N
	VASC	Venous thrombosis limb/ Vein thrombosis in right lower limb	2	14JAN2021	81/40	2	No	O	NA/TC	R (22FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262056	GENRL	Fatigue/ Fatigue	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	11FEB2021	1/2	2	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1226 12262058	GENRL	Injection site pain/ pain at injection site	1	03OCT2020	1/2	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Pyrexia/ Fever 38 C	2	26OCT2020	1/3	1	Yes		NA/TC	R (28OCT2020)	N/N
16-55/ C4591001 1226 12262059	GASTR	Diarrhoea/ Diarrhea	1	03OCT2020	1/1	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	26OCT2020	1/2	1	Yes		NA/TC	R (27OCT2020)	N/N
		Pyrexia/ fever (38 C)	2	26OCT2020	1/2	1	Yes		NA/TC	R (27OCT2020)	N/N
	MUSC	Pain in extremity/ arm pain	2	26OCT2020	1/2	1	Yes		NA/TC	R (27OCT2020)	N/N
	NERV	Headache/ headache	2	26OCT2020	1/2	1	Yes		NA/TC	R (27OCT2020)	N/N
16-55/ C4591001 1226 12262060	GENRL	Injection site pain/ Pain at the injection site	2	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001	GASTR	Toothache/ Toothache	2	20NOV2020	26/7	2	No	O	NA/TC	R (26NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12262062	INJ&P	Tooth fracture/ Fracture of the lower right third molar	2	20NOV2020	26/C	2	No	O	NA/TC	RG	N/N	
	GENRL	Injection site pain/ pain at the injection site#	3	13FEB2021	1/2	1	Yes		NA	R (14FEB2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ pain at the injection site#	3	08FEB2021	1/3	2	Yes		NA/TC	R (10FEB2021)	N/N	
1226 12262063		Malaise/ malaise#	3	08FEB2021	1/3	1	Yes		NA/TC	R (10FEB2021)	N/N	
	INV	Body temperature increased/ increased body temperature#	3	08FEB2021	1/3	1	Yes		NA/TC	R (10FEB2021)	N/N	
	NERV	Somnolence/ somnolence#	3	08FEB2021	1/3	1	Yes		NA/TC	R (10FEB2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ pain at injection site	1	03OCT2020	1/4	2	Yes		NA	R (06OCT2020)	N/N	
1226 12262064	GENRL	Fatigue/ fatigue	1	04OCT2020	2/2	2	Yes		NA	R (05OCT2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	03OCT2020	1/2	2	Yes		NA	R (04OCT2020)	N/N	
1226 12262065		Malaise/ Malaise	1	03OCT2020	1/2	2	Yes		NA	R (04OCT2020)	N/N	
16-55/ C4591001	MUSC	Pain in extremity/ Pain at right foot	1	10OCT2020	8/1	1	No	O	NA/TC	R (10OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262067	GENRL	Injection site pain/ pain at the injection site#	3	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1226 12262068	GENRL	Injection site pain/ Pain at the injection site	1	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ Headache	1	14OCT2020	10/2	2	No	O	NA	R (15OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	28OCT2020	1/1	2	Yes		NA/TC	R (28OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	28OCT2020	1/1	2	Yes		NA/TC	R (28OCT2020)	N/N
		Injection site pain/ Pain at the injection site	2	28OCT2020	1/3	2	Yes		NA/TC	R (30OCT2020)	N/N
	NERV	Headache/ Headache	2	28OCT2020	1/6	2	Yes		NA/TC	R (02NOV2020)	N/N
16-55/ C4591001 1226 12262071	NERV	Headache/ Headache	1	05OCT2020	1/1	1	Yes		NA/TC	R (05OCT2020)	N/N
	GENRL	Pyrexia/ Fever 37.3 C	2	28OCT2020	1/1	1	Yes		NA/TC	R (28OCT2020)	N/N
	NERV	Headache/ Headache	2	28OCT2020	1/1	1	Yes		NA/TC	R (28OCT2020)	N/N
16-55/ C4591001 1226 12262072	EYE	Eye pain/ retro eye pain	1	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue	1	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
		Injection site pain/ Pain at the injection site	1	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ headache	1	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1226 12262075	GENRL	Injection site pain/ pain at the injection site#	3	14FEB2021	2/2	2	Yes		NA	R (15FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	3	14FEB2021	2/2	2	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1226 12262076	GENRL	Injection site pain/ pain at injection site	1	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/Y
	GASTR	Diarrhoea/ diarrhea	1	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	29OCT2020	2/2	2	Yes		NA	R (30OCT2020)	N/N
		Pyrexia/ Fever 39.1 C	2	29OCT2020	2/2	2	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1226 12262078	GENRL	Injection site pain/ Pain at injection site#	3	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1226 12262079	GENRL	Injection site pain/ Pain at the injection site	1	05OCT2020	1/3	2	Yes		NA	R (07OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262080	GENRL	Chills/ Chills	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
		Pain/ Body ache	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Fatigue/ fatigue	1	07OCT2020	3/3	2	Yes		NA	R (09OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	1	07OCT2020	3/3	2	Yes		NA	R (09OCT2020)	N/N
	NERV	Headache/ headache	1	07OCT2020	3/3	2	Yes		NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/Y
		Injection site pain/ Pain at the injection site#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/Y
	GENRL	Injection site pain/ Pain at the injection site#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	16-55/ C4591001 1226 12262081	GENRL	Injection site pain/ Pain at the injection site	1	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)
16-55/ C4591001 1226 12262085	GENRL	Injection site pain/ Pain at injection site	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	1	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262086	GENRL	Injection site pain/ Pain at injection site	1	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1226 12262087	GENRL	Injection site pain/ Pain at injection site#	3	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1226 12262089	INFEC	Urinary tract infection/ Urinary tract infection	1	18OCT2020	13/5	3	No	O	NA/TC	R (22OCT2020)	Y/N
	GASTR	Nausea/ Nausea	2	06NOV2020	1/1	1	Yes		NA/TC	R (06NOV2020)	N/N
	GENRL	Chills/ Chills	2	06NOV2020	1/1	1	Yes		NA/TC	R (06NOV2020)	N/N
		Injection site pain/ Pain at injection site	2	06NOV2020	1/2	1	Yes		NA/TC	R (07NOV2020)	N/N
		Malaise/ Malaise	2	06NOV2020	1/1	1	Yes		NA/TC	R (06NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	06NOV2020	1/1	1	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1226 12262090	GENRL	Chills/ Chills#	3	13FEB2021	1/4	2	Yes		NA/TC	R (16FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	3	13FEB2021	1/4	2	Yes		NA/TC	R (16FEB2021)	N/N
	MUSC	Arthralgia/ Arthralgia#	3	13FEB2021	1/4	2	Yes		NA/TC	R (16FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262092	NERV	Headache/ Headache#	3	13FEB2021	1/4	2	Yes		NA/TC	R (16FEB2021)	N/N
	GENRL	Chills/ chills#	3	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N
		Injection site pain/ pain at the injection site#	3	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1226 12262095	MUSC	Myalgia/ muscle pain#	3	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N
	GENRL	Pyrexia/ Fever	1	07OCT2020	2/2	2	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1226 12262096	NERV	Headache/ Headache	1	08OCT2020	3/26	1	No	O	NA	R (02NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	14FEB2021	2/4	2	Yes		NA/TC	R (17FEB2021)	N/N
	INV	Body temperature increased/ Increased body temperature 37.5 C#	3	14FEB2021	2/4	2	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001	MUSC	Arthralgia/ Joint pain#	3	14FEB2021	2/4	2	Yes		NA/TC	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	3	14FEB2021	2/4	2	Yes		NA/TC	R (17FEB2021)	N/N
	MUSC	Arthralgia/ Joint pain in elbows	1	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262099 16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site#	3	13FEB2021	1/2	1	Yes		NA	R (14FEB2021)	N/N
1226 12262103	MUSC	Back pain/ Low back pain#	3	25FEB2021	13/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1226 12262104	GENRL	Injection site pain/ pain at injection site	1	08OCT2020	2/2	2	Yes		NA	R (09OCT2020)	N/N
		Pyrexia/ fever (38 C)	1	08OCT2020	2/1	2	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	28OCT2020	1/1	1	Yes		NA/TC	R (28OCT2020)	N/N
	GENRL	Chills/ Chills	2	29OCT2020	2/1	1	Yes		NA	R (29OCT2020)	N/N
	NERV	Headache/ Headache	2	29OCT2020	2/1	1	Yes		NA/TC	R (29OCT2020)	N/N
	GENRL	Chills/ Chills	2	30OCT2020	3/1	1	Yes		NA	R (30OCT2020)	N/N
	MUSC	Costochondritis/ Costochondritis in the sternal region	2	30OCT2020	3/1	3	No	O	NA	R (30OCT2020)	N/N
16-55/ C4591001 1226 12262105	NERV	Headache/ Headache	1	15OCT2020	9/4	1	No	O	NA/TC	R (18OCT2020)	N/N
	EAR	Ear pain/ (right) ear pain	2	15NOV2020	17/5	1	No	O	NA/TC	R (19NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12262106	MUSC	Myalgia/ Muscle pain#	3	14FEB2021	2/2	1	Yes		NA	R (15FEB2021)	N/N	
16-55/ C4591001 1226 12262107	GASTR	Gastroesophageal reflux disease/ gastroesophageal reflux disease	1	16OCT2020	9/C	1	No	O	NA/TC	RG	N/N	
	GENRL	Injection site pain/ Pain at the injection site#	3	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N	
16-55/ C4591001 1226 12262108	GENRL	Injection site pain/ pain at the injection site#	3	11FEB2021	2/3	1	Yes		NA/TC	R (13FEB2021)	N/N	
	MUSC	Myalgia/ muscle pain#	3	11FEB2021	2/3	1	Yes		NA/TC	R (13FEB2021)	N/N	
	NERV	Headache/ headache#	3	11FEB2021	2/3	1	Yes		NA/TC	R (13FEB2021)	N/N	
16-55/ C4591001 1226 12262110	GENRL	Injection site pain/ Pain at the injection site	1	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N	
	MUSC	Myalgia/ Muscle pain	1	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N	
	NERV	Headache/ Headache	1	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site	2	30OCT2020	2/1	1	Yes		NA	R (30OCT2020)	N/N	
	MUSC	Myalgia/ Muscle pain	2	30OCT2020	2/1	1	Yes		NA	R (30OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262111	NERV	Headache/ Headache	2	30OCT2020	2/1	1	Yes		NA	R (30OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	13FEB2021	1/3	1	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1226 12262112	NERV	Somnolence/ somnolence#	3	13FEB2021	1/3	1	Yes		NA	R (15FEB2021)	N/N
	GENRL	Pyrexia/ fever	1	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1226 12262113	INJ&P	Wound/ piercing-sharp accident	1	17OCT2020	10/2	1	No	O	NA/TC	R (18OCT2020)	N/N
	INV	Body temperature increased/ Increased body temperature 37.6 C	2	29OCT2020	2/2	1	Yes		NA/TC	R (30OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
	INV	Body temperature increased/ Body temperature elevated 37.3 C	1	09OCT2020	2/2	2	Yes		NA	R (10OCT2020)	N/N
	GENRL	Pyrexia/ Fever (39 C)	2	30OCT2020	1/2	2	Yes		NA/TC	R (31OCT2020)	N/N
16-55/ C4591001 1226 12262114	GENRL	Injection site pain/ Pain at the injection site#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	14FEB2021	2/2	1	Yes		NA/TC	R (15FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262115	MUSC	Pyrexia/ fever (38.5C)#	4	14FEB2021	2/1	2	Yes		NA/TC	R (14FEB2021)	N/N
		Myalgia/ myalgia#	4	14FEB2021	2/2	2	Yes		NA/TC	R (15FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Chills/ Chills	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	28OCT2020	2/1	1	Yes		NA/TC	R (28OCT2020)	N/N
16-55/ C4591001 1226 12262117	GENRL	Pyrexia/ Fever (38 C)	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N
	NERV	Headache/ Headache	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	1	10OCT2020	2/5	2	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1226 12262119	GENRL	Pyrexia/ fever (38.3 C)	2	29OCT2020	2/1	1	Yes		NA/TC	R (29OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001	NERV	Headache/ headache#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Chills/ chills	1	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12262120	GENRL	Pyrexia/ Fever 38 C	2	29OCT2020	2/1	1	Yes		NA/TC	R (29OCT2020)	N/N	
16-55/ C4591001 1226 12262121	INFEC	Cystitis/ cystitis	1	20OCT2020	12/13	2	No	O	NA/TC	R (01NOV2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	3	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N	
	GENRL	Injection site pain/ pain at the injection site#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N	
16-55/ C4591001 1226 12262125	GENRL	Injection site pain/ pain at the injection site#	3	13FEB2021	1/3	1	Yes		NA	R (15FEB2021)	N/N	
16-55/ C4591001 1226 12262126	GASTR	Diarrhoea/ Diarrhea	1	09OCT2020	1/1	1	Yes		NA/TC	R (09OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site	1	09OCT2020	1/5	2	Yes		NA/TC	R (13OCT2020)	N/N	
	GENRL	Pyrexia/ Fever 39.6 C	1	10OCT2020	2/1	3	Yes		NA/TC	R (10OCT2020)	N/N	
	MUSC	Arthralgia/ Joint pain	1	10OCT2020	2/4	1	Yes		NA	R (13OCT2020)	N/N	
		Myalgia/ Muscle pain	1	10OCT2020	2/4	1	Yes		NA	R (13OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site	2	30OCT2020	2/4	2	Yes		NA	R (02NOV2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12262127	MUSC	Pyrexia/ Fever 39.8 C	2	30OCT2020	2/2	2	Yes		NA	R (31OCT2020)	N/N	
		Myalgia/ Muscle pain	2	30OCT2020	2/2	2	Yes		NA	R (31OCT2020)	N/N	
16-55/ C4591001 1226 12262128	NERV	Headache/ Headache	1	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N	
	MUSC	Myalgia/ Muscle pain	1	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N	
16-55/ C4591001 1226 12262129	NERV	Headache/ Headache	2	31OCT2020	2/4	2	Yes		NA/TC	R (03NOV2020)	N/N	
	REPRO	Pelvic pain/ Pelvic pain	1	13OCT2020	5/3	2	No	O	NA/TC	R (15OCT2020)	N/N	
16-55/ C4591001 1226 12262130	NERV	Transient ischaemic attack/ Transient Ischemic Attack	2	04DEC2020	36/5	4	No	O	NA/TC	R (08DEC2020)	Y/N	
	GENRL	Injection site pain/ Pain at the injection site#	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N	
	GENRL	Injection site pain/ Pain at the injection site	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	2	31OCT2020	2/4	2	Yes		NA	R (03NOV2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site#	3	14FEB2021	2/2	2	Yes		NA/TC	R (15FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262131 16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site#	3	13FEB2021	1/3	1	Yes		NA	R (15FEB2021)	N/N
1226 12262133	GENRL	Injection site pain/ pain at the injection site#	4	06MAR2021	2/2	1	Yes		NA	R (07MAR2021)	N/N
	INV	Body temperature increased/ increased body temperature (37.5C)#	4	06MAR2021	2/2	1	Yes		NA	R (07MAR2021)	N/N
	MUSC	Arthralgia/ arthralgias#	4	06MAR2021	2/2	1	Yes		NA	R (07MAR2021)	N/N
	NERV	Headache/ headache#	4	06MAR2021	2/2	1	Yes		NA	R (07MAR2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
1226 12262135	GENRL	Injection site pain/ Pain at the injection site	1	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site	1	09OCT2020	1/3	1	Yes		NA/TC	R (11OCT2020)	N/N
1226 12262137	MUSC	Myalgia/ Muscle pain	1	11OCT2020	3/2	1	Yes		NA/TC	R (12OCT2020)	N/N
16-55/ C4591001											
1226 12262138											

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262141	GENRL	Injection site erythema/ Redness at the injection site	1	13OCT2020	1/3	2	Yes		NA	R (15OCT2020)	N/N
		Injection site pain/ Pain at the injection site	1	13OCT2020	1/3	2	Yes		NA	R (15OCT2020)	N/N
	GENRL	Chills/ Chills	1	14OCT2020	2/2	2	Yes		NA	R (15OCT2020)	N/N
	INV	Body temperature increased/ elevated body temperature (37.7 C)	1	14OCT2020	2/2	2	Yes		NA/TC	R (15OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	14OCT2020	2/2	2	Yes		NA	R (15OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	03NOV2020	1/2	1	Yes		NA	R (04NOV2020)	N/N
	GENRL	Chills/ Chills	2	04NOV2020	2/1	1	Yes		NA	R (04NOV2020)	N/N
	NERV	Headache/ Headache	2	04NOV2020	2/1	1	Yes		NA/TC	R (04NOV2020)	N/N
16-55/ C4591001 1226 12262144	GENRL	Injection site pain/ pain at the injection site#	3	16FEB2021	2/2	2	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ headache#	3	16FEB2021	2/2	2	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1226 12262146	MUSC	Arthralgia/ joint pain	1	16OCT2020	4/7	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262149	GENRL	Fatigue/ Fatigue#	3	13FEB2021	1/2	2	Yes		NA	R (14FEB2021)	N/N
		Injection site pain/ Pain at injection site#	3	13FEB2021	1/2	2	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1226 12262151	GENRL	Injection site pain/ Pain at the injection site	1	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Chills/ Chills	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
		Injection site pain/ Pain at the injection site	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
	NERV	Headache/ Headache	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1226 12262153	MUSC	Myalgia/ Muscle pain	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
	NERV	Headache/ Headache	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1226 12262157	GENRL	Injection site pain/ pain at the injection site#	3	14FEB2021	2/3	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1226 12262159	GENRL	Injection site pain/ Pain at injection site	1	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262162	GENRL	Injection site pain/ Pain at injection site	2	05NOV2020	1/2	1	Yes		NA/TC	R (06NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1226 12262163	GENRL	Injection site pain/ Pain at the injection site	1	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
	NERV	Headache/ Headache	1	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	06NOV2020	2/2	1	Yes		NA/TC	R (07NOV2020)	N/N
	NERV	Headache/ Headache	2	06NOV2020	2/2	1	Yes		NA/TC	R (07NOV2020)	N/N
16-55/ C4591001 1226 12262164	MUSC	Myalgia/ Myalgia	2	03NOV2020	1/2	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C4591001 1226 12262165	GENRL	Injection site pain/ pain at the injection site#	3	23FEB2021	1/3	1	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1226 12262169	GENRL	Malaise/ Malaise#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	14OCT2020	2/2	2	Yes		NA	R (15OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262170	GASTR	Nausea/ Nausea	2	04NOV2020	2/1	2	Yes		NA	R (04NOV2020)	N/N
	GENRL	Chills/ Chills	2	04NOV2020	2/1	2	Yes		NA	R (04NOV2020)	N/N
		Fatigue/ Fatigue	2	04NOV2020	2/1	2	Yes		NA	R (04NOV2020)	N/N
		Injection site pain/ Pain at injection site	2	04NOV2020	2/1	2	Yes		NA	R (04NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	04NOV2020	2/1	2	Yes		NA	R (04NOV2020)	N/N
	NERV	Headache/ Headache	2	04NOV2020	2/1	2	Yes		NA/TC	R (04NOV2020)	N/N
16-55/ C4591001 1226 12262182	EYE	Vitreous detachment/ Vitreous detachment	2	10JAN2021	68/16	2	No	O	NA/TC	R (25JAN2021)	N/N
16-55/ C4591001 1226 12262183	GENRL	Injection site pain/ pain at the injection site#	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1226 12262184	GENRL	Injection site pain/ Pain at injection site	1	14OCT2020	1/4	2	Yes		NA/TC	R (17OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	05NOV2020	1/1	1	Yes		NA	R (05NOV2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	14OCT2020	1/3	2	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12262185	GENRL	Injection site pain/ Pain at injection site	2	04NOV2020	1/2	1	Yes		NA	R (05NOV2020)	N/N	
16-55/ C4591001 1226 12262186	GENRL	Injection site pain/ Pain at injection site	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N	
16-55/ C4591001 1226 12262187	GENRL	Injection site pain/ Pain at the injection site	2	04NOV2020	1/1	1	Yes		NA	R (04NOV2020)	N/N	
16-55/ C4591001 1226 12262188	NERV	Syncope/ Lipothymia(Syncope)	2	02DEC2020	29/1	1	No	O	NA	R (02DEC2020)	N/N	
16-55/ C4591001 1226 12262189	GENRL	Injection site pain/ pain at the injection site#	3	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N	
16-55/ C4591001 1226 12262190	GENRL	Injection site pain/ Pain at injection site#	3	28JAN2021	1/2	2	Yes		NA/TC	R (29JAN2021)	N/N	
1226 12262191	GENRL	Fatigue/ fatigue#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N	
1226 12262192	GENRL	Pyrexia/ fever (38C)#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N	
1226 12262193	MUSC	Myalgia/ muscle pain#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N	
1226 12262194	NERV	Headache/ headache#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262195	GENRL	Fatigue/ Fatigue	2	05NOV2020	1/2	2	Yes		NA/TC	R (06NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	05NOV2020	1/2	2	Yes		NA/TC	R (06NOV2020)	N/N
	NERV	Headache/ Headache	2	05NOV2020	1/2	2	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1226 12262196	GASTR	Toothache/ Toothache	2	18JAN2021	76/7	1	No	O	NA/TC	R (24JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	22FEB2021	1/4	1	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1226 12262198	GENRL	Chills/ chills	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
		Injection site pain/ pain at injection site	1	15OCT2020	1/5	1	Yes		NA	R (19OCT2020)	N/N
	NERV	Somnolence/ somnolence	1	15OCT2020	1/2	2	Yes		NA	R (16OCT2020)	N/N
	GENRL	Chills/ chills	2	04NOV2020	1/2	1	Yes		NA	R (05NOV2020)	N/N
		Injection site pain/ pain at injection site	2	04NOV2020	1/4	1	Yes		NA	R (07NOV2020)	N/N
		Pyrexia/ fever (38 C)	2	04NOV2020	1/2	1	Yes		NA/TC	R (05NOV2020)	N/N
	NERV	Somnolence/ somnolence	2	04NOV2020	1/4	2	Yes		NA	R (07NOV2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262199	GENRL	Fatigue/ Fatigue#	3	13FEB2021	1/4	1	Yes		NA/TC	R (16FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	3	13FEB2021	1/4	1	Yes		NA/TC	R (16FEB2021)	N/N
16-55/ C4591001 1226 12262201	GENRL	Chills/ chills	2	04NOV2020	1/2	2	Yes		NA/TC	R (05NOV2020)	N/N
		Injection site pain/ pain at injection site	2	04NOV2020	1/2	2	Yes		NA/TC	R (05NOV2020)	N/N
	MUSC	Myalgia/ muscle pain	2	04NOV2020	1/2	2	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1226 12262205	GENRL	Injection site pain/ Pain at the injection site	2	04NOV2020	1/2	1	Yes		NA	R (05NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	04NOV2020	1/2	1	Yes		NA	R (05NOV2020)	N/N
16-55/ C4591001 1226 12262206	GENRL	Asthenia/ Asthenia	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
		Injection site pain/ Pain at the injection site	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1226 12262208	NERV	Headache/ Headache	2	06NOV2020	2/1	1	Yes		NA/TC	R (06NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Pain at the injection site#	3	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1226 12262209	GENRL	Pyrexia/ Fever 38.2 C	2	05NOV2020	2/1	1	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1226 12262211	GENRL	Injection site pain/ Pain at injection site	1	15OCT2020	1/1	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N
		Pain/ Body pain#	3	19FEB2021	1/3	2	Yes		NA/TC	R (21FEB2021)	N/N
		Pyrexia/ Fever 38 C#	3	19FEB2021	1/3	2	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1226 12262212	MUSC	Myalgia/ muscle pain	1	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	06NOV2020	2/1	1	Yes		NA/TC	R (06NOV2020)	N/N
	NERV	Headache/ Headache	2	06NOV2020	2/1	2	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1226 12262216	GENRL	Injection site pain/ Pain at the injection site#	3	13FEB2021	1/2	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site#	3	14FEB2021	2/2	1	Yes		NA	R (15FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262218 16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site	1	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N
1226 12262219	GENRL	Injection site pain/ pain at injection site	2	05NOV2020	1/2	1	Yes		NA/TC	R (06NOV2020)	N/N
	GENRL	Asthenia/ weakness	2	06NOV2020	2/1	1	Yes		NA/TC	R (06NOV2020)	N/N
	NERV	Headache/ headache	2	06NOV2020	2/1	1	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site	1	15OCT2020	1/5	2	Yes		NA	R (19OCT2020)	N/N
1226 12262220	NERV	Headache/ Headache	1	15OCT2020	1/5	2	Yes		NA	R (19OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
1226 12262221	MUSC	Myalgia/ Muscle pain (lower limbs)#	3	29JAN2021	3/6	2	Yes		NA/TC	R (03FEB2021)	N/N
	GENRL	Chills/ chills#	4	16FEB2021	2/1	3	Yes		NA/TC	R (16FEB2021)	N/N
		Pyrexia/ fever (38.5C)#	4	16FEB2021	2/1	2	Yes		NA/TC	R (16FEB2021)	N/N
16-55/ C4591001	NERV	Headache/ headache	1	16OCT2020	1/2	1	Yes		NA/TC	R (17OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine Subject	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262223	GENRL	Injection site pain/ Pain at injection site#	3	25JAN2021	1/3	2	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	17FEB2021	1/2	2	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	4	18FEB2021	2/1	2	Yes		NA/TC	R (18FEB2021)	N/N
		Fatigue/ Fatigue#	4	18FEB2021	2/1	2	Yes		NA/TC	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/1	2	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1226 12262225	GENRL	Injection site pain/ Pain at injection site	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Malaise/ Malaise	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1226 12262226	RESP	Oropharyngeal discomfort/ Throat discomfort	2	21DEC2020	45/1	1	No	O	NA	R (21DEC2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1226 12262227	GENRL	Injection site pain/ pain at the injection site#	3	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001	NERV	Headache/ Headache	1	16OCT2020	1/2	2	Yes		NA/TC	R (17OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262228	GENRL	Injection site pain/ Pain at injection site	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N
	NERV	Headache/ Headache	2	05NOV2020	1/1	2	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1226 12262230	SKIN	Pruritic Cutaneous Lesion (in the central region of the right arm next to the elbow)	2	28NOV2020	25/25	1	No	O	NA	R (22DEC2020)	N/N
16-55/ C4591001 1226 12262231	GASTR	Nausea/ Nausea	2	05NOV2020	2/1	1	Yes		NA	R (05NOV2020)	N/N
	NERV	Headache/ Headache	2	05NOV2020	2/1	1	Yes		NA	R (05NOV2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1226 12262232	GENRL	Pain/ Body pain	2	05NOV2020	2/3	1	Yes		NA/TC	R (07NOV2020)	N/N
	NERV	Headache/ Headache	2	05NOV2020	2/3	1	Yes		NA/TC	R (07NOV2020)	N/N
16-55/ C4591001 1226 12262233	GENRL	Injection site pain/ pain at the injection site#	3	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	2	06NOV2020	3/1	1	Yes		NA	R (06NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12262234	NERV	Headache/ Headache	2	06NOV2020	3/1	1	Yes		NA	R (06NOV2020)	N/N	
16-55/ C4591001 1226 12262236	GENRL	Injection site pain/ Pain at the injection site	1	16OCT2020	1/2	2	Yes		NA	R (17OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N	
		Injection site pain/ Pain at injection site	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N	
16-55/ C4591001 1226 12262237	GENRL	Injection site pain/ Pain at the injection site	1	16OCT2020	1/2	2	Yes		NA	R (17OCT2020)	N/N	
	GENRL	Chills/ Chills	2	05NOV2020	1/2	2	Yes		NA	R (06NOV2020)	N/N	
		Fatigue/ Fatigue	2	05NOV2020	1/2	2	Yes		NA	R (06NOV2020)	N/N	
		Injection site pain/ Pain at the injection site	2	05NOV2020	1/2	2	Yes		NA/TC	R (06NOV2020)	N/N	
16-55/ C4591001 1226 12262239	GENRL	Injection site pain/ Pain at the injection site	1	16OCT2020	1/2	2	Yes		NA	R (17OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N	
		Injection site pain/ Pain at the injection site	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262241	GENRL	Injection site pain/ pain at the injection site#	3	18FEB2021	1/4	1	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1226 12262242	GENRL	Injection site pain/ Pain at the injection site#	3	04FEB2021	1/4	2	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1226 12262243	GENRL	Injection site pain/ pain at injection site	1	16OCT2020	1/2	2	Yes		NA/TC	R (17OCT2020)	N/N
	MUSC	Pain in extremity/ Pain in the arm	2	05NOV2020	1/2	2	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1226 12262245	GENRL	Fatigue/ Fatigue	1	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 1226 12262247	GENRL	Pyrexia/ fever (39 C)#	3	23FEB2021	2/2	2	Yes		NA/TC	R (24FEB2021)	N/N
	NERV	Headache/ headache#	3	23FEB2021	2/2	2	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1226 12262249	GENRL	Malaise/ Malaise#	3	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262251	GENRL	Chills/ Chills	2	06NOV2020	1/2	2	Yes		NA/TC	R (07NOV2020)	N/N
		Pyrexia/ Fever	2	06NOV2020	1/2	2	Yes		NA/TC	R (07NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	06NOV2020	1/2	2	Yes		NA/TC	R (07NOV2020)	N/N
16-55/ C4591001 1226 12262252	GENRL	Injection site pain/ pain at the injection site#	3	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1226 12262255†	MUSC	Myalgia/ muscle pain	1	19OCT2020	4/4	2	Yes		NA/TC	R (22OCT2020)	N/N
	GASTR	Nausea/ Nauseas	2	06NOV2020	1/3	3	Yes		NA	R (08NOV2020)	N/N
		Vomiting/ Vomiting	2	06NOV2020	1/3	3	Yes		NA/TC	R (08NOV2020)	N/N
	GENRL	Chills/ Chills	2	06NOV2020	1/3	3	Yes		NA	R (08NOV2020)	N/N
		Injection site pain/ Pain at the injection site	2	06NOV2020	1/3	3	Yes		NA	R (08NOV2020)	N/N
		Pyrexia/ Fever 39 C	2	06NOV2020	1/3	3	Yes		NA/TC	R (08NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	06NOV2020	1/3	3	Yes		NA/TC	R (08NOV2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	31JAN2021	2/2	1	Yes		NA	R (01FEB2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262256		Injection site pain/ Pain at the injection site#	3	31JAN2021	2/2	1	Yes		NA	R (01FEB2021)	N/N
16-55/ C4591001 1226 12262258	GENRL	Injection site pain/ Pain at injection site	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1226 12262259	MUSC	Myalgia/ diffuse myalgia#	3	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1226 12262263	GENRL	Chills/ Chills	1	17OCT2020	1/2	2	Yes		NA	R (18OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	17OCT2020	1/2	2	Yes		NA	R (18OCT2020)	N/N
	GENRL	Chills/ Chills	2	07NOV2020	1/2	1	Yes		NA	R (08NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	07NOV2020	1/2	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C4591001 1226 12262267	GENRL	Injection site pain/ pain at the injection site#	3	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
16-55/ C4591001	NERV	Headache/ headache#	3	22FEB2021	3/2	1	Yes		NA/TC	R (23FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262269 16-55/ C4591001 1226 12262270	GENRL	Injection site pain/ Pain at the injection site	1	17OCT2020	1/3	2	Yes		NA/TC	R (19OCT2020)	N/N
		Pyrexia/ Fever 38 C	1	17OCT2020	1/3	2	Yes		NA/TC	R (19OCT2020)	N/N
	GENRL	Pyrexia/ Fever 39 C	2	12NOV2020	2/1	2	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1226 12262272	BLOOD	Lymphadenopathy/ left axillary lymph node enlargement#	3	24JAN2021	2/4	1	Yes		NA/TC	R (27JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	3	24JAN2021	2/4	1	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	21FEB2021	2/1	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1226 12262273	GENRL	Injection site pain/ Pain at injection site	1	17OCT2020	1/3	2	Yes		NA/TC	R (19OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	17OCT2020	1/3	2	Yes		NA/TC	R (19OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1226 12262274	INFEC	Upper respiratory tract infection/ Upper airway infection	2	20DEC2020	45/53	1	No	O	NA/TC	R (10FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262276	GENRL	Injection site pain/ pain at the injection site#	3	19FEB2021	1/3	2	Yes		NA	R (21FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	07NOV2020	2/1	1	Yes		NA/TC	R (07NOV2020)	N/N
	NERV	Headache/ Headache	2	07NOV2020	2/1	1	Yes		NA/TC	R (07NOV2020)	N/N
	INV	Body temperature increased/ Body Increased Temperature (37 C)	2	04FEB2021	91/1	1	No	O	NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	25JAN2021	1/4	1	Yes		NA/TC	R (28JAN2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N
	GENRL	Chills/ Chills#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1226 12262279	GENRL	Injection site pain/ Pain at the injection site#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	17FEB2021	2/1	2	Yes		NA	R (17FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12262284	MUSC	Myalgia/ Muscle pain#	4	17FEB2021	2/1	2	Yes		NA	R (17FEB2021)	N/N	
	NERV	Headache/ Headache#	4	17FEB2021	2/1	2	Yes		NA	R (17FEB2021)	N/N	
	GENRL	Asthenia/ Asthenia	2	05NOV2020	1/2	1	Yes		NA/TC	R (06NOV2020)	N/N	
			Chills/ Chills	2	05NOV2020	1/3	1	Yes		NA/TC	R (07NOV2020)	N/N
			Pyrexia/ Fever (38 C)	2	05NOV2020	1/3	1	Yes		NA/TC	R (07NOV2020)	N/N
	INV	Body temperature increased/ Increased body temperature 37.8 C	2	05NOV2020	1/2	1	Yes		NA/TC	R (06NOV2020)	N/N	
	16-55/ C4591001 1226 12262286	GASTR	Diarrhoea/ Diarrhea	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N	
			Injection site pain/ Pain at the injection site	1	17OCT2020	1/2	1	Yes		NA/TC	R (18OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	05NOV2020	1/3	2	Yes		NA/TC	R (07NOV2020)	N/N	
NERV	Headache/ Headache	2	05NOV2020	1/3	2	Yes		NA/TC	R (07NOV2020)	N/N		
16-55/ C4591001 1226 12262287	GENRL	Chills/ chills#	3	20FEB2021	1/1	2	Yes		NA	R (20FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262289	NERV	Headache/ headache#	3	20FEB2021	1/3	2	Yes		NA/TC	R (22FEB2021)	N/N
	GASTR	Vomiting/ vomit#	3	22FEB2021	3/1	2	Yes		NA	R (22FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	20FEB2021	1/3	1	Yes		NA/TC	R (22FEB2021)	N/N
	NERV	Headache/ headache#	3	20FEB2021	1/3	1	Yes		NA/TC	R (22FEB2021)	N/N
	GENRL	Injection site oedema/ edema at injection site	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
	NERV	Injection site pain/ pain at injection site	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
	NERV	Tension headache/ intermittent tension headache	1	05NOV2020	20/2	1	Yes		NA/TC	R (06NOV2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1226 12262292	NERV	Headache/ Headache	1	17OCT2020	1/2	1	Yes		NA/TC	R (18OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	19OCT2020	3/3	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1226 12262293	INV	Body temperature increased/ Increased body temperature (37.2 C)	2	23NOV2020	18/1	1	No	O	NA	R (23NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Nausea/ Nausea	2	29NOV2020	24/1	1	No	O	NA/TC	R (29NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	20FEB2021	1/2	2	Yes		NA/TC	R (21FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	3	20FEB2021	1/2	2	Yes		NA/TC	R (21FEB2021)	N/N
	GENRL	Chills/ Chills#	3	21FEB2021	2/1	2	Yes		NA/TC	R (21FEB2021)	N/N
		Pyrexia/ Fever 39 C#	3	21FEB2021	2/1	3	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1226 12262295	GENRL	Injection site pain/ Pain at the injection site	1	17OCT2020	1/2	2	Yes		NA	R (18OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	06NOV2020	2/1	2	Yes		NA/TC	R (06NOV2020)	N/N
		Pyrexia/ Fever 38.3 C	2	06NOV2020	2/1	1	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1226 12262297	GENRL	Fatigue/ Fatigue	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N
		Injection site pain/ Pain at the injection site	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N
	NERV	Headache/ Headache	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1226 12262298	GENRL	Injection site pain/ pain at the injection site#	3	21FEB2021	2/2	1	Yes		NA	R (22FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262299	GASTR	Nausea/ Nauseas	1	18OCT2020	2/3	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	18OCT2020	2/3	1	Yes		NA/TC	R (20OCT2020)	N/N
	NERV	Headache/ Headache	1	18OCT2020	2/3	1	Yes		NA/TC	R (20OCT2020)	N/N
	GENRL	Pyrexia/ Fever 38 C	2	11NOV2020	1/5	2	Yes		NA/TC	R (15NOV2020)	N/N
	NERV	Headache/ Headache	2	11NOV2020	1/5	2	Yes		NA/TC	R (15NOV2020)	N/N
16-55/ C4591001 1226 12262301	GENRL	Injection site pain/ pain at the injection site#	3	20FEB2021	1/4	2	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1226 12262303	GENRL	Pyrexia/ fever#	3	20FEB2021	1/2	2	Yes		NA/TC	R (21FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	3	20FEB2021	1/2	2	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1226 12262304	GENRL	Injection site pain/ Pain at the injection site	1	18OCT2020	2/2	1	Yes		NA	R (19OCT2020)	N/N
	GENRL	Chills/ Chills	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N
		Injection site pain/ Pain at the injection site	2	05NOV2020	1/3	1	Yes		NA/TC	R (07NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262307	GENRL	Injection site pain/ Pain at the injection site	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1226 12262309	GENRL	Injection site pain/ pain at the injection site#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
		Pyrexia/ fever#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1226 12262311	GENRL	Injection site pain/ Pain at the injection site#	3	23FEB2021	1/4	2	Yes		NA	R (26FEB2021)	N/N
	GENRL	Chills/ Chills#	3	26FEB2021	4/1	1	Yes		NA	R (26FEB2021)	N/N
		Pain/ Body pain#	3	26FEB2021	4/1	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1226 12262314	GENRL	Injection site pain/ pain at the injection site#	3	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1226 12262315	GENRL	Injection site pain/ Pain at injection site	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
	NERV	Headache/ Headache	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262316	GENRL	Fatigue/ Fatigue#	3	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1226 12262317	GENRL	Injection site pain/ Pain at the injection site	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1226 12262318	GENRL	Fatigue/ Fatigue#	3	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
	GENRL	Pyrexia/ Fever 38.7 C#	3	23FEB2021	2/2	2	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1226 12262319	GENRL	Chills/ Chills	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
		Injection site pain/ Pain at injection site	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
	NERV	Headache/ Headache	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1226 12262320	GENRL	Injection site pain/ Pain at injection site#	3	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262321	GENRL	Chills/ Chills	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	11NOV2020	1/3	2	Yes		NA/TC	R (13NOV2020)	N/N
		Pyrexia/ Fever (38.6C)	2	11NOV2020	1/3	2	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1226 12262327	MUSC	Myalgia/ Muscle pain	2	11NOV2020	1/3	2	Yes		NA/TC	R (13NOV2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
		Malaise/ Unspecified malaise	1	19OCT2020	1/3	2	Yes		NA	R (21OCT2020)	N/N
		Pyrexia/ Fever 38 C	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	07NOV2020	1/4	2	Yes		NA/TC	R (10NOV2020)	N/N
		Pain/ Body pain	2	07NOV2020	1/4	2	Yes		NA/TC	R (10NOV2020)	N/N
16-55/ C4591001 1226 12262329	NERV	Headache/ Headache	2	07NOV2020	1/7	2	Yes		NA/TC	R (13NOV2020)	N/N
	MUSC	Arthralgia/ Arthralgia (knees and ankles)	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262330	GENRL	Injection site pain/ Pain at the injection site#	3	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N
	NERV	Somnolence/ Somnolence	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1226 12262331	MUSC	Myalgia/ Myalgia#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Chills/ Chills	1	19OCT2020	1/2	2	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C4591001 1226 12262334		Injection site pain/ Pain at the injection site	1	19OCT2020	1/2	2	Yes		NA/TC	R (20OCT2020)	N/N
	GENRL	Chills/ Chills	2	08NOV2020	2/1	2	Yes		NA	R (08NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 1226 12262335	NERV	Headache/ Headache	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Pain/ Body pain	2	12NOV2020	2/2	1	Yes		NA/TC	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	12NOV2020	2/2	1	Yes		NA/TC	R (13NOV2020)	N/N
	GENRL	Pain/ body aches	1	20OCT2020	2/4	1	Yes		NA/TC	R (23OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262337	GENRL	Injection site pain/ Pain at the injection site#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Asthenia/ Asthenia#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	19FEB2021	2/3	1	Yes		NA/TC	R (21FEB2021)	N/N
		Pyrexia/ Fever#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1226 12262338	GENRL	Pain/ body aches	1	21OCT2020	3/1	1	Yes		NA/TC	R (21OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	07NOV2020	1/2	1	Yes		NA	R (08NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	07NOV2020	1/2	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C4591001 1226 12262340	GASTR	Diarrhoea/ Diarrhea	1	19OCT2020	1/1	1	Yes		NA	R (19OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	08NOV2020	2/2	1	Yes		NA	R (09NOV2020)	N/N
16-55/ C4591001 1226 12262341	GENRL	Fatigue/ Fatigue#	3	19FEB2021	1/6	1	Yes		NA/TC	R (24FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12262346	GENRL	Injection site pain/ Pain at injection site#	3	19FEB2021	1/6	1	Yes		NA/TC	R (24FEB2021)	N/N	
		Pyrexia/ Fever (38.5 C)#	3	19FEB2021	1/2	1	Yes		NA/TC	R (20FEB2021)	N/N	
		Injection site pain/ pain at the injection site#	3	22FEB2021	1/4	1	Yes		NA	R (25FEB2021)	N/Y	
16-55/ C4591001 1226 12262347	GENRL	Fatigue/ Fatigue	1	19OCT2020	1/3	1	Yes		NA/TC	R (21OCT2020)	N/N	
16-55/ C4591001 1226 12262348	GENRL	Injection site pain/ Pain at injection site	1	19OCT2020	1/3	1	Yes		NA/TC	R (21OCT2020)	N/N	
		Pyrexia/ Fever 38.3 C	1	23OCT2020	5/3	1	Yes		NA	R (25OCT2020)	N/N	
16-55/ C4591001 1226 12262350	NERV	Headache/ Headache#	3	29JAN2021	5/3	1	Yes		NA/TC	R (31JAN2021)	N/N	
	GENRL	Injection site pain/ Pain at the injection site	2	11NOV2020	1/3	1	Yes		NA/TC	R (13NOV2020)	N/N	
16-55/ C4591001 1226 12262351	MUSC	Myalgia/ Muscle pain	2	11NOV2020	1/3	1	Yes		NA/TC	R (13NOV2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12262353	GENRL	Asthenia/ Asthenia	1	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N	
	GENRL	Injection site pain/ pain at the injection site#	3	20FEB2021	1/2	2	Yes		NA	R (21FEB2021)	N/N	
16-55/ C4591001 1226 12262354	NERV	Dizziness/ dizziness#	3	20FEB2021	1/1	2	Yes		NA	R (20FEB2021)	N/N	
	GENRL	Injection site pain/ pain at the injection site#	3	20FEB2021	1/3	2	Yes		NA	R (22FEB2021)	N/N	
16-55/ C4591001 1226 12262356	GENRL	Injection site pain/ Pain at injection site	2	19NOV2020	1/2	1	Yes		NA	R (20NOV2020)	N/N	
	NERV	Syncope/ Vasovagal syncope	2	01DEC2020	13/1	2	No	O	NA/TCN	R (01DEC2020)	N/N	
16-55/ C4591001 1226 12262357	GENRL	Injection site pain/ Pain at the injection site	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	11NOV2020	1/4	2	Yes		NA/TC	R (14NOV2020)	N/N	
16-55/ C4591001 1229 12291012		Pyrexia/ Fever 39 C	2	11NOV2020	1/4	2	Yes		NA/TC	R (14NOV2020)	N/N	
	MUSC	Myalgia/ localised non specific myalgia	2	19OCT2020	5/9	1	No	CND	NA	R (27OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1229 12291016	NERV	Hemiplegia/ Left Sided Hemiplegia#	4	10MAR2021	10/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1229 12291031	NERV	Headache/ Headache	1	28SEP2020	1/1	1	No	O	NA	R (28SEP2020)	N/N	
16-55/ C4591001 1229 12291033	NERV	Headache/ Headache	2	03NOV2020	15/17	1	No	O	NA/TC	R (19NOV2020)	N/N	
16-55/ C4591001 1229 12291037	MUSC	Pain in extremity/ Mechanical Pain on left arm	2	25NOV2020	37/12	1	No	O	NA/TC	R (06DEC2020)	N/N	
16-55/ C4591001 1229 12291059	INFEC	Gingivitis/ Gingivitis	2	25OCT2020	5/5	1	No	O	NA/TC	R (29OCT2020)	N/N	
16-55/ C4591001 1229 12291061	GENRL	Injection site injury/ Soft tissue injury on left shoulder(injection site)	2	21OCT2020	1/8	1	Yes		NA/TC	R (28OCT2020)	N/N	
16-55/ C4591001 1229 12291062	INFEC	Urinary tract infection/ Urinary tract infection	2	22OCT2020	2/4	1	No	O	NA/TC	R (25OCT2020)	N/N	
16-55/ C4591001 1229 12291063†	MUSC	Back pain/ Lower back pain	2	19NOV2020	30/8	1	No	O	NA/TC	R (26NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1229 12291064	VASC	Hypertension/ hypertension	1	09OCT2020	10/C	1	No	O	NA/TC	N	N/N	
	NERV	Burning sensation/ Sensation of burning feet	1	11OCT2020	12/20	1	No	O	NA	R (30OCT2020)	N/N	
16-55/ C4591001 1229 12291066	MUSC	Back pain/ Lower backache	2	01NOV2020	12/22	1	No	O	NA/TC	R (22NOV2020)	N/N	
16-55/ C4591001 1229 12291083†	METAB	Diabetes mellitus/ Diabetes Mellitus	2	28DEC2020	68/C	4	No	O	NA	N	Y/N	
	INFEC	COVID-19 pneumonia/ Covid 19 Pneumonia	2	01JAN2021	72/5	4	No	O	NA/W	F (05JAN2021)	Y/N	
16-55/ C4591001 1229 12291096†	GASTR	Gastroesophageal reflux disease/ Reflux Oesophagitis	2	29OCT2020	7/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1229 12291104	GENRL	Peripheral swelling/ Painful Swelling Feet	1	12OCT2020	8/30	1	No	O	NA	R (10NOV2020)	N/N	
16-55/ C4591001 1229 12291119	SKIN	Dermatitis allergic/ allergic dermatitis on left hand	2	06NOV2020	11/C	1	No	CND	NA/TC/TCN	N	N/N	
16-55/ C4591001	PSYCH	Insomnia/ Insomnia	1	14OCT2020	8/19	1	No	O	NA	R (01NOV2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1229 12291130†	INFEC	Folliculitis/ Folliculitis on head.	2	23NOV2020	27/17	1	No	O	NA/TC	R (09DEC2020)	N/N
16-55/ C4591001 1229 12291135†	SKIN	Urticaria/ Urticaria	2	20NOV2020	24/13	1	No	O	NA/TC	R (02DEC2020)	N/N
16-55/ C4591001 1229 12291141	NERV	Headache/ HEADACHE	2	17NOV2020	21/3	2	No	O	NA/TC	R (19NOV2020)	N/N
16-55/ C4591001 1229 12291181†	NERV	Dizziness/ Dizziness	1	27OCT2020	16/3	1	No	O	NA	R (29OCT2020)	N/N
16-55/ C4591001 1229 12291188	SKIN	Eczema/ Eczema-Neck	2	18NOV2020	17/25	1	No	O	NA/TC	R (12DEC2020)	N/N
16-55/ C4591001 1229 12291190	GENRL	Injection site reaction/ Left arm stiffness on injection side.	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1229 12291209	NERV	Migraine/ Worsening Migraine	1	14OCT2020	1/5	1	Yes		NA	R (18OCT2020)	N/Y
16-55/ C4591001	GASTR	Dyspepsia/ Heartburn	1	02NOV2020	20/7	1	No	O	NA/TC	R (08NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1229 12291215†	GASTR	Gastritis/ Gastritis	2	15NOV2020	12/41	1	No	O	NA/TC	R (25DEC2020)	N/N
1229 12291216	SKIN	Erythema/ Erythema medial aspect on Humerus Left upper extremity (not by injection site)	1	23SEP2020	1/7	2	Yes		NA/TC	R (29SEP2020)	N/N
1230 12301001	INJ&P	Ankle fracture/ Broken Ankle	1	12OCT2020	20/22	1	No	O	NA/TC/TCN	R (02NOV2020)	N/N
1230 12301011	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	1	20OCT2020	22/C		No	O	P	UNK	N/N
1230 12301045†	MUSC	Myalgia/ New onset of muscle pain.#	3	08FEB2021	1/3	2	Yes		NA	R (10FEB2021)	N/Y
1230 12301047	MUSC	Myalgia/ New onset of muscle pain.#	3	29JAN2021	2/4	3	Yes		NA/TC	R (01FEB2021)	N/N
1230 12301057	GENRL	Injection site pain/ Pain at injection site.#	3	07FEB2021	11/14	2	Yes		NA	R (20FEB2021)	N/N
	GENRL	Peripheral swelling/ Swelling left upper arm.#	4	17FEB2021	2/4	2	Yes		NA	R (20FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1230 12301060 16-55/ C4591001 1230 12301077 16-55/ C4591001 1230 12301114 16-55/ C4591001 1230 12301129 16-55/ C4591001 1230 12301134 16-55/ C4591001	MUSC	Myalgia/ New onset of muscle pain.#	4	17FEB2021	2/4	2	Yes		NA	R (20FEB2021)	N/N
	MUSC	Arthralgia/ New onset of joint pain left upper wrist#	4	19FEB2021	4/15	3	Yes		NA/TC	R (05MAR2021)	N/N
	NERV	Headache/ Headache#	3	11FEB2021	1/2	2	Yes		NA	R (12FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain in left arm.#	3	17FEB2021	1/2	2	Yes		NA	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	3	18FEB2021	2/1	2	Yes		NA	R (18FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain in upper arms and legs.#	3	18FEB2021	2/1	2	Yes		NA	R (18FEB2021)	N/N
	GENRL	Fatigue/ Moderate Fatigue	1	08OCT2020	4/2	2	Yes		NA/TC	R (09OCT2020)	N/N
	NERV	Headache/ Severe Headache	1	08OCT2020	4/2	3	Yes		NA/TC	R (09OCT2020)	N/N
	INJ&P	Thermal burn/ Burn Wound on Left forearm	1	23OCT2020	19/C	2	No	O	NA/TCN	RG	N/N
	METAB	Hyperlipidaemia/ Hyper Lipidemia	2	22DEC2020	57/C	1	No	CND	NA/TC	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1230 12301147 16-55/ C4591001	MUSC	Myalgia/ Muscle pain in left upper arm#	3	16FEB2021	1/2	2	Yes		NA	R (17FEB2021)	N/N	
1230 12301181 16-55/ C4591001	RESP	Bronchospasm/ BRONCHOSPASM	2	13JAN2021	76/2	1	No	O	NA/TC	R (14JAN2021)	N/N	
1230 12301211 16-55/ C4591001	MUSC	Myalgia/ Generalized Muscle Pain	2	31OCT2020	2/3	3	Yes		NA/TC	R (02NOV2020)	N/N	
1230 12301214 16-55/ C4591001	SKIN	Rash/ abdomen skin rash	2	17SEP2020	22/4	1	No	O	NA	R (20SEP2020)	N/N	
1231 12311001		Rash/ back skin rash	2	17SEP2020	22/4	1	No	O	NA	R (20SEP2020)	N/N	
		Rash/ both arms skin rash	2	17SEP2020	22/4	1	No	O	NA	R (20SEP2020)	N/N	
16-55/ C4591001 1231 12311003	MUSC	Back pain/ mild low back pain	2	18SEP2020	23/14	1	No	O	NA/TC	R (01OCT2020)	N/N	
	INFEC	Tooth infection/ Odontogenic infection#	3	25FEB2021	6/C	1	No	O	NA/TCN	N	N/N	
16-55/ C4591001	NERV	Headache/ Headache	2	19SEP2020	24/1	1	No	O	NA	R (19SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12311008 16-55/ C4591001	NERV	Sciatica/ chronic lumbociatalgia exacerbated	1	25AUG2020	16/12	2	No	O	NA/TC	R (05SEP2020)	N/N	
1231 12311027	INFEC	Soft tissue infection/ Right elbow soft tissue infection	1	03SEP2020	25/12	1	No	O	NA/TC	R (14SEP2020)	N/N	
	MUSC	Myalgia/ MUSCLE PAIN IN BOTH UPPER LIMBS	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N	
16-55/ C4591001	INFEC	Tooth infection/ Upper molar infection	2	09SEP2020	8/8	1	No	O	NA/TC	R (16SEP2020)	N/N	
1231 12311036 16-55/ C4591001	PSYCH	Anxiety disorder/ Anxiety Disorder	2	26SEP2020	26/1	2	No	O	NA	R (26SEP2020)	N/N	
1231 12311043	INJ&P	Heat stroke/ insolation	2	01NOV2020	62/2	1	No	O	NA/TC	R (02NOV2020)	N/N	
16-55/ C4591001	VASC	Hypertension/ high blood pressure	2	24SEP2020	24/1	1	No	O	NA/TC	R (24SEP2020)	N/N	
1231 12311051 16-55/ C4591001	INFEC	Tooth infection/ odontogenic infection	2	03SEP2020	3/29	2	No	O	NA/TCN	R (01OCT2020)	N/N	
1231 12311052	MUSC	Back pain/ low back pain	2	24OCT2020	54/7	1	No	O	NA	R (30OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311058	EAR	Deafness unilateral/ hearing loss in the left ear	2	27SEP2020	27/12	1	No	O	NA	R (08OCT2020)	N/N	
16-55/ C4591001 1231 12311065	MUSC	Myalgia/ Myalgia	2	20OCT2020	50/2	1	No	O	NA/TC	R (21OCT2020)	N/N	
16-55/ C4591001 1231 12311072	MUSC	Back pain/ Low back pain#	3	26JAN2021	2/1	1	No	O	NA	R (26JAN2021)	N/N	
	REPRO	Metrorrhagia/ metrorrhagia#	3	30JAN2021	6/3	1	No	O	NA	R (01FEB2021)	N/N	
16-55/ C4591001 1231 12311074	EAR	Tinnitus/ exacerbation of bilateral tinnitus.	1	30AUG2020	19/31	2	No	O	NA/TC	R (29SEP2020)	N/N	
16-55/ C4591001 1231 12311077	INJ&P	Tooth fracture/ BROKEN SECOND MOLAR	2	28SEP2020	28/1	1	No	O	NA/TC	R (28SEP2020)	N/N	
	SURG	Dental care/ DENTAL TREATMENT	2	28SEP2020	28/1	1	No	O	NA/TC/TCN	R (28SEP2020)	N/N	
16-55/ C4591001 1231 12311081	INFEC	Arthritis bacterial/ septic arthritis of the right knee.	2	13DEC2020	104/C	3	No	O	NA/TC/TCN	RG	Y/N	
16-55/ C4591001	MUSC	Tenosynovitis stenosaurs/ De Quervain's tenosynovitis	1	17AUG2020	6/64	2	No	O	NA/TC/TCN	R (19OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12311085 16-55/ C4591001	EYE	Chalazion/ Chalazion	2	03OCT2020	33/C	2	No	O	NA/TC	RG	N/N	
1231 12311095 16-55/ C4591001	GASTR	Diarrhoea/ Diarrhea	1	23AUG2020	12/3	1	No	O	NA	R (25AUG2020)	N/N	
1231 12311097	GASTR	Diarrhoea/ Diarrhea	2	09SEP2020	8/1	1	No	O	NA/TCN	R (09SEP2020)	N/N	
16-55/ C4591001	GASTR	Dyspepsia/ dyspepsia	2	20SEP2020	19/9	1	No	O	NA	R (28SEP2020)	N/N	
1231 12311105 16-55/ C4591001	GENRL	Pyrexia/ Fever#	4	18FEB2021	1/1	1	Yes		NA/TC	R (18FEB2021)	N/N	
1231 12311109 16-55/ C4591001	VASC	Phlebitis superficial/ Superficial phlebitis of the left arm	2	11OCT2020	38/19	2	No	O	NA/TC	R (29OCT2020)	N/N	
1231 12311112 16-55/ C4591001	RENAL	Nephrolithiasis/ worsening of renal lithiasis	2	21NOV2020	79/7	3	No	O	NA/TC	R (27NOV2020)	Y/N	
1231 12311118 16-55/ C4591001	MUSC	Myalgia/ Myalgia	1	19AUG2020	7/11	1	No	O	NA	R (29AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12311121	INJ&P	Joint dislocation/ right shoulder dislocation	2	22SEP2020	22/1	3	No	O	NA/TC/TCN	RS (22SEP2020)	N/N	
16-55/ C4591001 1231 12311126	NERV	Road traffic accident/ MOTOR VEHICLE ACCIDENT Peripheral nerve lesion/ Right index finger collateral nerve lesion	2	22SEP2020	22/1	3	No	O	NA/TC/TCN	RS (22SEP2020)	N/N	
16-55/ C4591001 1231 12311128	NERV	Headache/ headache	2	13SEP2020	11/3	1	No	O	NA/TC	R (15SEP2020)	N/N	
16-55/ C4591001 1231 12311130	NERV	Dizziness/ Dizziness#	3	12MAR2021	4/2	1	No	O	NA	R (13MAR2021)	N/N	
16-55/ C4591001 1231 12311135	INFEC	Genital herpes/ exacerbated genital herpes	2	27SEP2020	26/9	1	No	O	NA/TC/TCN	R (05OCT2020)	N/N	
16-55/ C4591001 1231 12311147	INJ&P	Exposure during pregnancy/ Exposure during pregnancy (female partner)	1	07NOV2020	87/C		No	O	NA	UNK	N/N	
16-55/ C4591001	MUSC	Arthralgia/ Joint pain	2	10SEP2020	7/36	2	No	O	NA/TC	R (15OCT2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12311152	MUSC	Arthralgia/ pain in right knee	2	07OCT2020	34/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1231 12311164	GASTR	Abdominal pain/ Abdominal pain	2	02SEP2020	1/2	3	No	O	NA/TC/TCN	R (03SEP2020)	N/N	
16-55/ C4591001 1231 12311166	SKIN	Dermatitis bullous/ bullous lesion on right hand	2	30SEP2020	28/31	1	No	O	NA/TC	R (30OCT2020)	N/N	
16-55/ C4591001 1231 12311176	MUSC	Arthralgia/ Left shoulder arthralgia	2	20OCT2020	48/8	1	No	O	NA/TC	R (27OCT2020)	N/N	
16-55/ C4591001 1231 12311176	INFEC	Tooth infection/ Dental infection	2	08SEP2020	5/7	1	No	O	NA/TC	R (14SEP2020)	N/N	
16-55/ C4591001 1231 12311183	INJ&P	Tooth fracture/ Tooth fracture	2	08SEP2020	5/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1231 12311183	INFEC	Oral herpes/ Cold sores	2	31OCT2020	58/3	1	No	O	NA	R (02NOV2020)	N/N	
16-55/ C4591001 1231 12311191	GASTR	Toothache/ Toothache	2	27SEP2020	26/4	2	No	O	NA/TC	R (30SEP2020)	N/N	
16-55/ C4591001 1231 12311191	INFEC	Cystitis/ Cystitis	1	09OCT2020	57/3	1	No	O	NA/TC	R (11OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311195	INFEC	Conjunctivitis/ Conjunctivitis	1	20AUG2020	7/2	1	No	O	NA/TC	R (21AUG2020)	N/N	
16-55/ C4591001 1231 12311199	INFEC	Genital herpes simplex/ Genital herpes simplex type 2	2	16SEP2020	14/13	1	No	O	NA/TC	R (28SEP2020)	N/N	
16-55/ C4591001 1231 12311202	INFEC	Tooth infection/ Odontogenic infection	2	26FEB2021	177/2	2	No	O	NA/TC/TCN	R (27FEB2021)	N/N	
16-55/ C4591001 1231 12311205	INJ&P	Ulna fracture/ Left arm olecranon fracture	2	17SEP2020	15/149	3	No	O	NA/TC/TCN	R (12FEB2021)	Y/N	
16-55/ C4591001 1231 12311207	METAB	Type 2 diabetes mellitus/ Type 2 diabetes	2	01JAN2021	120/38	1	No	O	NA/TC/TCN	RS (07FEB2021)	N/N	
16-55/ C4591001 1231 12311208	SURG	Tooth extraction/ Lower right canine extraction	1	03SEP2020	21/3	1	No	O	NA/TC	R (05SEP2020)	N/N	
16-55/ C4591001 1231 12311211	INJ&P	Fall/ Fall from his own height	1	19SEP2020	37/1	2	No	O	NA	R (19SEP2020)	N/N	
	MUSC	Coccydynia/ Coccigodinia	1	19SEP2020	37/22	2	No	O	NA/TC/TCN	R (10OCT2020)	N/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311229	CARD	Tachycardia/ tachycardia	2	06OCT2020	33/39	2	No	O	NA	R (13NOV2020)	N/N	
16-55/ C4591001 1231 12311231	INFEC	Tooth infection/ dental infection	1	24AUG2020	11/7	2	No	O	NA/TC	R (30AUG2020)	N/N	
16-55/ C4591001 1231 12311232	GENRL	Injection site pain/ injection site pain#	3	20JAN2021	1/2	1	Yes		NA/TC	R (21JAN2021)	N/N	
	INFEC	Hordeolum/ stye in left eye#	3	21JAN2021	2/5	1	No	O	NA/TC	R (25JAN2021)	N/N	
	GENRL	Asthenia/ asthenia#	3	22JAN2021	3/2	1	Yes		NA	R (23JAN2021)	N/N	
	NERV	Headache/ mild headache#	3	22JAN2021	3/2	1	Yes		NA/TC	R (23JAN2021)	N/N	
	GENRL	Asthenia/ asthenia#	4	11FEB2021	3/2	1	Yes		NA	R (12FEB2021)	N/N	
		Chills/ chills#	4	11FEB2021	3/2	1	Yes		NA	R (12FEB2021)	N/N	
	INV	Body temperature increased/ Increased body temperature#	4	11FEB2021	3/2	1	Yes		NA/TC	R (12FEB2021)	N/N	
	MUSC	Arthralgia/ generalized arthralgias#	4	11FEB2021	3/2	1	Yes		NA	R (12FEB2021)	N/N	
		Myalgia/ myalgia#	4	11FEB2021	3/2	1	Yes		NA/TC	R (12FEB2021)	N/N	
16-55/ C4591001	VASC	Hypertension/ exacerbation of arterial hypertension	2	15SEP2020	14/3	1	No	O	NA/TC/TCN	R (17SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12311233	GASTR	Odynophagia/ Odynophagia	2	16SEP2020	15/4	1	No	O	NA	R (19SEP2020)	N/N	
16-55/ C4591001 1231 12311238	GENRL	Asthenia/ asthenia	2	16SEP2020	15/2	1	No	O	NA	R (17SEP2020)	N/N	
16-55/ C4591001 1231 12311243	SKIN	Rash pruritic/ pruritic rash	1	18AUG2020	5/4	2	Yes		NA/TC	R (21AUG2020)	N/N	
16-55/ C4591001 1231 12311246	MUSC	Back pain/ low back pain	2	31JAN2021	152/28	2	No	O	NA/TC	R (27FEB2021)	N/N	
16-55/ C4591001 1231 12311248	EYE	Blepharitis/ Left blepharitis	2	30SEP2020	27/10	1	No	O	NA/TC	R (09OCT2020)	N/N	
		Eyelid pain/ PAIN OF THE UPPER LEFT EYELID	2	30SEP2020	27/10	1	No	O	NA/TC	R (09OCT2020)	N/N	
		Eyelids pruritus/ ITCHING OF THE UPPER LEFT EYELID	2	30SEP2020	27/10	1	No	O	NA/TC	R (09OCT2020)	N/N	
16-55/ C4591001 1231 12311251	MUSC	Intervertebral disc protrusion/ disc herniation L4-L5#	2	25JAN2021	144/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001	INFEC	Appendicitis/ acute appendicitis	2	18SEP2020	15/19	3	No	O	NA/TC/TCN	R (06OCT2020)	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12311281	INV	Electrocardiogram QT prolonged/ QT interval prolongation	2	18SEP2020	15/1	1	No	O	NA	R (18SEP2020)	N/N	
16-55/ C4591001 1231 12311294	INFEC	Pyelonephritis/ pyelonephritis	2	12SEP2020	6/9	3	No	O	NA/TC	R (20SEP2020)	N/N	
	INJ&P	Bone fissure/ Fissure of left elbow bone	2	23OCT2020	47/37	1	No	O	NA/TC/TCN	R (28NOV2020)	N/N	
		Joint dislocation/ Dislocation of the left elbow	2	23OCT2020	47/37	1	No	O	NA/TC/TCN	R (28NOV2020)	N/N	
	HEPAT	Cholecystitis acute/ Acute cholecystitis	2	12DEC2020	97/33	3	No	O	NA/TC/TCN	R (13JAN2021)	Y/N	
16-55/ C4591001 1231 12311295	BLOOD	Lymphadenopathy/ Left axillary adenopathy	2	05SEP2020	3/16	1	Yes		NA/TC/TCN	R (20SEP2020)	N/N	
	NERV	Tension headache/ Tension headache	2	05OCT2020	33/11	2	No	O	NA/TC	R (15OCT2020)	N/N	
16-55/ C4591001 1231 12311301	RESP	Asthma/ Moderate asthma attack	1	26AUG2020	12/5	2	No	O	NA/TC	R (30AUG2020)	N/N	
	GENRL	Asthenia/ Asthenia#	3	28JAN2021	1/7	2	Yes		NA	R (03FEB2021)	N/N	
		Injection site pain/ Injection site pain#	3	28JAN2021	1/4	3	Yes		NA	R (31JAN2021)	N/N	
	NERV	Headache/ Headache#	3	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12311306	INFEC	Urinary tract infection/ urinary infection#	3	09FEB2021	13/9	1	No	O	NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1231 12311306	GENRL	Chest pain/ Self-limited oppressive chest pain	1	02SEP2020	19/1	1	No	O	NA	R (02SEP2020)	N/N
16-55/ C4591001 1231 12311315	BLOOD	Anaemia/ anemia	2	25SEP2020	23/12	2	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1231 12311334	NEOPL	Malignant melanoma/ Pigmented epithelioid melanoma of the vagina	2	25SEP2020	23/C	2	No	O	NA/TC/TCN	RG	Y/N
16-55/ C4591001 1231 12311334	INFEC	Genitourinary chlamydia infection/ Genital Chlamydia trachomatis infection	2	15FEB2021	162/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1231 12311336	INJ&P	Procedural dizziness/ Post blood extraction dizziness	2	07OCT2020	35/1	1	No	O	NA	R (07OCT2020)	N/N
16-55/ C4591001 1231 12311338	GASTR	Gastrointestinal disorder/ Gastrointestinal syndrome	2	09SEP2020	3/2	2	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1231 12311348	GENRL	Injection site pain/ Injection site pain*		15AUG2020	1/4	1	Yes		NA/TC	R (18AUG2020)	N/N
16-55/ C4591001	GENRL	Influenza like illness/ Flu like syndrome	1	20AUG2020	6/9	3	No	O	NA	R (28AUG2020)	Y/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12311352	INFEC	Urinary tract infection/ high urinary infection	1	20AUG2020	6/71	2	No	O	NA/TC	R (29OCT2020)	N/N	
	GASTR	Vomiting/ Vomiting	1	29AUG2020	15/4	1	No	O	NA	R (01SEP2020)	N/N	
16-55/ C4591001 1231 12311361	NERV	Paraesthesia/ Both upper limbs paresthesia	2	04SEP2020	1/1	1	No	O	NA	R (04SEP2020)	N/N	
	PSYCH	Generalised anxiety disorder/ generalized anxiety	2	07OCT2020	34/48	1	No	O	NA/TC/TCN	R (23NOV2020)	N/N	
	MUSC	Arthralgia/ Polyarthralgias	2	12OCT2020	39/43	1	No	O	NA/TC	R (23NOV2020)	N/N	
16-55/ C4591001 1231 12311375	MUSC	Myalgia/ Myalgia in the region of the shoulder and left shoulder blade	2	06SEP2020	4/1	2	Yes		NA/TC	R (06SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia of moderate intensity below the left shoulder blade	2	26SEP2020	24/1	2	No	O	NA/TC	R (26SEP2020)	N/N	
	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	01OCT2020	29/143	1	No	O	NA/TC	R (20FEB2021)	N/N	
16-55/ C4591001 1231 12311387	INJ&P	Exposure during pregnancy/ Drug Exposed Pregnancy	2	07NOV2020	65/C		No	O	NA	UNK	N/N	
	INFEC	Urinary tract infection/ Complicated Urinary Tract Infection	2	04JAN2021	123/15	3	No	O	NA/TC	R (18JAN2021)	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311388	NERV	Headache/ headache	1	16AUG2020	2/8	1	No	O	NA	R (23AUG2020)	N/N	
	MUSC	Myalgia/ GENERALIZED MYALGIA	1	18AUG2020	4/7	1	Yes		NA	R (24AUG2020)	N/N	
	MUSC	Arthralgia/ ARTHRALGIA	1	21AUG2020	7/4	1	No	O	NA	R (24AUG2020)	N/N	
	SURG	Tooth extraction/ Programmed extraction of the right third molar	2	26SEP2020	24/1	1	No	CND	NA/TC/TCN	R (26SEP2020)	N/N	
16-55/ C4591001 1231 12311402	NERV	Headache/ worsening headache	1	08OCT2020	55/2	1	No	O	NA	R (09OCT2020)	N/N	
16-55/ C4591001 1231 12311403	MUSC	Synovial cyst/ Right wrist ganglion	2	04NOV2020	60/42	1	No	O	NA/TC	R (15DEC2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	15JAN2021	1/3	2	Yes		NA/TC	R (17JAN2021)	N/N	
16-55/ C4591001 1231 12311409	GASTR	Vomiting/ vomits*		15AUG2020	/1	1	No	O	P/TCN/W	R (15AUG2020)	N/N	
	NERV	Syncope/ Syncope*		15AUG2020	/1	2	No	O	P/TCN/W	R (15AUG2020)	N/N	
16-55/ C4591001 1231 12311410	REPRO	Amenorrhoea/ Amenorrhoea	2	16SEP2020	11/C	1	No	O	NA	RG	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12311412	MUSC	Musculoskeletal chest pain/ Torax pain. refered muscular. type opressive.	2	15SEP2020	1/52	2	No	O	NA	R (05NOV2020)	N/N
16-55/ C4591001 1231 12311414	INFEC	Urinary tract infection/ urinary infection	1	30AUG2020	16/8	1	No	O	NA/TC	R (06SEP2020)	N/N
	SKIN	Rash/ Skin rash on the back (dorsal and lumbar area)	2	29OCT2020	56/1	1	No	O	NA/TC	R (29OCT2020)	N/N
16-55/ C4591001 1231 12311418	GASTR	Inguinal hernia/ bilateral inguinal hernia	1	27AUG2020	13/2	2	No	O	NA	R (28AUG2020)	N/N
		Irritable bowel syndrome/ irritable bowel syndrome	1	27AUG2020	13/C	2	No	O	NA/TC/TCN	RG	N/N
	EYE	Eye pruritus/ Eye itching#	2	03FEB2021	153/7	1	No	O	NA/TC	R (09FEB2021)	N/N
16-55/ C4591001 1231 12311427	RESP	Bronchospasm/ Bronchospasm	2	08SEP2020	6/39	2	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1231 12311428	GENRL	Pyrexia/ fever	2	18SEP2020	12/1	1	No	O	NA	R (18SEP2020)	N/N
16-55/ C4591001 1231 12311436	GASTR	Diarrhoea/ diarrhea	2	30SEP2020	28/2	1	No	O	NA/TCN	R (01OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311444	SKIN	Dermatitis contact/ contact dermatitis	1	19AUG2020	5/53	1	No	O	NA	R (10OCT2020)	N/N	
		Rash maculo-papular/ non pruritic maculopapular cervical rash	1	19AUG2020	5/53	1	No	O	NA	R (10OCT2020)	N/N	
16-55/ C4591001 1231 12311448	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	2	09NOV2020	64/C		No	O	NA	UNK	N/N	
16-55/ C4591001 1231 12311465	RESP	Bronchospasm/ MILD BRONCHOSPASM	2	30SEP2020	28/2	1	No	O	NA/TC	R (01OCT2020)	N/N	
16-55/ C4591001 1231 12311473	MUSC	Back pain/ low back pain	1	20AUG2020	6/2	1	No	O	NA/TC	R (21AUG2020)	N/N	
16-55/ C4591001 1231 12311475	GASTR	Diarrhoea/ diarrhea	1	22AUG2020	8/2	1	No	O	NA	R (23AUG2020)	N/N	
16-55/ C4591001 1231 12311479	METAB	Dyslipidaemia/ worsening of dyslipidemia	2	02JAN2021	121/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1231 12311480	SKIN	Rash/ skin rash, left laterocervical region	2	27SEP2020	25/14	1	No	O	NA/TC	R (10OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311481	RESP	Rhinitis allergic/ Allergic rhinitis worsening#	3	30JAN2021	10/26	1	No	O	NA/TC	R (24FEB2021)	N/N	
	MUSC	Myalgia/ Generalized muscle pain#	4	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N	
	NERV	Headache/ Headache#	4	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N	
16-55/ C4591001 1231 12311483	RESP	Rhinitis allergic/ allergic rhinitis	2	30SEP2020	28/1	1	No	O	NA/TC	R (30SEP2020)	N/N	
16-55/ C4591001 1231 12311492	REPRO	Penile vein thrombosis/ Thrombosis of superficial vein of penis	2	14SEP2020	8/27	1	No	O	NA/TC	R (10OCT2020)	N/N	
	INJ&P	Post procedural haemorrhage/ Bleeding after sampling	2	07OCT2020	31/1	1	No	O	NA/TCN	R (07OCT2020)	N/N	
16-55/ C4591001 1231 12311499	MUSC	Plantar fasciitis/ PLANTAR FASCITIS	1	10SEP2020	26/120	1	No	O	NA/TC	R (07JAN2021)	N/N	
	GENRL	Chills/ Chills	2	20OCT2020	30/54	2	No	O	NA/TC	R (12DEC2020)	N/N	
	NERV	Headache/ Headache	2	20OCT2020	30/45	2	No	O	NA/TC	R (03DEC2020)	N/N	
16-55/ C4591001 1231 12311507	INFEC	Vulvovaginal mycotic infection/ Vaginal mycosis	2	17SEP2020	11/3	1	No	O	NA/TC	R (19SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311513	SURG	Tooth extraction/ Elective extraction of three third molars	2	03OCT2020	26/1	1	No	O	NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001 1231 12311520	INFEC	Folliculitis/ Folliculitis in upper dorsal area and nape.	2	07NOV2020	62/12	1	No	O	NA/TC	R (18NOV2020)	N/N	
16-55/ C4591001 1231 12311530	PSYCH	Anxiety disorder/ Anxiety disorder	2	26OCT2020	49/3	2	No	O	NA/TC	R (28OCT2020)	N/N	
16-55/ C4591001 1231 12311532	VASC	Hypertension/ arterial hypertension	1	27AUG2020	12/4	1	No	O	NA/TC	R (30AUG2020)	N/N	
16-55/ C4591001 1231 12311538	INFEC	Gangrene/ Rightfoot transmetatarsal limited gangrene	2	03DEC2020	88/77	3	No	O	NA/TC/TCN	RS (17FEB2021)	Y/N	
16-55/ C4591001 1231 12311544	GENRL	Chills/ chills	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N	
		Injection site erythema/ Erythema at the injection site	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N	
		Injection site pain/ Injection site pain	2	04SEP2020	1/2	1	Yes		NA/TC	R (05SEP2020)	N/N	
16-55/ C4591001	EYE	Eyelid oedema/ unilateral bipalpebral edema	2	09SEP2020	2/34	1	No	O	NA	R (12OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12311548	SKIN	Pruritus/ Pruritus of the face and neck	2	09SEP2020	2/34	1	No	O	NA	R (12OCT2020)	N/N	
16-55/ C4591001 1231 12311550	BLOOD	Anaemia/ Anemia	2	17FEB2021	164/9	1	No	O	NA/TC	RS (25FEB2021)	N/N	
	GENRL	Pyrexia/ Fever#	3	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	3	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N	
16-55/ C4591001 1231 12311556	GENRL	Asthenia/ Asthenia	2	23SEP2020	17/1	1	No	O	NA	R (23SEP2020)	N/N	
	INJ&P	Ligament rupture/ Rupture of the anterior cruciate ligament of the left knee	2	21NOV2020	76/75	2	No	O	NA/TCN	R (03FEB2021)	Y/N	
		Meniscus injury/ Rupture of the external meniscus of the left knee	2	21NOV2020	76/75	2	No	O	NA/TC/TCN	R (03FEB2021)	Y/N	
16-55/ C4591001 1231 12311580	RESP	Rhinitis allergic/ Allergic rhinitis#	3	05MAR2021	14/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1231 12311584	INFEC	Conjunctivitis/ Conjunctivitis	2	16SEP2020	9/8	1	No	O	NA/TC	R (23SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311607	MUSC	Muscle contracture/ Left deltoid muscle contracture	2	01OCT2020	24/2	1	No	O	NA/TC	R (02OCT2020)	N/N	
16-55/ C4591001 1231 12311635	INJ&P	Exposure during pregnancy/ Drug exposed pregnancy ( female partner )	2	20NOV2020	78/		No	O	NA	R	N/N	
	NEOPL	Benign hydatidiform mole/ Molar pregnancy in partner	2	JAN2021	120/	3	No	O	NA	R	Y/N	
16-55/ C4591001 1231 12311638	MUSC	Neck pain/ cervical pain	2	04OCT2020	27/54	1	No	O	NA/TC	R (26NOV2020)	N/N	
	PSYCH	Anxiety disorder/ Anxiety disorder	2	12OCT2020	35/29	2	No	O	NA/TC/TCN	R (09NOV2020)	N/N	
		Depression/ Depression	2	12OCT2020	35/29	2	No	O	NA/TC/TCN	RS (09NOV2020)	N/N	
16-55/ C4591001 1231 12311643	GASTR	Gastroesophageal reflux disease/ gastroesophageal reflux	1	25AUG2020	10/6	1	No	O	NA	R (30AUG2020)	N/N	
16-55/ C4591001 1231 12311651	NERV	Dizziness/ Lipothymia Dizziness	1	17AUG2020	2/3	1	No	O	NA/TC/TCN	R (19AUG2020)	N/N	
	INFEC	Urinary tract infection/ urinary infection#	3	09FEB2021	13/8	1	No	O	NA/TC	R (16FEB2021)	N/N	
	PSYCH	Anxiety/ Anxiety#	3	15FEB2021	19/C	1	No	O	NA/TC	RG	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311653	CARD	Palpitations/ worsening heart palpitations	2	SEP2020	1/	1	No	O	NA	R (16OCT2020)	N/N	
	GENRL	Pyrexia/ Fever	2	08SEP2020	2/1	3	Yes		NA/TC	R (08SEP2020)	N/N	
	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	28SEP2020	22/19	1	No	O	NA/TC	R (16OCT2020)	N/N	
		Hypocalcaemia/ Hypocalcemia	2	28SEP2020	22/19	1	No	O	NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001 1231 12311660	RESP	Dyspnoea/ Dyspnea	1	22AUG2020	7/2	1	No	O	NA	R (23AUG2020)	N/N	
16-55/ C4591001 1231 12311661	GENRL	Injection site pain/ pain at the injection site	2	27SEP2020	21/10	1	Yes		NA	R (06OCT2020)	N/N	
	GENRL	Peripheral swelling/ swelling in the left arm	2	29SEP2020	23/8	1	Yes		NA	R (06OCT2020)	N/N	
	INJ&P	Contusion/ bruise in the left arm	2	29SEP2020	23/8	1	Yes		NA	R (06OCT2020)	N/N	
16-55/ C4591001 1231 12311683	GENRL	Pyrexia/ fever	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N	
16-55/ C4591001 1231 12311686	GASTR	Haemorrhoids/ hemorrhoids	2	21SEP2020	14/C	2	No	O	NA/TC	RG	N/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311689	GENRL	Oedema peripheral/ Left ankle Edema	1	01SEP2020	16/63	1	No	O	NA	R (02NOV2020)	N/N	
	MUSC	Arthralgia/ pain in the left ankle	1	01SEP2020	16/63	1	No	O	NA	R (02NOV2020)	N/N	
16-55/ C4591001 1231 12311691	NERV	Headache/ Headache#	3	05FEB2021	12/1	2	No	O	NA/TC	R (05FEB2021)	N/N	
16-55/ C4591001 1231 12311701	GASTR	Dyspepsia/ Dyspepsia	1	17AUG2020	1/8	3	Yes		NA/TC/TCN	R (24AUG2020)	N/N	
16-55/ C4591001 1231 12311711	INFEC	Urosepsis/ Urosepsis	2	15SEP2020	9/8	3	No	O	NA/TC	R (22SEP2020)	Y/N	
16-55/ C4591001 1231 12311712	INFEC	Tooth infection/ Odontogenic infection	2	23SEP2020	16/1	1	No	O	NA/TCN	R (23SEP2020)	N/N	
16-55/ C4591001 1231 12311714	REPRO	Genital erythema/ Nonspecific glans erythema	2	24SEP2020	18/2	1	No	O	NA/TC	R (25SEP2020)	N/N	
16-55/ C4591001 1231 12311719	NERV	Headache/ headache	2	07SEP2020	1/3	2	Yes		NA/TC	R (09SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311724	INFEC	Rhinitis/ rhinitis	1	19AUG2020	3/8	1	No	O	NA	R (26AUG2020)	N/N	
	RESP	Rhinitis allergic/ allergic rhinitis	2	02OCT2020	26/2	1	No	O	NA	R (03OCT2020)	N/N	
16-55/ C4591001 1231 12311730	NEOPL	Invasive ductal breast carcinoma/ Right breast invasive ductal carcinoma	2	15NOV2020	70/C	2	No	O	NA	N	Y/N	
16-55/ C4591001 1231 12311731	NERV	Headache/ HEADACHE	1	05SEP2020	20/2	2	No	O	NA/TC/TCN	R (06SEP2020)	N/N	
	NERV	Headache/ headache	2	03OCT2020	26/1	2	No	O	NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001 1231 12311734	GASTR	Dyspepsia/ Dyspepsia	2	22OCT2020	46/3	1	No	O	NA	R (24OCT2020)	N/N	
16-55/ C4591001 1231 12311735	INJ&P	Fall/ Bicycle fall	2	04FEB2021	151/1	1	No	O	NA	R (04FEB2021)	N/N	
		Limb injury/ Right hand scaphoid trauma	2	04FEB2021	151/C	1	No	O	NA/TC/TCN	RG	N/N	
16-55/ C4591001 1231 12311740	EAR	Tinnitus/ ringing in both ears	2	08SEP2020	2/C	3	No	O	NA	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311746	EAR	Vertigo/ Vertigo	2	01OCT2020	25/8	2	No	O	NA	R (08OCT2020)	N/N	
16-55/ C4591001 1231 12311755	SKIN	Pruritus allergic/ allergic reaction producing pruritus at the chin	1	22AUG2020	6/2	1	Yes		NA	R (23AUG2020)	N/N	
	SKIN	Rash pruritic/ pruritic rash on arm, armpit and part of the left chest.	2	13SEP2020	7/4	1	No	O	NA/TC	R (16SEP2020)	N/N	
	INJ&P	Limb injury/ Stabbing trauma on right thumb	2	08OCT2020	32/1	1	No	O	NA/TC	R (08OCT2020)	N/N	
	INFEC	Cellulitis/ cellulitis of the righth thumb	2	10OCT2020	34/15	1	No	O	NA/TC/TCN	R (24OCT2020)	N/N	
	RESP	Rhinitis allergic/ Exacerbation of allergic rhinitis#	3	09MAR2021	2/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1231 12311760	SKIN	Pruritus/ pruritus upper region of both feet and palmar aspect of both wrists	1	24AUG2020	8/2	1	No	O	NA	R (25AUG2020)	N/N	
16-55/ C4591001 1231 12311761	SKIN	Alopecia/ alopecia	2	05FEB2021	151/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1231 12311763	GENRL	Injection site pain/ injection site pain	2	08SEP2020	2/14	1	Yes		NA	R (21SEP2020)	N/N	
16-55/ C4591001	HEPAT	Biliary colic/ biliary colic	2	30OCT2020	54/5	3	No	O	NA/TC	R (03NOV2020)	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12311766 16-55/ C4591001	NERV	Dizziness/ dizziness	1	18AUG2020	2/11	1	No	O	NA	R (28AUG2020)	N/N	
1231 12311769 16-55/ C4591001	GASTR	Diarrhoea/ diarrhea	2	14SEP2020	8/3	1	No	O	NA	R (16SEP2020)	N/N	
1231 12311770	NERV	Headache/ headache	2	14SEP2020	8/3	1	No	O	NA	R (16SEP2020)	N/N	
	GASTR	Odynophagia/ odynophagia	2	17SEP2020	11/4	1	No	O	NA	R (20SEP2020)	N/N	
16-55/ C4591001	GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux	1	28AUG2020	12/91	1	No	O	NA/TC	R (26NOV2020)	N/N	
1231 12311780 16-55/ C4591001	INJ&P	Fall/ Subject fell down on the street	2	23SEP2020	17/1	1	No	O	NA	R (23SEP2020)	N/N	
1231 12311786	NEOPL	Chondroma/ Right knee chondroma	2	29SEP2020	23/C	1	No	O	NA	N	N/N	
	RESP	Asthmatic crisis/ Asthmatic crisis	2	04OCT2020	28/4	2	No	O	NA/TC	R (07OCT2020)	N/N	
16-55/ C4591001	PSYCH	Depression/ depression.	1	20AUG2020	4/36	2	No	O	NA/TC/TCN	R (24SEP2020)	N/N	
1231 12311788												

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311793	MUSC	Back pain/ Low back pain	1	05SEP2020	20/2	1	No	O	NA/TC	R (06SEP2020)	N/N	
16-55/ C4591001 1231 12311794	METAB	Insulin resistance/ Worsening of the insuline resistance.	2	20SEP2020	14/19	2	No	O	NA/TC	R (08OCT2020)	N/N	
16-55/ C4591001 1231 12311797	VASC	Hypertension/ arterial hypertension	2	25SEP2020	19/8	1	No	O	NA/TC	R (02OCT2020)	N/N	
16-55/ C4591001 1231 12311799	MUSC	Back pain/ Left low back pain	2	23SEP2020	16/C	1	No	O	NA	N	N/N	
	RESP	Dysphonia/ Intermittent Dysphonia	2	23SEP2020	16/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1231 12311801	MUSC	Muscle contracture/ Left back, muscle contracture	1	29AUG2020	13/4	2	No	O	NA/TC/TCN	R (01SEP2020)	N/N	
16-55/ C4591001 1231 12311811	SKIN	Pityriasis/ Pityriasis	1	25AUG2020	9/51	1	No	O	NA	R (14OCT2020)	N/N	
16-55/ C4591001 1231 12311812	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	05JAN2021	121/60		No	O	NA	R (05MAR2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	PREG	Abortion spontaneous/ Complete miscarriage	2	27FEB2021	174/12	3	No	O	NA/TC	R (10MAR2021)	Y/N
16-55/ C4591001 1231 12311816	GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux disease	1	15DEC2020	121/79	1	No	O	NA/TC	R (03MAR2021)	N/N
16-55/ C4591001 1231 12311819	VASC	Hypertension/ Exacerbation of arterial hypertension.#	2	09MAR2021	183/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1231 12311825	NERV	Migraine/ Migraine crisis	1	05SEP2020	20/1	2	No	O	NA	R (05SEP2020)	N/N
	NERV	Migraine/ Migraine crisis	2	08NOV2020	35/2	1	No	O	NA/TC	R (09NOV2020)	N/N
16-55/ C4591001 1231 12311827	MUSC	Osteoarthritis/ Right acromioclavicular osteoarthritis	2	17SEP2020	10/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C4591001 1231 12311834	INJ&P	Foot fracture/ Hallux fracture and second toe of the right foot	2	16SEP2020	10/35	3	No	O	NA/TC/TCN	R (20OCT2020)	Y/N
16-55/ C4591001 1231 12311836	INFEC	Herpes simplex/ herpes simplex type 1 in the right nasal wing	1	19AUG2020	3/4	1	No	O	NA/TC	R (22AUG2020)	N/N
	INFEC	Herpes simplex/ herpes simplex type 1 on the left wing of the nose	2	10SEP2020	3/3	1	No	O	NA/TC	R (12SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311837	PSYCH	Anxiety/ anxiety crisis	2	03OCT2020	27/2	2	No	O	NA/TC/TCN	R (04OCT2020)	N/N	
	INFEC	Oral herpes/ Herpes labialis, single lesion	2	20OCT2020	44/8	1	No	O	NA	R (27OCT2020)	N/N	
	IMMUN	Jarisch-Herxheimer reaction/ Jarisch-herxheimer	2	13NOV2020	68/2	2	No	O	NA/TC	R (14NOV2020)	N/N	
16-55/ C4591001 1231 12311844	METAB	Hypoglycaemia/ severe hipoglycemia	2	16OCT2020	40/1	3	No	O	NA	R (16OCT2020)	Y/N	
	NERV	Seizure/ seizure	2	16OCT2020	40/1	3	No	O	NA	R (16OCT2020)	N/N	
16-55/ C4591001 1231 12311850	SKIN	Rash/ Skin Rash on legs, arms and back	1	25AUG2020	9/2	1	No	O	NA/TC	R (26AUG2020)	N/N	
	GASTR	Abdominal pain upper/ Abdominal pain in the right upper quadrant#	3	22JAN2021	3/2	1	No	O	NA	R (23JAN2021)	N/N	
		Diarrhoea/ diarrhea#	3	22JAN2021	3/2	1	Yes		NA	R (23JAN2021)	N/N	
	INFEC	Subcutaneous abscess/ Right armpit abscess#	4	02MAR2021	22/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1231 12311854	GASTR	Gastroesophageal reflux disease/ gastroesophageal reflux	2	21OCT2020	45/85	2	No	O	NA/TC	R (13JAN2021)	N/N	
	INFEC	Helicobacter infection/ Helicobacter Pylori infection	2	21OCT2020	45/104	2	No	O	NA/TC	R (01FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311862	BLOOD	Lymphadenopathy mediastinal/ mediastinal lymphadenopathy	2	23DEC2020	108/63	2	No	O	NA	RS (23FEB2021)	N/N	
		Lymphadenopathy/ Cervical lymphadenopathy	2	23DEC2020	108/63	2	No	O	NA	RS (23FEB2021)	N/N	
16-55/ C4591001 1231 12311862	VASC	Aortic stenosis/ Severe aortic stenosis	2	13OCT2020	35/C	3	No	O	NA/TC	RG	Y/N	
	RESP	Pulmonary mass/ pulmonary nodules	2	04JAN2021	118/51	1	No	O	NA	RS (23FEB2021)	N/N	
16-55/ C4591001 1231 12311863	EYE	Episcleritis/ bilateral episcleritis	1	04SEP2020	19/19	1	No	O	NA/TC	R (22SEP2020)	N/N	
16-55/ C4591001 1231 12311865	BLOOD	Lymphadenopathy/ right axillary adenopathy	2	10SEP2020	3/3	1	Yes		NA	R (12SEP2020)	N/N	
16-55/ C4591001 1231 12311885	INFEC	Urinary tract infection/ urinary infection	2	29SEP2020	22/5	1	No	O	NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001 1231 12311888	NERV	Migraine/ Worsening migraine	1	25AUG2020	8/14	1	No	O	NA/TC	R (07SEP2020)	N/N	
16-55/ C4591001 1231 12311889	SKIN	Rash pruritic/ Pruritic rash in abdomen.	2	10SEP2020	3/3	1	No	O	NA/TCN	R (12SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311901	NERV	Headache/ headache	2	04OCT2020	27/2	2	No	O	NA/TC	R (05OCT2020)	N/N	
	HEPAT	Cholecystitis chronic/ chronic lithiasic cholecystitis	2	27OCT2020	50/134	2	No	O	NA/TC/TCN	R (09MAR2021)	Y/N	
16-55/ C4591001 1231 12311908	GASTR	Odynophagia/ odynophagia	2	09SEP2020	2/2	2	No	O	NA	R (10SEP2020)	N/N	
	NERV	Headache/ headache	2	09SEP2020	2/2	2	No	O	NA/TC	R (10SEP2020)	N/N	
16-55/ C4591001 1231 12311926	NERV	Syncope/ Syncope*		18AUG2020	/1	2	No	O	NA/W	R (18AUG2020)	N/N	
16-55/ C4591001 1231 12311941	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	07JAN2021	121/C	1	No	O	NA/TC	RG	N/N	
	INFEC	Infected dermal cyst/ Sebaceous cyst infection in thoracic region	2	01FEB2021	146/12	1	No	O	NA/TC	R (12FEB2021)	N/N	
16-55/ C4591001 1231 12311951	INFEC	Tooth infection/ Odontogenic infection	2	23SEP2020	15/23	1	No	O	NA/TC	R (15OCT2020)	N/N	
16-55/ C4591001 1231 12311964	INFEC	Tooth abscess/ Periodontogenic abscess	2	15SEP2020	9/8	1	No	O	NA/TC	R (22SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12311969	REPRO	Erectile dysfunction/ Erectile dysfunction*		18AUG2020	1/81	1	No	O	NA	R (06NOV2020)	N/N
	CARD	Tricuspid valve incompetence/ mild tricuspid regurgitation	2	03OCT2020	27/24	1	No	O	NA	R (26OCT2020)	N/N
16-55/ C4591001 1231 12312002	NERV	Headache/ headache	1	01SEP2020	15/1	3	No	O	NA	R (01SEP2020)	N/N
16-55/ C4591001 1231 12312004	PSYCH	Generalised anxiety disorder/ generalized anxiety disorder	2	15SEP2020	6/1	2	No	O	NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1231 12312010	INFEC	Gastroenteritis/ gastroenteritis	2	17SEP2020	10/7	1	No	O	NA/TC/TCN	R (23SEP2020)	N/N
16-55/ C4591001 1231 12312019	INJ&P	Contusion/ bruising on both upper limbs	2	30SEP2020	22/14	1	No	O	NA	R (13OCT2020)	N/N
16-55/ C4591001 1231 12312024	GASTR	Dyspepsia/ Pyrosis	2	27SEP2020	20/30	1	No	O	NA	R (26OCT2020)	N/N
		Salivary gland mucocoele/ Lower lip mucocele	2	27SEP2020	20/110	1	No	O	NA	R (14JAN2021)	N/N
		Stomatitis/ mouth sores	2	27SEP2020	20/110	1	No	O	NA/TC	R (14JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312029	MUSC	Pain in extremity/ Lower limbs pain	2	07OCT2020	30/2	1	No	O	NA	R (08OCT2020)	N/N
16-55/ C4591001 1231 12312029	GASTR	Toothache/ odontogenic pain	1	27AUG2020	10/44	2	No	O	NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1231 12312036	GASTR	Abdominal pain/ abdominal pain	2	25SEP2020	17/7	1	No	O	NA/TC/TCN	R (01OCT2020)	N/N
16-55/ C4591001 1231 12312037	SKIN	Hand dermatitis/ dermatitis on both hands	2	08OCT2020	30/14	1	No	O	NA	R (21OCT2020)	N/N
16-55/ C4591001 1231 12312037	GASTR	Vomiting/ Threw up	2	09OCT2020	31/1	1	No	O	NA	R (09OCT2020)	N/N
16-55/ C4591001 1231 12312042	NERV	Headache/ headache	2	18OCT2020	41/3	1	No	O	NA/TC	R (20OCT2020)	N/N
16-55/ C4591001 1231 12312046	INJ&P	Skin laceration/ Cutting wound on left hand	2	04OCT2020	28/6	1	No	O	NA/TC/TCN	R (09OCT2020)	N/N
16-55/ C4591001 1231 12312048	GASTR	Toothache/ Worsening of odontogenic pain	2	13OCT2020	37/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001	GASTR	Abdominal pain/ Abdominal pain	2	16OCT2020	33/4	2	No	O	NA	R (19OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12312056 16-55/ C4591001	GENRL	Pyrexia/ Fever	2	09SEP2020	2/1	2	Yes		NA/TC	R (09SEP2020)	N/N
1231 12312063 16-55/ C4591001	SKIN	Rash maculo-papular/ generalized maculopapular rash	2	21NOV2020	73/4	1	No	O	NA/TC	R (24NOV2020)	N/N
1231 12312067 16-55/ C4591001	INFEC	Herpes zoster/ Herpes zoster in left dorsal region	2	08NOV2020	63/12	1	No	O	NA/TC	R (19NOV2020)	N/N
1231 12312068 16-55/ C4591001	RESP	Rhinitis allergic/ worsening of allergic rhinitis	2	01FEB2021	145/8	1	No	O	NA/TC	R (08FEB2021)	N/N
1231 12312069 16-55/ C4591001	PSYCH	Depression/ depression	2	15FEB2021	161/C	1	No	O	NA/TC	RG	N/N
1231 12312074 16-55/ C4591001	INFEC	Tooth infection/ Dental infection	2	02OCT2020	26/43	1	No	O	NA/TC	R (13NOV2020)	N/N
1231 12312075 16-55/ C4591001	IMMUN	Seasonal allergy/ seasonal rhinitis	2	08OCT2020	3/4	1	No	O	NA	R (11OCT2020)	N/N
1231 12312077											

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INFEC	Gingivitis/ gingivitis	2	16OCT2020	11/5	1	No	O	NA/TC	R (20OCT2020)	N/N
16-55/ C4591001 1231 12312078	NERV	Migraine/ Worsening of Migraine	1	25AUG2020	8/36	2	No	O	NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 1231 12312080	BLOOD	Lymphadenopathy/ left inguinal adenopathy	2	20OCT2020	43/15	1	No	O	NA	R (03NOV2020)	N/N
16-55/ C4591001 1231 12312087	GENRL	Injection site pain/ Pain at the injection site	1	19AUG2020	2/3	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001 1231 12312118	NEOPL	Uterine leiomyoma/ uterine myoma	2	16OCT2020	39/76	1	No	O	NA	R (30DEC2020)	N/N
16-55/ C4591001 1231 12312119	GASTR	Toothache/ Left upper 2nd molar pain	2	16SEP2020	10/15	1	No	O	NA/TC/TCN	R (30SEP2020)	N/N
16-55/ C4591001 1231 12312125	INFEC	Appendicitis/ Acute appendicitis	2	06JAN2021	122/37	3	No	O	NA/TC/TCN	R (11FEB2021)	Y/N
		Peritonitis/ Peritonitis	2	06JAN2021	122/37	3	No	O	NA/TC/TCN	R (11FEB2021)	Y/N
	CARD	Atrial fibrillation/ Acute Paroxysmal Atrial Fibrillation with High Ventricular Response.	2	11JAN2021	127/5	1	No	O	NA/TC	RS (15JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12312128	INJ&P	Joint injury/ right knee trauma	2	20SEP2020	13/11	2	No	O	NA/TC	R (30SEP2020)	N/N	
		Road traffic accident/ Vehicular accident	2	20SEP2020	13/1	2	No	O	NA	R (20SEP2020)	N/N	
16-55/ C4591001 1231 12312137	GENRL	Pyrexia/ Febrile syndrome	2	10SEP2020	2/1	3	Yes		NA/TC	R (10SEP2020)	N/N	
16-55/ C4591001 1231 12312152	INFEC	Urinary tract infection/ URINARY INFECTION	1	04SEP2020	18/11	1	No	O	NA/TC	R (14SEP2020)	N/N	
16-55/ C4591001 1231 12312160	GASTR	Odynophagia/ Odynophagia	2	08SEP2020	2/2	1	No	O	NA/TC	R (09SEP2020)	N/N	
16-55/ C4591001 1231 12312168	GENRL	Pyrexia/ Fever	2	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N	
	NERV	Headache/ Headache	2	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N	
16-55/ C4591001 1231 12312174	GASTR	Dental caries/ dental caries	2	08NOV2020	61/2	1	No	O	NA/TC/TCN	R (09NOV2020)	N/N	
16-55/ C4591001	RESP	Rhinitis allergic/ Allergic rhinitis.	2	01OCT2020	22/2	1	No	O	NA/TC	R (02OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12312191 16-55/ C4591001	EYE	Chalazion/ chalazion	2	11OCT2020	31/4	2	No	O	NA	R (14OCT2020)	N/N
1231 12312204 16-55/ C4591001	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	29SEP2020	23/62		No	O	NA	R (29NOV2020)	N/N
1231 12312205	PREG	Abortion spontaneous/ Spontaneous abortion	2	26NOV2020	81/4	2	No	O	NA/TC/TCN	R (29NOV2020)	Y/N
16-55/ C4591001 1231 12312211	GENRL	Injection site pain/ Injection site pain in right deltoid	2	12SEP2020	4/4	2	Yes		NA	R (15SEP2020)	N/N
1231 12312211	MUSC	Myalgia/ Generalized myalgia	2	12SEP2020	4/4	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1231 12312212	SURG	Drug titration/ dose search to achieve euthyroidism	2	08OCT2020	29/1	1	No	O	NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1231 12312216	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	10FEB2021	155/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1231 12312219	NERV	Headache/ Headache	1	29AUG2020	11/2	1	No	O	NA	R (30AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312227	GENRL	Injection site pain/ Injection site pain#	2	21JAN2021	136/2	1	Yes		NA/TC	R (22JAN2021)	N/N
	GENRL	Asthenia/ asthenia#	3	22JAN2021	2/1	1	Yes		NA/TC	R (22JAN2021)	N/N
	NERV	Headache/ Headache#	3	22JAN2021	2/3	1	Yes		NA/TC	R (24JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	12SEP2020	4/1	1	Yes		NA	R (12SEP2020)	N/N
	MUSC	Back pain/ Dorsalgia	2	30SEP2020	22/3	1	No	O	NA	R (02OCT2020)	N/N
	MUSC	Neck pain/ Cervicalgia	2	30SEP2020	22/3	1	No	O	NA/TCN	R (02OCT2020)	N/N
	NERV	Headache/ Headache	1	19AUG2020	1/2	3	No	O	NA	R (20AUG2020)	N/N
	PSYCH	Anxiety/ anxiety crisis	2	14SEP2020	4/27	2	No	O	NA/TC	R (10OCT2020)	N/N
	PSYCH	Depression/ Depression	2	14SEP2020	4/27	2	No	O	NA/TC	R (10OCT2020)	N/N
	IMMUN	Seasonal allergy/ Exacerbation of usual seasonal allergic rhinitis	2	27SEP2020	19/2	1	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C4591001 1231 12312244	NERV	Headache/ Headache	1	25AUG2020	7/52	1	No	O	NA/TC	R (15OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312245	GENRL	Injection site pain/ Pain at injection site#	3	08MAR2021	3/3	1	Yes		NA/TC	R (10MAR2021)	N/N
	MUSC	Neck pain/ Cervicalgia#	3	08MAR2021	3/3	1	Yes		NA/TC/TCN	R (10MAR2021)	N/N
	NERV	Headache/ headache#	3	08MAR2021	3/1	1	Yes		NA/TC	R (08MAR2021)	N/N
16-55/ C4591001 1231 12312266	GENRL	Pyrexia/ fever#	3	23FEB2021	1/4	1	Yes		NA/TC	R (26FEB2021)	N/N
	NERV	Headache/ headache#	3	23FEB2021	1/6	1	Yes		NA/TC	R (28FEB2021)	N/N
	GASTR	Vomiting/ vomiting#	3	25FEB2021	3/1	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1231 12312268	MUSC	Tendonitis/ Bilateral hand tendinitis	2	27SEP2020	17/73	1	No	O	NA/TC	R (08DEC2020)	N/N
		Tendonitis/ Right shoulder tendinitis	2	27SEP2020	17/73	1	No	O	NA/TC	R (08DEC2020)	N/N
16-55/ C4591001 1231 12312270	INJ&P	Limb injury/ Wound on the right leg	2	18OCT2020	38/9	1	No	O	NA/TC	R (26OCT2020)	N/N
16-55/ C4591001 1231 12312276	GENRL	Injection site pain/ Pain at Injection site#	3	27JAN2021	2/4	2	Yes		NA/TC	R (30JAN2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12312282	MUSC	Muscle contracture/ muscle contracture in left quadriceps	2	29SEP2020	22/1	3	No	O	NA	R (29SEP2020)	N/N	
16-55/ C4591001 1231 12312284	GASTR	Dental caries/ dental cavities	1	20AUG2020	2/84	1	No	O	NA/TC/TCN	R (11NOV2020)	N/N	
16-55/ C4591001 1231 12312286	GASTR	Odynophagia/ Odynophagia	1	29AUG2020	11/2	1	No	O	NA	R (30AUG2020)	N/N	
16-55/ C4591001 1231 12312287	GASTR	Abdominal pain upper/ Mild and intermittent epigastric abdominal pain.	2	10SEP2020	2/28	1	No	O	NA	R (07OCT2020)	N/N	
16-55/ C4591001 1231 12312296	GASTR	Diarrhoea/ Diarrhea	1	21AUG2020	3/1	1	No	O	NA	R (21AUG2020)	N/N	
16-55/ C4591001 1231 12312300	RESP	Sleep apnoea syndrome/ sleep apnea	2	26SEP2020	17/153	2	No	O	NA/TCN	RS (25FEB2021)	N/N	
	MUSC	Back pain/ Back pain	2	05OCT2020	26/2	2	No	O	NA/TC	R (06OCT2020)	N/N	
16-55/ C4591001 1231 12312303	MUSC	Arthralgia/ Left omalgia	1	19AUG2020	1/116	2	No	O	NA	R (12DEC2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12312317	NERV	Headache/ Headache	2	09SEP2020	3/9	1	Yes		NA/TC/TCN	R (17SEP2020)	N/N	
16-55/ C4591001 1231 12312320	EAR	Vertigo/ vertiginous syndrome	1	08SEP2020	21/14	2	No	O	NA/TC	R (21SEP2020)	N/N	
	EAR	Vertigo/ vertiginous syndrome	1	20SEP2020	33/27	2	No	O	NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001 1231 12312330	NERV	Dizziness/ Dizziness	1	20AUG2020	2/16	2	No	O	NA/TC	R (04SEP2020)	N/N	
16-55/ C4591001 1231 12312333	MUSC	Tenosynovitis stenosaurs/ exacerbation of Right hand pain secondary to previous Quervain's tenosynovitis	2	28SEP2020	22/2	2	No	O	NA/TC	R (29SEP2020)	N/N	
	SURG	Medical device implantation/ Radiocarpal clamping	2	28SEP2020	22/2	2	No	O	NA/TC	R (29SEP2020)	N/N	
16-55/ C4591001 1231 12312335	METAB	Hypoglycaemia/ Severe hypoglycemia	2	16DEC2020	100/8	3	No	O	NA/TC	R (23DEC2020)	Y/N	
16-55/ C4591001 1231 12312346	RESP	Rhinitis allergic/ Exacerbation of allergic rhinitis	2	15SEP2020	9/4	1	No	O	NA/TC	R (18SEP2020)	N/N	
16-55/ C4591001	NERV	Paraesthesia/ left upper limb paresthesia	2	15SEP2020	5/22	1	No	O	NA	R (06OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12312351	GASTR	Acute abdomen/ Acute medical abdomen	2	22SEP2020	14/4	2	No	O	NA	R (25SEP2020)	N/N
16-55/ C4591001	BLOOD	Iron deficiency anaemia/ Iron deficiency anemia	1	05OCT2020	48/C	1	No	O	NA/TC	RG	N/N
1231 12312360	REPRO	Testicular torsion/ Testicular torsion	2	28OCT2020	50/2	2	No	O	NA/TCN	R (29OCT2020)	N/N
16-55/ C4591001	INFEC	Tooth infection/ odontogenic infection#	3	13MAR2021	19/C	1	No	O	NA	N	N/N
1231 12312365	NERV	Headache/ Intermittent Headache	1	21AUG2020	3/94	2	No	O	NA/TC	R (22NOV2020)	N/N
16-55/ C4591001	EAR	Meniere's disease/ Worsening of Meniere's Syndrome	1	24SEP2020	37/15	2	No	O	NA/TC/TCN	R (08OCT2020)	N/N
1231 12312366	PSYCH	Mental disorder/ Worsening of psychiatric disorder	2	15OCT2020	7/20	1	No	O	NA/TC/TCN	R (03NOV2020)	N/N
16-55/ C4591001	INFEC	Skin infection/ scar infection	2	14OCT2020	30/9	1	No	O	NA/TC	R (22OCT2020)	N/N
1231 12312372											
16-55/ C4591001											
1231 12312373											

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312378	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	24DEC2020	108/C		No	O	NA	UNK	N/N
16-55/ C4591001 1231 12312382	GENRL	Pyrexia/ fever (39 C)	2	09SEP2020	2/5	2	Yes		NA/TC	R (13SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	09SEP2020	2/5	2	Yes		NA/TC	R (13SEP2020)	N/N
	NERV	Headache/ Headache	2	09SEP2020	2/5	2	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1231 12312384	METAB	Dyslipidaemia/ worsening dyslipidemia	2	20SEP2020	13/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12312385	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ Fever	2	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1231 12312390	MUSC	Osteochondritis/ Osteochondritis	1	05SEP2020	18/2	2	No	O	NA	R (06SEP2020)	Y/N
16-55/ C4591001 1231 12312391	GENRL	Pyrexia/ FEVER	2	11SEP2020	3/1	2	Yes		NA/TC	R (11SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312405	SURG	Dental implantation/ Dental implant	2	19SEP2020	13/1	1	No	O	NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1231 12312411	MUSC	Neck pain/ Neck pain#	3	11FEB2021	15/12	1	No	O	NA/TC/TCN	R (22FEB2021)	N/N
16-55/ C4591001 1231 12312414	GASTR	Gastroesophageal reflux disease/ gastroesophageal reflux	1	25AUG2020	7/15	2	No	O	NA/TC/TCN	R (08SEP2020)	N/N
	GASTR	Abdominal pain upper/ Epigastralgia#	3	08FEB2021	19/5	1	No	O	NA	R (12FEB2021)	N/N
	MUSC	Back pain/ Chronic low back pain exacerbation#	3	08FEB2021	19/4	2	No	O	NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1231 12312419	GENRL	Chills/ Chills	2	10SEP2020	2/1	3	Yes		NA/TC	R (10SEP2020)	N/N
		Pyrexia/ fever	2	10SEP2020	2/1	3	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1231 12312420	INFEC	Appendicitis/ Acute Appendicitis	2	28DEC2020	110/16	3	No	O	NA/TC/TCN	R (12JAN2021)	Y/N
16-55/ C4591001 1231 12312424	GENRL	Illness/ Sickness	2	11NOV2020	65/3	1	No	O	NA	R (13NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12312426	MUSC	Back pain/ Low back pain	1	31AUG2020	13/4	2	No	O	NA/TC/TCN	R (03SEP2020)	N/N	
16-55/ C4591001 1231 12312434	NERV	Dizziness/ dizziness	2	10SEP2020	2/16	1	No	O	NA/TCN	R (25SEP2020)	N/N	
	INV	Blood cholesterol increased/ increased total cholesterol	2	15DEC2020	98/C	1	No	O	NA/TCN	N	N/N	
16-55/ C4591001 1231 12312435	MUSC	Back pain/ Acute low back pain	1	08SEP2020	21/3	1	No	O	NA/TC	R (10SEP2020)	N/N	
16-55/ C4591001 1231 12312439	MUSC	Back pain/ acute low back pain	1	31AUG2020	13/11	1	No	O	NA/TC	R (10SEP2020)	N/N	
16-55/ C4591001 1231 12312444	MUSC	Myalgia/ muscle pain in left arm	1	21AUG2020	2/2	3	Yes		NA/TCN	R (22AUG2020)	N/N	
16-55/ C4591001 1231 12312464	NERV	Headache/ Intermittent headache	2	17SEP2020	8/80	1	No	O	NA/TC	R (05DEC2020)	N/N	
		Paraesthesia/ Upper limb paresthesias	2	17SEP2020	8/135	1	No	O	NA/TC/TCN	R (29JAN2021)	N/N	
	CONG	Arnold-Chiari malformation/ Chiari Syndrome Type I	2	03DEC2020	85/C	1	No	O	NA	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12312472	INFEC	Urinary tract infection/ urinary infection	2	21FEB2021	166/6	1	No	O	NA/TC	R (26FEB2021)	N/N	
16-55/ C4591001 1231 12312476	HEPAT	Bile duct stone/ Choledochal lithiasis	2	23JAN2021	136/C	3	No	O	NA	N	Y/N	
	HEPAT	Biliary colic/ Biliary colic	2	25FEB2021	169/C	3	No	O	NA/TC	N	Y/N	
16-55/ C4591001 1231 12312477	RESP	Rhinitis allergic/ worsening of allergic rhinitis	1	26AUG2020	7/1	1	No	O	NA	R (26AUG2020)	N/N	
	ENDO	Hypothyroidism/ WORSE OF HYPOTHYROIDISM	2	04FEB2021	147/36	1	No	O	NA/TC	R (11MAR2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	08MAR2021	1/2	1	Yes		NA/TC	R (09MAR2021)	N/N	
	NERV	Headache/ HEADACHE#	3	09MAR2021	2/C	2	Yes		NA/TC	N	N/N	
16-55/ C4591001 1231 12312488	INFEC	Vulvovaginal mycotic infection/ vaginal yeast infection	2	03OCT2020	23/4	2	No	O	NA/TC	R (06OCT2020)	N/N	
16-55/ C4591001 1231 12312491	CARD	Tachycardia/ tachycardia#	3	20FEB2021	1/1	1	No	O	NA	R (20FEB2021)	N/N	
	ENDO	Thyroid disorder/ Thyroid dysfunction#	3	20FEB2021	1/C	1	No	O	NA	N	N/Y	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	VASC	Hypertension/ arterial hypertension#	3	20FEB2021	1/1	1	No	O	NA	R (20FEB2021)	N/Y
16-55/ C4591001 1231 12312503	METAB	Vitamin D deficiency/ Hypovitaminosis D	2	28SEP2020	19/62	1	No	O	NA/TC	R (28NOV2020)	N/N
16-55/ C4591001 1231 12312529	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	30NOV2020	81/C		No	O	NA	UNK	N/N
16-55/ C4591001 1231 12312531	INFEC	Tooth infection/ dental infection	2	16SEP2020	4/10	1	No	O	NA/TC/TCN	R (25SEP2020)	N/N
16-55/ C4591001 1231 12312532	INFEC	Gingivitis/ gingivitis	2	29SEP2020	19/8	1	No	O	NA	R (06OCT2020)	N/N
16-55/ C4591001 1231 12312533	MUSC	Tendonitis/ exacerbation of tendonitis in the left wrist	2	30SEP2020	21/14	2	No	O	NA	R (13OCT2020)	N/N
16-55/ C4591001 1231 12312538	METAB	Vitamin D deficiency/ Hypovitaminosis D	2	16SEP2020	7/34	1	No	O	NA/TC	R (19OCT2020)	N/N
16-55/ C4591001 1231 12312546	NERV	Presyncope/ lipothymia (presyncope)	2	09OCT2020	29/1	2	No	O	NA	R (09OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12312559	NERV	Dizziness/ dizziness	1	23AUG2020	4/2	1	No	O	NA	R (24AUG2020)	N/N	
16-55/ C4591001 1231 12312572	INFEC	Abscess limb/ Right gluteal abscess	2	04FEB2021	150/C	1	No	O	NA/TC/TCN	RG	N/N	
	SKIN	Peau d'orange/ right buttock cellulite.	2	04FEB2021	150/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1231 12312573	NERV	Headache/ Intermittent Headache#	4	11MAR2021	22/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1231 12312576	RENAL	Renal colic/ Renal colic	2	20OCT2020	42/1	2	No	O	NA/TC	R (20OCT2020)	N/N	
	RENAL	Hydronephrosis/ Right hydronephrosis	2	05NOV2020	58/C	2	No	O	NA/TC	N	N/N	
		Nephrolithiasis/ nephrolithiasis	2	05NOV2020	58/47	3	No	O	NA/TC/TCN	R (21DEC2020)	Y/N	
	HEPAT	Cholelithiasis/ Gallstones	2	06NOV2020	59/3	1	No	O	NA	R (08NOV2020)	N/N	
	GENRL	Injection site erythema/ erythema at the injection site#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/Y	
16-55/ C4591001 1231 12312577	NEOPL	Metastases to central nervous system/ Brain metastasis	1	28AUG2020	9/C	2	No	O	P/TC	N	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12312593	CARD	Acute coronary syndrome/ Acute coronary syndrome without ST-T segment elevation	2	16SEP2020	6/4	2	No	O	NA/TC	R (19SEP2020)	Y/N	
		Bundle branch block right/ right bundle branch block	2	16SEP2020	6/4	1	No	O	NA	R (19SEP2020)	N/N	
16-55/ C4591001 1231 12312611	SKIN	Eczema/ Acute eczema in the cervical region and on the wrists	2	11SEP2020	3/20	1	No	O	NA/TC	R (30SEP2020)	N/N	
16-55/ C4591001 1231 12312617	RESP	Snoring/ primary snoring	2	11SEP2020	2/46	2	No	O	NA/TC/TCN	R (26OCT2020)	N/N	
	MUSC	Back pain/ Back pain	2	01OCT2020	22/3	1	No	O	NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001 1231 12312639	GENRL	Axillary pain/ right armpit pain	2	29SEP2020	21/2	1	No	O	NA/TC	R (30SEP2020)	N/N	
16-55/ C4591001 1231 12312645	RENAL	Renal colic/ mild renal colic	1	04SEP2020	16/2	1	No	O	NA/TC	R (05SEP2020)	N/N	
16-55/ C4591001 1231 12312647	MUSC	Myalgia/ myalgia in left hemibody predominantly left arm and cervical region	2	10SEP2020	1/23	1	Yes		NA/TC	R (02OCT2020)	N/N	
16-55/ C4591001	METAB	Type 2 diabetes mellitus/ Diabetes mellitus type 2	2	20DEC2020	104/57	2	No	O	NA/TC	RS (14FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12312648 16-55/ C4591001	REPRO	Menstruation delayed/ menstrual delay	2	18SEP2020	8/18	1	No	O	NA	R (05OCT2020)	N/N
1231 12312649 16-55/ C4591001	INFEC	Otitis externa/ External otitis#	3	08MAR2021	17/C	1	No	O	NA/TC	N	N/N
1231 12312660 16-55/ C4591001	INJ&P	Procedural dizziness/ post-blood extraction lipothymia (dizziness)	2	07OCT2020	29/1	2	No	O	NA	R (07OCT2020)	N/N
1231 12312666 16-55/ C4591001	CARD	Sinus tachycardia/ Sinus tachycardia	2	27SEP2020	19/3	2	No	O	NA	R (29SEP2020)	N/N
1231 12312674 16-55/ C4591001	INJ&P	Hand fracture/ left hand, ring finger, first phalange fracture.#	2	11MAR2021	185/C	1	No	O	NA/TCN	N	N/N
1231 12312681 16-55/ C4591001	INFEC	Rhinitis/ RHINITIS	2	13SEP2020	5/8	1	No	O	NA	R (20SEP2020)	N/N
1231 12312683 16-55/ C4591001	MUSC	Myalgia/ Myalgia on internal area of left arm#	3	26FEB2021	2/11	2	Yes		NA/TC	R (08MAR2021)	N/N
1231 12312687											

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	BLOOD	Lymphadenopathy/ Adenopathy in the left supraclavicular area#	3	27FEB2021	3/9	2	Yes		NA/TC	R (07MAR2021)	N/N
16-55/ C4591001 1231 12312688	MUSC	Pain in extremity/ Lower limb pain	2	09SEP2020	1/2	1	No	O	NA	R (10SEP2020)	N/N
16-55/ C4591001 1231 12312696	CARD	Acute coronary syndrome/ acute coronary syndrome	2	22NOV2020	74/48	3	No	O	NA/TC/TCN	R (08JAN2021)	Y/N
16-55/ C4591001 1231 12312712	GASTR	Toothache/ First lower left molar pain	2	20SEP2020	13/6	1	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1231 12312714	MUSC	Myalgia/ Muscle Pain in left arm	1	20AUG2020	1/6	2	Yes		NA/TC	R (25AUG2020)	N/N
	NERV	Headache/ Headache	1	20AUG2020	1/6	2	Yes		NA/TC	R (25AUG2020)	N/N
	MUSC	Back pain/ LOW BACK PAIN	1	06SEP2020	18/7	2	No	O	NA/TC	R (12SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	06SEP2020	18/7	2	No	O	NA/TC	R (12SEP2020)	N/N
	SKIN	Rash erythematous/ Pruritic erythematous rash of the legs, face, and trunk	2	10SEP2020	2/3	2	Yes		NA	R (12SEP2020)	N/N
	MUSC	Back pain/ Back pain	2	29SEP2020	21/98	1	No	O	NA/TC	R (04JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	PSYCH	Generalised anxiety disorder/ Generalized anxiety disorder	2	10DEC2020	93/23	2	No	O	NA/TC	RS (01JAN2021)	N/N	
	PSYCH	Generalised anxiety disorder/ worsening of generalized anxiety disorder#	3	04MAR2021	8/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1231 12312725	SKIN	Dermatitis allergic/ Skin allergy due to mites	2	14NOV2020	68/19	1	No	O	NA/TC	R (02DEC2020)	N/N	
16-55/ C4591001 1231 12312743	GENRL	Chest pain/ precordial pain	2	26SEP2020	18/5	2	No	O	NA/TC	R (30SEP2020)	N/N	
16-55/ C4591001 1231 12312747	NERV	Sciatica/ lumbocentralgia	2	12SEP2020	2/2	2	No	O	NA	R (13SEP2020)	N/N	
16-55/ C4591001 1231 12312753	GENRL	Injection site pain/ Injection site pain.	2	16OCT2020	36/85	1	Yes		NA	R (08JAN2021)	N/N	
16-55/ C4591001 1231 12312759	GENRL	Injection site pain/ Pain at the injection site	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N	
	GENRL	Fatigue/ fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	
		Pyrexia/ Fever	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N	
	MUSC	Arthralgia/ arthralgia	2	12SEP2020	2/C	1	Yes		NA/TC	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312761	NERV	Headache/ headache	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Paraesthesia/ left foot paresthesia	2	31OCT2020	51/2	1	No	O	NA	R (01NOV2020)	N/N
16-55/ C4591001 1231 12312770	MUSC	Paraesthesia/ right upper limb paresthesia	2	31OCT2020	51/3	1	No	O	NA	R (02NOV2020)	N/N
		Arthralgia/ Left knee pain	2	14SEP2020	4/24	1	No	O	NA	R (07OCT2020)	N/N
16-55/ C4591001 1231 12312787	GENRL	Pyrexia/ fever	2	12SEP2020	2/1	3	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1231 12312790	EAR	Sudden hearing loss/ sudden hearing loss in the right ear	2	02OCT2020	22/15	1	No	O	NA/TC	R (16OCT2020)	N/N
	NERV	Headache/ headache	1	29AUG2020	9/1	1	No	O	NA	R (29AUG2020)	N/N
16-55/ C4591001 1231 12312796	RESP	Dysphonia/ Worsening of dysphonia	2	28SEP2020	20/72	1	No	O	NA	R (08DEC2020)	N/N
16-55/ C4591001 1231 12312807	EYE	Keratitis/ corneal keratitis	2	23NOV2020	75/6	2	No	O	NA/TC	R (28NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312826	PSYCH	Anxiety/ exacerbation of anxiety disorder	1	04SEP2020	15/11	1	No	CD	NA/TC/TCN	R (14SEP2020)	N/N
16-55/ C4591001 1231 12312836	MUSC	Arthralgia/ Bilateral hip arthralgia	2	11SEP2020	1/72	1	Yes		NA	R (21NOV2020)	N/N
16-55/ C4591001 1231 12312840	NERV	Sciatica/ Lumbociatalgia	2	21SEP2020	11/122	3	No	O	NA/TC/TCN	R (20JAN2021)	N/N
16-55/ C4591001 1231 12312842	MUSC	Myalgia/ Generalized muscle pain#	4	05FEB2021	2/1	1	Yes		NA/TC	R (05FEB2021)	N/N
16-55/ C4591001 1231 12312847	MUSC	Back pain/ Low back pain	2	07DEC2020	86/51	1	No	O	NA/TC	R (26JAN2021)	N/N
16-55/ C4591001 1231 12312850	INJ&P	Animal bite/ Cat bite	2	28SEP2020	18/1	1	No	O	NA/TC/TCN	R (28SEP2020)	N/N
16-55/ C4591001 1231 12312853	NERV	Headache/ headache	2	16SEP2020	6/38	1	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1231 12312854	CARD	Arrhythmia supraventricular/ Arrhythmia supraventricular	2	17SEP2020	7/3	4	No	O	NA/TC/TCN	R (19SEP2020)	Y/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12312868	INJ&P	Craniocerebral injury/ minor cranioencephalic trauma	2	08OCT2020	1/1	1	No	O	NA	R (08OCT2020)	N/N	
	NERV	Syncope/ syncope	2	08OCT2020	1/1	3	No	O	NA/TCN	R (08OCT2020)	Y/N	
16-55/ C4591001 1231 12312871	INFEC	Skin infection/ Dermal infection	1	27AUG2020	7/9	1	No	O	NA/TC	R (04SEP2020)	N/N	
16-55/ C4591001 1231 12312874	NERV	Paraesthesia/ Paresthesias on the right side of the face#	4	28FEB2021	5/1	1	No	O	NA	R (28FEB2021)	N/N	
16-55/ C4591001 1231 12312883	BLOOD	Lymphadenopathy/ Left axillary adenopathy	1	27AUG2020	7/35	1	No	O	NA	R (30SEP2020)	N/N	
16-55/ C4591001 1231 12312892	GENRL	Pyrexia/ Febrile syndrome	2	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N	
16-55/ C4591001 1231 12312895	PSYCH	Anxiety/ Anxiety crisis	2	29SEP2020	19/1	2	No	O	NA	R (29SEP2020)	N/N	
16-55/ C4591001 1231 12312911	INFEC	Pharyngitis/ Pharyngitis	2	01OCT2020	23/11	1	No	O	NA/TC	R (11OCT2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12312923	NERV	Headache/ Frontal headache with retroorbital pain	1	28AUG2020	8/4	1	No	O	NA	R (31AUG2020)	N/N	
	SKIN	Hyperhidrosis/ Sweating	1	28AUG2020	8/4	1	No	O	NA	R (31AUG2020)	N/N	
16-55/ C4591001 1231 12312927	INFEC	Tooth infection/ Tooth infection	2	04OCT2020	24/5	1	No	O	NA/TC	R (08OCT2020)	N/N	
16-55/ C4591001 1231 12312928	GASTR	Oral mucosa haematoma/ left cheek internal mucosa hematoma	2	14SEP2020	4/2	1	No	O	NA	R (15SEP2020)	N/N	
16-55/ C4591001 1231 12312930	SKIN	Pruritus/ pruritus in hemiright face, neck, torso, upper back, upper abdomen both arms from shoulder to hand	2	04OCT2020	25/4	1	No	O	NA	R (07OCT2020)	N/N	
		Rash/ skin rash in hemiright face, neck, torso, upper back, upper abdomen both arms from shoulder to hand	2	04OCT2020	25/4	1	No	O	NA/TC	R (07OCT2020)	N/N	
16-55/ C4591001 1231 12312933	INFEC	Urinary tract infection/ urinary infection	2	25SEP2020	15/6	1	No	O	NA	R (30SEP2020)	N/N	
16-55/ C4591001 1231 12312941	MUSC	Myalgia/ Generalized Myalgia	1	31AUG2020	11/5	1	No	O	NA	R (04SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12312947	SKIN	Urticaria/ intermittent urticaria on lower limbs	2	07DEC2020	88/C	1	No	O	NA	N	N/N	
	METAB	Type 2 diabetes mellitus/ Type 2 diabetes	2	23SEP2020	13/C	1	No	O	NA/TC/TCN	RG	N/N	
16-55/ C4591001 1231 12312955	VASC	Hypertension/ Hypertension	2	23SEP2020	13/C	1	No	O	NA/TC/TCN	RG	N/N	
	RESP	Cough/ cough	2	30SEP2020	22/7	1	No	O	NA/TC	R (06OCT2020)	N/N	
16-55/ C4591001 1231 12312982	GENRL	Injection site pain/ mild pain at the injection site	1	23AUG2020	3/3	1	Yes		NA	R (25AUG2020)	N/N	
16-55/ C4591001 1231 12312984	INFEC	Suspected COVID-19/ Suspected COVID-19 Illness	2	09SEP2020	1/6	3	No	O	NA/TC	R (14SEP2020)	Y/N	
	PSYCH	Anxiety/ severe anxiety	2	23SEP2020	15/22	3	No	O	NA	R (14OCT2020)	N/N	
	GENRL	Injection site pain/ Shooting pain at injection site	2	11SEP2020	2/40	1	Yes		NA	R (20OCT2020)	N/N	
16-55/ C4591001 1231 12312985	GENRL	Injection site pruritus/ itching at the injection site	2	15OCT2020	36/1	1	Yes		NA	R (15OCT2020)	N/N	
	MUSC	Back pain/ Low back pain	1	08SEP2020	19/1	3	No	O	NA/TC/TCN	R (08SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312990	GENRL	Pyrexia/ febrile syndrome	1	22AUG2020	2/2	1	Yes		NA/TC	R (23AUG2020)	N/N
16-55/ C4591001 1231 12312991	MUSC	Muscle contracture/ interscapular muscle contracture in right dorsal region	2	12SEP2020	2/10	2	No	O	NA/TC/TCN	R (21SEP2020)	N/N
	INFEC	Cellulitis/ Cellulitis (left maxillary region)	2	02OCT2020	22/19	1	No	O	NA/TC	R (20OCT2020)	N/N
16-55/ C4591001 1231 12312994	INJ&P	Bone fissure/ LEFT ELBOW BONE FISSURE	2	03FEB2021	126/C	2	No	O	NA/TC	RG	N/N
		Fall/ fall from own height	2	03FEB2021	126/1	2	No	O	NA/TC	R (03FEB2021)	N/N
16-55/ C4591001 1231 12312996	RESP	Asthmatic crisis/ SEVERE ASTHMATIC CRYISIS	2	21OCT2020	42/9	3	No	O	NA/TC/TCN	R (29OCT2020)	Y/N
16-55/ C4591001 1231 12313002	RESP	Asthmatic crisis/ asthmatic crisis	2	15SEP2020	7/23	2	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1231 12313014	NERV	Paraesthesia/ paresthesias in right upper limb	2	27SEP2020	17/1	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001	EAR	Tinnitus/ Bilateral tinnitus	1	24AUG2020	4/5	1	No	O	NA	R (28AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12313026 16-55/ C4591001	NERV	Migraine/ Migraine	1	22AUG2020	2/1	2	No	O	NA/TC	R (22AUG2020)	N/N	
1231 12313028	GENRL	Injection site erythema/ Erythema at the injection site	2	12SEP2020	2/4	1	Yes		NA	R (15SEP2020)	N/N	
		Injection site lymphadenopathy/ Axillary and cervical lymphadenopathy ipsilateral to the injection site	2	12SEP2020	2/6	1	Yes		NA	R (17SEP2020)	N/N	
		Injection site warmth/ slight increase in temperature at injection site	2	12SEP2020	2/4	1	Yes		NA/TC	R (15SEP2020)	N/N	
	REPRO	Metrorrhagia/ Metrorrhagia	2	13SEP2020	3/7	1	No	O	NA	R (19SEP2020)	N/N	
	NERV	Optic neuritis/ Optic Neuritis	2	01DEC2020	82/C	3	No	O	NA/TC	RG	Y/N	
16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site	1	22AUG2020	1/3	2	Yes		NA/TC	R (24AUG2020)	N/N	
1231 12313034	NERV	Paraesthesia/ paresthesia in left arm	1	22AUG2020	1/3	2	No	O	NA/TC	R (24AUG2020)	N/N	
16-55/ C4591001	INFEC	Cystitis/ Cystitis	2	20SEP2020	8/5	1	No	O	NA/TC	R (24SEP2020)	N/N	
1231 12313045 16-55/ C4591001	GENRL	Pyrexia/ fever	2	11SEP2020	2/2	2	Yes		NA/TC	R (12SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12313061 16-55/ C4591001	PSYCH	Bruxism/ migraine associated with bruxism	1	22AUG2020	1/32	2	No	O	NA/TC	R (22SEP2020)	N/N
1231 12313070	PSYCH	Bruxism/ migraine associated with bruxism	1	06SEP2020	16/1	2	No	O	NA/TC	R (06SEP2020)	N/N
	GASTR	Haemorrhoids/ Worsening of external hemorrhoids#	3	13MAR2021	9/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001	GENRL	Asthenia/ Asthenia#	4	12FEB2021	1/2	1	Yes		NA/TC	R (13FEB2021)	N/N
1231 12313075		Pyrexia/ Fever#	4	12FEB2021	1/2	1	Yes		NA/TC	R (13FEB2021)	N/N
	MUSC	Arthralgia/ generalized arthralgias#	4	12FEB2021	1/2	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001	VASC	Hypotension/ Symptomatic hypotension	1	09SEP2020	19/1	1	No	O	NA	R (09SEP2020)	N/N
1231 12313087											
16-55/ C4591001	GENRL	Pyrexia/ Fever	2	15SEP2020	2/1	3	Yes		NA/TC	R (15SEP2020)	N/N
1231 12313088											
16-55/ C4591001	SKIN	Rash/ Skin rash on face#	3	19FEB2021	29/7	1	No	O	NA/TC	R (25FEB2021)	N/N
1231 12313098											

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12313107	INFEC	Rhinitis/ Rhinitis	2	05OCT2020	23/6	1	No	O	NA/TC	R (10OCT2020)	N/N	
16-55/ C4591001 1231 12313113	METAB	Vitamin D deficiency/ Vitamin D deficiency	2	06JAN2021	118/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1231 12313115	NERV	Headache/ headache	1	06SEP2020	16/11	1	No	O	NA	R (16SEP2020)	N/N	
16-55/ C4591001 1231 12313117	RESP	Rhinitis allergic/ Worsening of Allergic rhinitis	2	01OCT2020	21/2	1	No	O	NA	R (02OCT2020)	N/N	
16-55/ C4591001 1231 12313129	NERV	Headache/ right hemicrania headache	1	30AUG2020	9/2	2	No	O	NA/TC	R (31AUG2020)	N/N	
	NERV	Headache/ right hemicrania headache	1	09SEP2020	19/2	2	No	O	NA/TC	R (10SEP2020)	N/N	
	NERV	Headache/ Right hemicrania headache	2	20SEP2020	10/1	1	No	O	NA/TC	R (20SEP2020)	N/N	
16-55/ C4591001 1231 12313130	MUSC	Bone swelling/ Pain and swelling in the left cheekbone	1	07SEP2020	17/2	1	No	O	NA	R (08SEP2020)	N/N	
16-55/ C4591001	ENDO	Thyroid mass/ Thyroid nodules	2	30OCT2020	47/C	1	No	O	NA	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12313140	NEOPL	Papillary thyroid cancer/ Suspected papillary thyroid carcinoma	2	28JAN2021	137/C	3	No	O	NA/TCN	N	Y/N	
16-55/ C4591001 1231 12313160	MUSC	Arthralgia/ Joint pain	1	24AUG2020	3/3	3	No	O	NA/TC	R (26AUG2020)	N/N	
16-55/ C4591001 1231 12313161	REPRO	Menorrhagia/ Hypermenorrhea	2	07OCT2020	28/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1231 12313163	NERV	Syncope/ Vasovagal syncope	2	09OCT2020	29/1	1	No	O	NA	R (09OCT2020)	N/N	
16-55/ C4591001 1231 12313164	GASTR	Odynophagia/ Transient discomfort when swallowing	1	02SEP2020	12/1	1	No	O	NA	R (02SEP2020)	N/N	
16-55/ C4591001 1231 12313167	MUSC	Pain in extremity/ Lower right limb pain	2	09OCT2020	27/2	2	No	O	NA/TC	R (10OCT2020)	N/N	
16-55/ C4591001 1231 12313174	SKIN	Erythema nodosum/ erythema nodosum	2	22OCT2020	40/35	1	No	O	NA	R (25NOV2020)	N/N	
16-55/ C4591001	GENRL	Chest pain/ nonspecific chest pain	1	29AUG2020	8/3	1	No	O	NA	R (31AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12313175	MUSC	Neck pain/ Neck pain	1	18SEP2020	28/44	2	No	O	NA/TC	R (31OCT2020)	N/N	
16-55/ C4591001 1231 12313179	REPRO	Breast pain/ increased pain in the left breast	1	03SEP2020	13/49	1	No	O	NA	R (21OCT2020)	N/N	
16-55/ C4591001 1231 12313180	BLOOD	Anaemia/ exacerbation of anemia	2	01OCT2020	22/21	1	No	O	NA	R (21OCT2020)	N/N	
16-55/ C4591001 1231 12313180	NERV	Headache/ Headache	2	13NOV2020	64/1	1	No	O	NA	R (13NOV2020)	N/N	
16-55/ C4591001 1231 12313182	INJ&P	Road traffic accident/ Bike accident	2	24NOV2020	75/1	1	No	O	NA	R (24NOV2020)	N/N	
16-55/ C4591001 1231 12313184	INJ&P	Tooth fracture/ Rupture of 2 teeth (upper right incisor and upper right canine)	2	24NOV2020	75/C	1	No	O	NA/TC/TCN	RG	N/N	
16-55/ C4591001 1231 12313182	CARD	Palpitations/ palpitations	2	24SEP2020	14/89	1	No	O	NA	R (21DEC2020)	N/N	
16-55/ C4591001 1231 12313184	NERV	Carpal tunnel syndrome/ right carpal tunnel syndrome	2	15OCT2020	36/128	2	No	O	NA/TCN	R (19FEB2021)	Y/N	
16-55/ C4591001 1231 12313191	NERV	Headache/ Headache	2	14SEP2020	1/13	1	Yes		NA	R (26SEP2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313193	SKIN	Rash/ skin rash located on the face	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
	RENAL	Haematuria/ haematuria	1	25AUG2020	4/29	1	No	O	NA	R (22SEP2020)	N/N
16-55/ C4591001 1231 12313198	RENAL	Urinary bladder polyp/ Bladder polyp	2	18SEP2020	9/C	1	No	O	NA/TCN	RG	Y/N
	NERV	Migraine/ Exacerbation of migraine	2	20SEP2020	7/6	2	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1231 12313205	NERV	Headache/ Headache	2	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/Y
16-55/ C4591001 1231 12313211	NERV	Sciatica/ Worsening of lumbosciatalgia	2	22SEP2020	13/31	1	No	O	NA/TCN	R (22OCT2020)	N/N
	GENRL	Fatigue/ fatigue	1	28AUG2020	7/1	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001 1231 12313212	MUSC	Muscle contracture/ cervical contracture	1	11FEB2021	174/3	2	No	O	NA/TC	R (13FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	12SEP2020	3/1	1	Yes		NA	R (12SEP2020)	N/N
		Odynophagia/ Odynophagia	2	12SEP2020	3/3	1	No	O	NA	R (14SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12313216 16-55/ C4591001 1231 12313231 16-55/ C4591001 1231 12313232 16-55/ C4591001 1231 12313235 16-55/ C4591001 1231 12313238 16-55/ C4591001 1231 12313244	MUSC	Neck pain/ CERVICAL PAIN	2	14NOV2020	66/13	1	No	O	NA	R (26NOV2020)	N/N	
	NERV	Burning sensation/ Burning sensation in left elbow crease	2	18SEP2020	8/9	1	No	O	NA	R (26SEP2020)	N/N	
	NERV	Headache/ headache	2	09OCT2020	27/2	2	No	O	NA/TC	R (10OCT2020)	N/N	
	MUSC	Back pain/ low back pain	2	01JAN2021	110/52	1	No	O	NA/TC	R (21FEB2021)	N/N	
	GENRL	Injection site pain/ pain in the injection site	2	23SEP2020	11/3	1	Yes		NA	R (25SEP2020)	N/N	
	VASC	Systolic hypertension/ Systolic Hypertension	2	18NOV2020	67/7	1	No	O	NA	R (24NOV2020)	N/N	
	INJ&P	Muscle strain/ righth calf muscle strain	2	07OCT2020	27/6	1	No	O	NA	R (12OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue#	3	27FEB2021	2/2	1	Yes		NA/TC	R (28FEB2021)	N/N	
			Injection site pain/ Pain at injection site#	3	27FEB2021	2/2	1	Yes		NA/TC	R (28FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313249	NERV	Pyrexia/ Fever#	3	27FEB2021	2/2	1	Yes		NA/TC	R (28FEB2021)	N/N
		Headache/ Headache#	3	27FEB2021	2/2	1	Yes		NA/TC	R (28FEB2021)	N/N
16-55/ C4591001 1231 12313249	INFEC	Herpes zoster/ Herpes zoster	1	05SEP2020	15/6	1	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1231 12313255	ENDO	Hypothyroidism/ Exacerbation of hypothyroidism	2	16SEP2020	6/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12313257	REPRO	Ovarian cyst/ ovarian cyst	2	05OCT2020	26/45	1	No	O	NA	R (18NOV2020)	N/N
16-55/ C4591001 1231 12313259	EYE	Ulcerative keratitis/ Corneal ulcer in left eye	2	31JAN2021	144/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12313265	GASTR	Odynophagia/ odynophagia	2	09OCT2020	29/8	1	No	O	NA	R (16OCT2020)	N/N
16-55/ C4591001 1231 12313283	GASTR	Colitis/ Sigmoiditis#	2	20JAN2021	132/11	2	No	O	NA/TC	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	26JAN2021	1/2	2	Yes		NA	R (27JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pyrexia/ fever of 38.9 C#	3	27JAN2021	2/2	3	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1231 12313284	INFEC	Papilloma viral infection/ human papillomavirus infection	1	12SEP2020	22/1	1	No	O	NA	R (12SEP2020)	N/N
16-55/ C4591001 1231 12313289	GENRL	Asthenia/ Asthenia	2	07OCT2020	2/3	1	No	O	NA	R (09OCT2020)	N/N
16-55/ C4591001 1231 12313290	GASTR	Abdominal pain/ Nonspecific abdominal pain	2	09OCT2020	27/12	1	No	O	NA	R (20OCT2020)	N/N
	GENRL	Asthenia/ Asthenia#	3	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
		Injection site pain/ Pain at the injection site#	3	29JAN2021	1/2	3	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1231 12313302	INFEC	Genital herpes/ Genital herpes#	3	30JAN2021	3/17	2	No	O	NA/TC	R (15FEB2021)	N/N
16-55/ C4591001 1231 12313308	GENRL	Pyrexia/ FEVER (39 Degrees C)	2	11SEP2020	1/4	3	Yes		NA/TC	R (14SEP2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	2	15SEP2020	5/3	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001	NERV	Presyncope/ Vasovagal episode	2	09OCT2020	30/1	2	No	O	NA	R (09OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12313314 16-55/ C4591001	SURG	Cataract operation/ left eye cataract surgery	2	25SEP2020	15/1	2	No	O	NA	R (25SEP2020)	N/N
1231 12313316 16-55/ C4591001	PSYCH	Insomnia/ insomnia	2	29SEP2020	17/18	2	No	O	NA/TC	R (16OCT2020)	N/N
1231 12313326 16-55/ C4591001	GENRL	Injection site pruritus/ itching at the injection site	1	24AUG2020	2/15	1	Yes		NA/TC	R (07SEP2020)	N/N
1231 12313327 16-55/ C4591001	IMMUN	Seasonal allergy/ seasonal allergy	1	06SEP2020	15/48	1	No	O	NA/TC	R (23OCT2020)	N/N
1231 12313329	EAR	Allergic otitis media/ allergic otitis media	2	06OCT2020	24/33	1	No	O	NA	R (07NOV2020)	N/N
	GASTR	Nausea/ nausea	2	08OCT2020	26/2	1	No	CD	NA	R (09OCT2020)	N/N
16-55/ C4591001 1231 12313335	NERV	Dizziness/ DIZZINESS	2	12OCT2020	30/1	1	No	O	NA	R (12OCT2020)	N/N
16-55/ C4591001 1231 12313340	GENRL	Injection site haematoma/ Injection site hematoma left deltoid	1	23AUG2020	1/8	1	Yes		NA	R (30AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313345	MUSC	Back pain/ low back pain	2	25SEP2020	15/8	1	No	O	NA	R (02OCT2020)	N/N
	MUSC	Neck pain/ cervicalgia	2	12OCT2020	32/31	2	No	O	NA/TC/TCN	R (11NOV2020)	N/N
	NEOPL	Clear cell renal cell carcinoma/ Clear cell renal cell carcinoma	2	12OCT2020	32/C	3	No	O	NA/TCN	N	Y/N
	EAR	Tinnitus/ bilateral tinnitus	2	13OCT2020	33/44	2	No	O	NA	R (25NOV2020)	N/N
16-55/ C4591001 1231 12313353	MUSC	Back pain/ Right back pain	1	27AUG2020	5/4	1	No	O	NA	R (30AUG2020)	N/N
16-55/ C4591001 1231 12313356	INFEC	Rhinitis/ Rhinitis	2	14SEP2020	2/34	1	No	O	NA	R (17OCT2020)	N/N
16-55/ C4591001 1231 12313357	GENRL	Pyrexia/ Febrile Syndrome	1	25AUG2020	3/1	3	Yes		NA/TC	R (25AUG2020)	N/N
16-55/ C4591001 1231 12313369	INJ&P	Eyelid injury/ Right upper eyelid injury.	2	01DEC2020	79/4	1	No	O	NA	R (04DEC2020)	N/N
16-55/ C4591001 1231 12313370	NERV	Headache/ Headache	2	20SEP2020	8/2	2	No	O	NA/TC	R (21SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313378	INJ&P	Tooth fracture/ Rupture of the lower left second molar#	3	02FEB2021	9/1	1	No	O	NA/TC/TCN	R (02FEB2021)	N/N
16-55/ C4591001 1231 12313386	MUSC	Muscle contracture/ Cervical contracture	2	02OCT2020	22/3	2	No	O	NA/TC	R (04OCT2020)	N/N
16-55/ C4591001 1231 12313395	RESP	Rhinitis allergic/ allergic rhinitis	1	04OCT2020	43/2	1	No	O	NA	R (05OCT2020)	N/N
16-55/ C4591001 1231 12313400	CARD	Palpitations/ Palpitations	2	10OCT2020	28/1	1	No	O	NA	R (10OCT2020)	N/N
	VASC	Hypertension/ Hypertension	2	10OCT2020	28/1	1	No	O	NA	R (10OCT2020)	N/N
	IMMUN	Seasonal allergy/ Worsening of seasonal allergic rhinitis	2	29OCT2020	47/4	1	No	O	NA/TC	R (01NOV2020)	N/N
16-55/ C4591001 1231 12313404	NERV	Headache/ Headache	2	13SEP2020	1/8	1	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1231 12313406	GENRL	Fatigue/ Fatigue	1	24AUG2020	2/2	1	Yes		NA	R (25AUG2020)	N/N
16-55/ C4591001	SKIN	Acne/ Acne	1	05SEP2020	14/3	1	No	O	NA/TC	R (07SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12313419 16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	23AUG2020	1/7	2	Yes		NA/TC	R (29AUG2020)	N/N	
1231 12313429 16-55/ C4591001	INFEC	Vulvovaginal candidiasis/ vulvovaginal candidiasis	2	12OCT2020	29/4	1	No	O	NA/TC	R (15OCT2020)	N/N	
1231 12313430 16-55/ C4591001	SKIN	Acne/ acne exacerbation	2	02NOV2020	53/19	1	No	O	NA/TC	R (20NOV2020)	N/N	
1231 12313432 16-55/ C4591001	SKIN	Pityriasis rosea/ Pityriasis rosea	2	29SEP2020	17/30	2	No	O	NA/TC	R (28OCT2020)	N/N	
1231 12313437	INFEC	Renal abscess/ Right kidney abscess	2	07DEC2020	86/C	2	No	O	NA/TC/TCN	RG	Y/N	
16-55/ C4591001	GENRL	Pyrexia/ Fever	1	23AUG2020	1/2	1	Yes		NA/TC	R (24AUG2020)	N/N	
1231 12313454	INJ&P	Ligament sprain/ right ankle sprain	1	12SEP2020	21/26	3	No	O	NA/TC	R (07OCT2020)	N/N	
	INFEC	Furuncle/ boils in interglutal cleft and right inguinal region	1	02NOV2020	72/2	2	No	O	NA/TC	R (03NOV2020)	N/N	
16-55/ C4591001	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	08OCT2020	25/C	2	No	O	NA/TC	RG	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12313465 16-55/ C4591001	SURG	Tooth extraction/ extraction of 2 teeth#	1	22SEP2020	31/1	1	No	O	NA/TC/TCN	R (22SEP2020)	N/N	
1231 12313467 16-55/ C4591001	MUSC	Plantar fasciitis/ left plantar fasciitis	1	21SEP2020	30/8	1	No	O	NA/TC/TCN	R (28SEP2020)	N/N	
1231 12313470	NERV	Carpal tunnel syndrome/ Right hand carpal tunnel syndrome	2	25JAN2021	126/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1231 12313471	MUSC	Myalgia/ Deltoid pain	1	06SEP2020	15/1	1	No	O	NA/TCN	R (06SEP2020)	N/N	
	VASC	Haematoma/ hematoma in left deltoid region	2	18SEP2020	6/3	1	No	O	NA	R (20SEP2020)	N/N	
	MUSC	Muscle contracture/ cervical contracture	2	07NOV2020	56/7	2	No	O	NA/TC/TCN	R (13NOV2020)	N/N	
16-55/ C4591001 1231 12313489	SKIN	Rash/ GENERALIZED RASH	1	12SEP2020	21/7	1	No	O	NA	R (18SEP2020)	N/N	
16-55/ C4591001 1231 12313492	SOCCI	Stress at work/ Work Stress#	1	05OCT2020	44/32	1	No	O	NA/TC	R (05NOV2020)	N/N	
16-55/ C4591001	INFEC	Furuncle/ Furunculosis in axillary and left inginal region#	1	14OCT2020	53/11	1	No	O	NA/TC	R (24OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12313497 16-55/ C4591001	INFEC	Tooth infection/ upper left second molar infection#	2	01OCT2020	17/4	1	No	O	NA/TC	R (04OCT2020)	N/N
1231 12313501 16-55/ C4591001	HEPAT	Cholelithiasis/ cholelithiasis	2	24DEC2020	103/13	3	No	O	NA/TC/TCN	R (05JAN2021)	Y/N
1231 12313504 16-55/ C4591001	NERV	Headache/ Headache	1	04SEP2020	13/2	2	No	O	NA/TC	R (05SEP2020)	N/N
1231 12313507	GENRL	Injection site pain/ injection site pain in left arm	2	13SEP2020	1/26	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1231 12313508	MUSC	Arthralgia/ arthralgias#	2	01OCT2020	15/37	1	No	O	NA	R (06NOV2020)	N/N
16-55/ C4591001 1231 12313512	EAR	Vertigo/ Vertiginous syndrome#	1	05SEP2020	14/1	3	No	O	NA/TCN	R (05SEP2020)	N/N
16-55/ C4591001 1231 12313513	GENRL	Asthenia/ asthenia	2	22SEP2020	10/6	2	No	O	NA	R (27SEP2020)	N/N
		Pyrexia/ fever	2	22SEP2020	10/2	1	No	O	NA/TC/TCN	R (23SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313516	NERV	Headache/ headache	2	22SEP2020	10/3	1	No	O	NA/TC	R (24SEP2020)	N/N
	INFEC	Cellulitis/ facial cellulitis	1	23AUG2020	1/6	1	No	O	NA/TC	R (28AUG2020)	N/N
16-55/ C4591001 1231 12313525	MUSC	Intervertebral disc degeneration/ Multiple degenerative disc disease	2	22FEB2021	165/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1231 12313542	METAB	Metabolic syndrome/ Metabolic syndrome#	2	15OCT2020	31/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12313547	GASTR	Nausea/ nausea#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1231 12313551	GENRL	Pyrexia/ fever#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
	NERV	Headache/ headache#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1231 12313551	MUSC	Muscle contracture/ Cervical contracture#	1	21OCT2020	60/1	2	No	O	NA	R (21OCT2020)	N/N
	NERV	Headache/ Headache#	1	21OCT2020	60/1	2	No	O	NA/TC	R (21OCT2020)	N/N
16-55/ C4591001	MUSC	Tendonitis/ Right forearm Tendinitis	1	24AUG2020	2/108	1	No	O	NA	R (09DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12313575 16-55/ C4591001	NERV	Sciatica/ Lumbociatalgia	2	03OCT2020	23/1	2	No	O	NA	R (03OCT2020)	N/N	
1231 12313576 16-55/ C4591001	GENRL	Injection site erythema/ Erythema at the injection site of the left upper limb#	3	08MAR2021	1/C	1	Yes		NA	RG	N/N	
1231 12313580 16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	23AUG2020	1/3	1	Yes		NA	R (25AUG2020)	N/N	
1231 12313605	MUSC	Myalgia/ Myalgia	1	23AUG2020	1/3	2	Yes		NA	R (25AUG2020)	N/N	
	INFEC	Conjunctivitis/ Conjunctivitis	2	21NOV2020	70/3	1	No	O	NA/TC	R (23NOV2020)	N/N	
16-55/ C4591001 1231 12313613	SKIN	Rash/ upper limbs rash	2	13JAN2021	123/5	1	No	O	NA/TC/TCN	R (17JAN2021)	N/N	
16-55/ C4591001 1231 12313631	REPRO	Pruritus genital/ genital itching	2	15SEP2020	3/46	1	No	O	NA/TC	R (30OCT2020)	N/N	
16-55/ C4591001 1231 12313636	INV	Body temperature increased/ Body temperature increased	2	01OCT2020	18/2	1	No	O	NA	R (02OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12313637	NERV	Paraesthesia/ Paresthesia in the scapular and lumbar region	2	13SEP2020	1/30	1	No	O	NA	R (12OCT2020)	N/N	
16-55/ C4591001 1231 12313644	INFEC	Tinea versicolour/ Tinea Versicolor	2	06OCT2020	24/57	1	No	O	NA	R (01DEC2020)	N/N	
16-55/ C4591001 1231 12313646	MUSC	Myalgia/ Muscle pain	2	17SEP2020	2/2	3	No	O	NA/TC	R (18SEP2020)	N/N	
	MUSC	Trigger finger/ TRigger Finger	2	24SEP2020	9/16	2	No	O	NA/TC	R (09OCT2020)	N/N	
	EYE	Conjunctival haemorrhage/ subconjunctival hemorrhage	2	02OCT2020	17/3	1	No	O	NA/TC	R (04OCT2020)	N/N	
	INJ&P	Skin laceration/ Cutting wound second phalanx of left hand	2	11OCT2020	26/4	2	No	O	NA/TC	R (14OCT2020)	N/N	
16-55/ C4591001 1231 12313653	NERV	Ischaemic stroke/ Ischemic Stroke	2	06NOV2020	55/78	3	No	O	NA/TC	RS (22JAN2021)	Y/N	
16-55/ C4591001 1231 12313660	RENAL	Dysuria/ Dysuria#	3	05MAR2021	2/6	1	No	O	NA	R (10MAR2021)	N/N	
	INFEC	Urinary tract infection/ Urinary tract infection#	3	12MAR2021	9/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001	MUSC	Rheumatoid arthritis/ Rheumatoid arthritis	2	01NOV2020	50/C	1	No	O	NA	RG	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12313664	METAB	Hyperuricaemia/ Hyperuricemia	2	14NOV2020	63/77	1	No	O	NA/TC	RS (29JAN2021)	N/N	
16-55/ C4591001 1231 12313682	MUSC	Arthralgia/ Arthralgia in the hands and feet	2	01JAN2021	109/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1231 12313684	MUSC	Arthralgia/ left shoulder arthralgia	1	27AUG2020	4/8	1	No	O	NA	R (03SEP2020)	N/N	
16-55/ C4591001 1231 12313685	SKIN	Rash/ RASH ON LEFT ARM AND HEMITHORAX	2	18SEP2020	6/7	1	No	O	NA	R (24SEP2020)	N/N	
16-55/ C4591001 1231 12313689	HEPAT	Cholecystitis/ Cholecystitis	2	25DEC2020	104/35	2	No	O	NA/TC/TCN	R (28JAN2021)	Y/N	
16-55/ C4591001 1231 12313693	GASTR	Toothache/ Left hemiarcaled upper premolar tooth pain	2	07OCT2020	25/15	1	No	O	NA/TC/TCN	R (21OCT2020)	N/N	
16-55/ C4591001 1231 12313695	NERV	Dysgeusia/ Dysgeusia	2	19SEP2020	7/17	1	No	O	NA	R (05OCT2020)	N/N	
16-55/ C4591001	GENRL	Application site pain/ Application site pain#	3	25FEB2021	1/7	2	Yes		NA	R (03MAR2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12313698	MUSC	Myalgia/ Muscle pain#	3	25FEB2021	1/3	1	Yes		NA/TC	R (27FEB2021)	N/N	
16-55/ C4591001 1231 12313702	GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux	2	01OCT2020	17/91	1	No	O	NA/TC	R (30DEC2020)	N/N	
16-55/ C4591001 1231 12313713	GASTR	Toothache/ Left lower third molar tooth pain	2	03OCT2020	19/2	1	No	O	NA	R (04OCT2020)	N/N	
16-55/ C4591001 1231 12313715	GASTR	Nausea/ Nausea	2	13SEP2020	1/145	1	Yes		NA	R (04FEB2021)	N/N	
16-55/ C4591001 1231 12313715	INJ&P	Ankle fracture/ Right Ankle Fracture	2	02JAN2021	112/59	3	No	O	NA/TC/TCN	RS (01MAR2021)	Y/N	
16-55/ C4591001 1231 12313718	NERV	Fall/ Fall from own height. Migraine/ Migraine exacerbation	2	02JAN2021	112/1	3	No	O	NA	R (02JAN2021)	N/N	
16-55/ C4591001 1231 12313725	PSYCH	Anxiety disorder/ Anxiety disorder#	2	03OCT2020	21/4	2	No	O	NA	R (06OCT2020)	N/N	
16-55/ C4591001 1231 12313725	PSYCH	Anxiety disorder/ Anxiety disorder#	2	21FEB2021	162/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001	MUSC	Arthralgia/ Stabbing pain in scapular region bilateral intermittent	2	05OCT2020	23/15	2	No	O	NA/TC	R (19OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12313756	GENRL	Pain/ stabbing nonspecific trunk pain	2	10OCT2020	28/10	1	No	O	NA/TC	R (19OCT2020)	N/N	
	SKIN	Skin lesion/ Skin lesion in the left nasolabial fold	2	15DEC2020	94/C	2	No	O	NA	N	N/N	
16-55/ C4591001 1231 12313758	MUSC	Back pain/ muscle pain in the back	1	22OCT2020	60/4	1	No	O	NA/TC	R (25OCT2020)	N/N	
16-55/ C4591001 1231 12313759	GASTR	Diarrhoea/ Diarrhea	2	16OCT2020	33/2	2	No	O	NA/TC/TCN	R (17OCT2020)	N/N	
16-55/ C4591001 1231 12313773	GENRL	Asthenia/ Asthenia	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/N	
		Injection site pain/ Injection site pain	1	24AUG2020	1/63	1	Yes		NA	R (25OCT2020)	N/N	
16-55/ C4591001 1231 12313777	BLOOD	Lymphadenopathy/ left supraclavicular and axillary adenomegaly	2	16SEP2020	2/8	2	No	O	NA/TC	R (23SEP2020)	N/N	
16-55/ C4591001 1231 12313778	RESP	Allergic sinusitis/ Seasonal sinusitis	2	22SEP2020	10/6	1	No	O	NA/TC	R (27SEP2020)	N/N	
16-55/ C4591001	GASTR	Aphthous ulcer/ oral aphthae	2	15SEP2020	3/8	2	No	O	NA/TC	R (22SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12313780	INFECTION	Appendicitis/ Acute appendicitis	2	22OCT2020	39/16	2	No	O	NA/TC/TCN	R (06NOV2020)	Y/N	
1231 12313785	GASTROINTESTINAL	Toothache/ Toothache	2	06OCT2020	24/11	1	No	O	NA/TC	R (16OCT2020)	N/N	
1231 12313818	VASCULAR	Intermittent claudication/ intermittent claudication	1	27AUG2020	3/21	2	No	O	NA/TC	R (16SEP2020)	N/N	
1231 12313825	VASCULAR	Varicose vein/ Worsening pain from varicose veins	2	07OCT2020	23/4	1	No	O	NA/TC	R (10OCT2020)	N/N	
1231 12313831	GENERAL	Asthenia/ asthenia	1	26AUG2020	2/2	1	No	O	NA	R (27AUG2020)	N/N	
1231 12313832	MUSCULOSKELETAL	Back pain/ low back pain	2	07OCT2020	22/35	1	No	O	NA/TC/TCN	R (10NOV2020)	N/N	
1231 12313836	PSYCHIATRY	Depression/ Depressive syndrome#	2	22FEB2021	160/C	1	No	CD	NA/TC	N	N/N	
1231 12313837												

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313854	GENRL	Injection site pain/ Pain at the injection site	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/Y
16-55/ C4591001 1231 12313862	MUSC	Myalgia/ myalgia	2	20SEP2020	7/23	1	Yes		NA	R (12OCT2020)	N/N
16-55/ C4591001 1231 12313877	INFEC	Otitis media acute/ Left acute otitis media	2	09OCT2020	24/8	1	No	O	NA/TC	R (16OCT2020)	N/N
		Pharyngitis bacterial/ bacterial pharyngitis	2	09OCT2020	24/8	1	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1231 12313879	GENRL	Injection site pain/ Injection site pain	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/Y
	INJ&P	Exposure during pregnancy/ Exposure to Investigation product during pregnancy	1	12SEP2020	19/C		No	O	NA	UNK	N/N
	NERV	Headache/ headache	2	14SEP2020	2/9	3	No	O	NA/TC	R (22SEP2020)	N/N
	INFEC	Urinary tract infection/ Supected Complicated Urinary Tract Infection	2	31JAN2021	141/18	3	No	O	NA/TC	R (17FEB2021)	Y/N
16-55/ C4591001 1231 12313884	BLOOD	Lymphadenopathy/ right axillary adenopathy	2	18SEP2020	3/5	1	No	O	NA	R (22SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313893	GENRL	Vessel puncture site haematoma/ Blood draw site hematoma on left arm	2	14OCT2020	32/8	1	No	O	NA	R (21OCT2020)	N/N
16-55/ C4591001 1231 12313896	GENRL	Injection site pain/ Injection Site Pain	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/Y
	GASTR	Dental caries/ Caries in premolar and molar	1	01SEP2020	8/53	2	No	O	NA/TC/TCN	R (23OCT2020)	N/N
16-55/ C4591001 1231 12313902	INJ&P	Contusion/ Traumatic contusion in the arms	1	04SEP2020	11/9	2	No	O	NA/TCN	R (12SEP2020)	N/N
		Contusion/ Traumatic contusion in the trunk	1	04SEP2020	11/9	2	No	O	NA/TC/TCN	R (12SEP2020)	N/N
		Contusion/ Traumatic contusion on the face	1	04SEP2020	11/9	2	No	O	NA/TC/TCN	R (12SEP2020)	N/N
	PSYCH	Panic attack/ Panic attack	1	04SEP2020	11/42	2	No	O	NA/TC/TCN	R (15OCT2020)	N/N
16-55/ C4591001 1231 12313904	CARD	Palpitations/ Intermittent Palpitations.	2	15SEP2020	3/6	1	No	O	NA	R (20SEP2020)	N/N
	INV	Body temperature increased/ Body temperature increased	2	15SEP2020	3/6	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C4591001 1231 12313915	MUSC	Back pain/ low back pain#	3	27JAN2021	8/1	1	No	O	NA/TC	R (27JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12313916	MUSC	Back pain/ Low back pain	2	30SEP2020	18/26	1	No	O	NA/TC	R (25OCT2020)	N/N	
16-55/ C4591001 1231 12313921	MUSC	Muscle contracture/ Cervical muscular contracture	1	07SEP2020	14/6	1	No	O	NA/TC/TCN	R (12SEP2020)	N/N	
16-55/ C4591001 1231 12313925	RESP	Interstitial lung disease/ Right lung interstitial pneumonia	1	02SEP2020	9/8	2	No	O	NA/TC	R (09SEP2020)	N/N	
16-55/ C4591001 1231 12313927	MUSC	Arthralgia/ left shoulder pain	2	18SEP2020	6/C	2	No	O	NA/TC	N	N/N	
		Rotator cuff syndrome/ left rotator cuff tendonitis	2	18SEP2020	6/120	2	No	O	NA/TC/TCN	R (15JAN2021)	N/N	
16-55/ C4591001 1231 12313931	GASTR	Diarrhoea/ diarrhea	1	28AUG2020	4/3	1	No	O	NA	R (30AUG2020)	N/N	
	MUSC	Synovial cyst/ ganglion in right wrist joint	2	22SEP2020	10/C	1	No	O	NA	RG	N/N	
	MUSC	Back pain/ low back pain#	4	07MAR2021	23/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1231 12313935	GENRL	Injection site pain/ mild pain at the injection site	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12313939	GASTR	Diarrhoea/ Diarrhea	1	16SEP2020	23/2	1	No	O	NA	R (17SEP2020)	N/N	
16-55/ C4591001 1231 12313941	NERV	Headache/ Headache	1	30AUG2020	6/50	1	No	O	NA/TC	R (18OCT2020)	N/N	
16-55/ C4591001 1231 12313960	GENRL	Swelling face/ Swelling in cheeks	2	16OCT2020	32/1	1	No	O	NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001 1231 12313964	GENRL	Application site erythema/ Erythema at the application site	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N	
		Application site pain/ Pain at the application site	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N	
16-55/ C4591001 1231 12313967	MUSC	Tendon disorder/ righ shoulder tendinosis	1	07SEP2020	14/3	1	No	O	NA/TC	R (09SEP2020)	N/N	
16-55/ C4591001 1231 12313968	GENRL	Injection site pain/ Pain at injection site	1	26AUG2020	2/3	2	Yes		NA/TC	R (28AUG2020)	N/N	
16-55/ C4591001 1231 12313971	INJ&P	Wound/ Superficial incised wound on the forehead	2	25JAN2021	132/1	2	No	O	NA/TCN	R (25JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	IMMUN	Drug hypersensitivity/ Allergic reaction to naproxen	2	26JAN2021	133/1	2	No	O	NA/TC	R (26JAN2021)	N/N
16-55/ C4591001 1231 12313984	INJ&P	Ligament sprain/ right ankle sprain	2	30SEP2020	16/28	2	No	O	NA/TCN	R (27OCT2020)	N/N
16-55/ C4591001 1231 12313989	INFEC	Rhinitis/ rhinitis	2	24SEP2020	9/19	1	No	O	NA/TC	R (12OCT2020)	N/N
16-55/ C4591001 1231 12313993	PSYCH	Depression/ Worsening Depression	2	14OCT2020	30/21	2	No	O	NA/TC/TCN	R (03NOV2020)	N/N
16-55/ C4591001 1231 12313996	MUSC	Back pain/ Low back pain	2	09FEB2021	149/29	1	No	O	NA/TC/TCN	R (09MAR2021)	N/N
16-55/ C4591001 1231 12313998	INJ&P	Exposure during pregnancy/ Drug exposed pregnancy	2	25DEC2020	102/35		No	O	NA	R (28JAN2021)	N/N
	PREG	Abortion spontaneous complete/ Complete spontaneous abortion#	2	24JAN2021	132/16	3	No	O	NA/TC	R (08FEB2021)	Y/N
16-55/ C4591001 1231 12314010	INJ&P	Skin injury/ ERYTHEMATOUS AND FLAKY SKIN INJURIES IN TRUNK AND THIGHS	2	02OCT2020	18/25	1	No	O	NA	R (26OCT2020)	N/N
16-55/ C4591001	BLOOD	Iron deficiency anaemia/ Iron deficiency anemia#	3	01FEB2021	4/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12314016 16-55/ C4591001	GASTR	Dry mouth/ xerostomia	2	12OCT2020	28/42	1	No	O	NA/TCN	R (22NOV2020)	N/N	
1231 12314022 16-55/ C4591001	MUSC	Musculoskeletal chest pain/ muscle-type chest pain	2	22SEP2020	9/3	1	No	O	NA	R (24SEP2020)	N/N	
1231 12314032	GENRL	Chest pain/ Intermittent chest pain in the right pectoral	2	06OCT2020	23/2	1	No	O	NA	R (07OCT2020)	N/N	
	MUSC	Myalgia/ muscle pain in the upper inner third of the righth arm	2	06OCT2020	23/2	1	No	O	NA	R (07OCT2020)	N/N	
16-55/ C4591001	BLOOD	Lymphadenopathy/ Left axillary adenopathy	1	01SEP2020	8/17	2	No	O	NA	R (17SEP2020)	N/N	
1231 12314033 16-55/ C4591001	INJ&P	Exposure during pregnancy/ exposure during pregnancy	1	31AUG2020	7/71		No	O	NA	R (09NOV2020)	N/N	
1231 12314059 16-55/ C4591001	SKIN	Rash papular/ Papular rash in deltoid region of the right arm.	2	17OCT2020	33/4	1	No	O	NA/TC/TCN	R (20OCT2020)	N/N	
1231 12314073 16-55/ C4591001	RENAL	Pollakiuria/ NOCTURNE POLLAKIURIA	1	28AUG2020	3/62	2	No	O	NA	R (28OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12314075	MUSC	Back pain/ LOW BACK PAIN WORSENING	1	30AUG2020	5/24	2	No	O	NA/TC	R (22SEP2020)	N/N
	HEPAT	Cholelithiasis obstructive/ Cholestatic syndrome secondary to lithiasis#	2	05MAR2021	170/6	2	No	O	NA/TC	R (10MAR2021)	Y/N
16-55/ C4591001 1231 12314084	INFEC	Tooth infection/ Left wisdom tooth infection	1	28AUG2020	3/27	2	No	O	NA/TC/TCN	R (23SEP2020)	N/N
16-55/ C4591001 1231 12314104	INJ&P	Chest injury/ Trauma to the posterior region of the right rib cage	2	05NOV2020	52/1	1	No	O	NA/TC	R (05NOV2020)	N/N
	MUSC	Musculoskeletal chest pain/ pain in right posterior rib	2	05NOV2020	52/14	2	No	O	NA/TC	R (18NOV2020)	N/N
	NEOPL	Lipoma/ Lipoma in the right mid-axillary line	2	06NOV2020	53/1	1	No	O	NA	R (06NOV2020)	N/N
16-55/ C4591001 1231 12314111	EAR	Vertigo/ Vertigo	1	26AUG2020	1/13	1	No	O	NA/TC/TCN	R (07SEP2020)	N/N
	MUSC	Myalgia/ myalgia	1	26AUG2020	1/6	2	Yes		NA/TC/TCN	R (31AUG2020)	N/N
16-55/ C4591001 1231 12314128	BLOOD	Lymphadenopathy/ Left cervical adenopathy	1	27AUG2020	2/37	1	No	O	NA	R (02OCT2020)	N/N
	EAR	Ear pain/ left otalgia	1	27AUG2020	2/3	1	No	O	NA	R (29AUG2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12314132	GENRL	Injection site pain/ pain at the injection site.	1	11SEP2020	17/53	1	Yes		NA/TC	R (02NOV2020)	N/N
	NERV	Paraesthesia/ tingling in left arm	1	11SEP2020	17/C	1	Yes		NA/TC	N	N/N
16-55/ C4591001 1231 12314134	INJ&P	Exposure during pregnancy/ Drug Exposed Pregnancy	1	07DEC2020	104/69		No	O	NA	R (13FEB2021)	N/N
	PREG	Abortion incomplete/ incomplete abortion	1	11FEB2021	170/3	3	No	O	NA/TC/TCN	R (13FEB2021)	Y/N
16-55/ C4591001 1231 12314135	NERV	Headache/ Headache	2	12OCT2020	29/2	2	No	O	NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 1231 12314137	GENRL	Asthenia/ asthenia	2	19SEP2020	6/3	3	No	O	NA	R (21SEP2020)	N/N
	EYE	Blepharospasm/ blepharospasm	2	30SEP2020	17/3	1	No	O	NA	R (02OCT2020)	N/N
	ENDO	Hypothyroidism/ worsening of hypothyroidism	2	04MAR2021	172/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12314143	SURG	Dental care/ dental treatment	2	13OCT2020	30/1	1	No	O	NA/TC	R (13OCT2020)	N/N
16-55/ C4591001	ENDO	Hypothyroidism/ Hypothyroidism	1	01SEP2020	7/46	1	No	O	NA/TC	R (16OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12314152	GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux	1	01SEP2020	7/46	1	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1231 12314154	INFEC	Tooth infection/ Odontogenic infection#	4	13MAR2021	29/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12314155	INJ&P	Ligament sprain/ Right ankle sprain	2	19SEP2020	6/6	2	No	O	NA/TC/TCN	R (24SEP2020)	N/N
16-55/ C4591001 1231 12314156	GENRL	Injection site pain/ Injection site pain#	3	24FEB2021	2/3	1	Yes		NA/TC	R (26FEB2021)	N/N
		Pyrexia/ Fever#	3	24FEB2021	2/1	1	Yes		NA/TC	R (24FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	3	24FEB2021	2/1	1	Yes		NA/TC	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	3	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1231 12314188	REPRO	Menstruation delayed/ Menstrual delay	2	15SEP2020	2/58	1	No	O	NA/TC	R (11NOV2020)	N/N
16-55/ C4591001 1231 12314198	GENRL	Injection site pain/ Local pain at injection site	1	27AUG2020	2/2	2	Yes		NA/TC	R (28AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12314202	EYE	Conjunctival haemorrhage/ Subconjunctival hemorrhage left eye	2	12OCT2020	29/14	1	No	O	NA	R (25OCT2020)	N/N	
16-55/ C4591001 1231 12314203	INFEC	Pustule/ Pustulosis in upper limbs and lumbar area.	2	17SEP2020	3/43	1	No	O	NA	R (29OCT2020)	N/N	
16-55/ C4591001 1231 12314212	INJ&P	Joint injury/ Right knee trauma	2	29SEP2020	14/42	2	No	O	NA/TC/TCN	R (09NOV2020)	N/N	
16-55/ C4591001 1231 12314223	GASTR	Odynophagia/ odynophagia	2	29SEP2020	16/3	1	No	O	NA/TC	R (01OCT2020)	N/N	
	REPRO	Metrorrhagia/ Metrorrhagia	2	01MAR2021	169/8	1	No	O	NA	R (08MAR2021)	N/N	
16-55/ C4591001 1231 12314224	NERV	Sciatica/ Flare-up of sciatica	2	19SEP2020	5/52	2	No	O	NA/TC/TCN	R (09NOV2020)	N/N	
	MUSC	Arthralgia/ Migratory arthralgias in upper limbs	2	10OCT2020	26/4	2	No	O	NA	R (13OCT2020)	N/N	
16-55/ C4591001 1231 12314229	GASTR	Irritable bowel syndrome/ irritable bowel	1	01SEP2020	7/45	1	No	O	NA/TC/TCN	R (15OCT2020)	N/N	
16-55/ C4591001	SURG	Tooth extraction/ tooth extraction#	4	26FEB2021	9/1	1	No	O	NA/TC	R (26FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12314230 16-55/ C4591001	NERV	Headache/ headache	2	23SEP2020	8/4	1	No	O	NA	R (26SEP2020)	N/N	
1231 12314251 16-55/ C4591001	INJ&P	Radius fracture/ Intra-articular Left Radius Fracture	2	09OCT2020	3/5	2	No	O	NA/TC/TCN	R (13OCT2020)	N/N	
1231 12314256	SOCCI	High risk sexual behaviour/ Risky sexual behavior	2	24OCT2020	18/1	1	No	O	NA/TC	R (24OCT2020)	N/N	
16-55/ C4591001 1231 12314263	GENRL	Injection site papule/ multiple small itchy papules located on the left arm, extending from the injection site to the elbow	1	31AUG2020	6/3	1	Yes		NA	R (02SEP2020)	N/N	
	GENRL	Injection site papule/ multiple small itchy papules located on the left arm, extending from the injection site to the elbow	2	18SEP2020	5/3	1	Yes		NA/TC	R (20SEP2020)	N/N	
16-55/ C4591001 1231 12314265	MUSC	Synovitis/ Synovitis in both knees	1	31AUG2020	6/C	2	No	O	NA/TC/TCN	RG	N/N	
16-55/ C4591001 1231 12314267	INFEC	Tonsillitis/ tonsillitis	2	08OCT2020	25/6	2	No	O	NA/TC	R (13OCT2020)	N/N	
16-55/ C4591001	GASTR	Stomatitis/ stomatitis	2	19SEP2020	2/19	2	No	O	NA/TC	R (07OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12314269 16-55/ C4591001	RENAL	Dysuria/ Dysuria	2	01OCT2020	18/39	1	No	O	NA	R (08NOV2020)	N/N	
1231 12314270 16-55/ C4591001	EAR	Tinnitus/ Left ear tinnitus	2	23SEP2020	8/77	2	No	O	NA/TC/TCN	R (08DEC2020)	N/N	
1231 12314277	MUSC	Temporomandibular joint syndrome/ Temporomandibular joint dysfunction	2	23SEP2020	8/77	2	No	O	NA/TC/TCN	R (08DEC2020)	N/N	
16-55/ C4591001	GENRL	Pyrexia/ fever	2	15SEP2020	2/2	3	Yes		NA/TC	R (16SEP2020)	N/N	
1231 12314278 16-55/ C4591001	SKIN	Skin lesion/ Skin lesion on the thumb of the right hand#	4	28FEB2021	19/8	1	No	O	NA/TC/TCN	R (07MAR2021)	N/N	
1231 12314280 16-55/ C4591001	GASTR	Abdominal pain upper/ Epigastralgia	1	28AUG2020	3/15	2	No	O	NA	R (11SEP2020)	N/N	
1231 12314290 16-55/ C4591001	GENRL	Pyrexia/ Fever#	3	25FEB2021	1/3	2	Yes		NA	R (27FEB2021)	N/N	
1231 12314294	MUSC	Arthralgia/ Generalized arthralgias#	3	25FEB2021	1/3	2	Yes		NA	R (27FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12314297	METAB	Myalgia/ generalized myalgias#	3	25FEB2021	1/3	2	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1231 12314297	METAB	Diabetes mellitus inadequate control/ Uncompensated diabetes	2	17SEP2020	4/14	1	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1231 12314298	GASTR	Gastritis/ Worsening gastritis	1	27AUG2020	2/3	1	No	O	NA/TC	R (29AUG2020)	N/N
16-55/ C4591001 1231 12314308	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	10DEC2020	86/C		No	O	NA	UNK	N/N
16-55/ C4591001 1231 12314327	GENRL	Injection site pain/ pain at injection site#	4	13FEB2021	1/5	2	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1231 12314329	INFEC	Pharyngitis/ Pharyngitis	1	27AUG2020	2/5	2	No	O	NA/TC	R (31AUG2020)	N/N
16-55/ C4591001 1231 12314343	INFEC	Pharyngotonsillitis/ Putaceous pharyngotonsillitis	1	29AUG2020	4/4	2	No	O	NA/TC	R (01SEP2020)	N/N
16-55/ C4591001 1231 12314351	GENRL	Application site pain/ Pain at application site.#	4	12MAR2021	2/2	2	Yes		NA/TC	R (13MAR2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12314358	MUSC	Pyrexia/ Fever#	4	12MAR2021	2/1	3	Yes		NA/TC	R (12MAR2021)	N/N
		Arthralgia/ Arthralgia in left elbow	2	24SEP2020	11/121	1	No	O	NA	R (22JAN2021)	N/N
		Musculoskeletal chest pain/ Intermittent chest muscle pain	2	24SEP2020	11/113	1	No	O	NA/TC	R (14JAN2021)	N/N
16-55/ C4591001 1231 12314360	METAB	Vitamin D deficiency/ Hypovitaminosis D	2	27OCT2020	44/C	1	No	O	NA/TC	RG	N/N
	GENRL	Chills/ Chills	2	09OCT2020	24/1	1	No	O	NA	R (09OCT2020)	N/N
16-55/ C4591001 1231 12314368	BLOOD	Fatigue/ Fatigue	2	09OCT2020	24/1	1	No	O	NA	R (09OCT2020)	N/N
		Lymphadenopathy/ Supraclavicular adenopathy (left)	1	29AUG2020	4/56	1	No	O	NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1231 12314372	RESP	Tonsillar hypertrophy/ swollen tonsils	2	18SEP2020	3/21	1	No	O	NA/TC	R (08OCT2020)	N/N
	INJ&P	Exposure during pregnancy/ Drug Exposed Pregnancy	2	25OCT2020	39/C		No	O	NA	UNK	N/N
16-55/ C4591001 1231 12314395	REPRO	Haemospermia/ Hemospermia	2	26SEP2020	12/1	1	No	O	NA	R (26SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INJ&P	Exposure during pregnancy/ Exposure during pregnancy (female partner)	2	12NOV2020	59/C		No	O	NA	UNK	N/N
16-55/ C4591001 1231 12314400	RESP	Asthma/ asthma exacerbation	2	26SEP2020	11/5	1	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1231 12314405	EAR	Vertigo/ two second-long episodes of vertigo	1	27AUG2020	1/1	1	No	O	NA	R (27AUG2020)	N/N
	GENRL	Injection site pain/ local pain at the injection site	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1231 12314407	INJ&P	Multiple injuries/ Polytrauma	2	20SEP2020	5/93	3	No	O	NA/TC/TCN	R (21DEC2020)	Y/N
	RESP	Epistaxis/ Epistaxis	2	20SEP2020	5/30	2	No	O	NA/TCN	R (19OCT2020)	N/N
	VASC	Subgaleal haematoma/ subgaleal hematoma	2	20SEP2020	5/51	2	No	O	NA/TCN	R (09NOV2020)	N/N
16-55/ C4591001 1231 12314416	NERV	Sciatica/ lumbosciatica	1	11SEP2020	16/54	1	No	O	NA/TC	R (03NOV2020)	N/N
16-55/ C4591001 1231 12314417	NERV	Syncope/ Vasovagal syncope	2	15DEC2020	91/1	2	No	O	NA/TCN	R (15DEC2020)	N/N
16-55/ C4591001	INFEC	Urinary tract infection/ urinary infection	2	20OCT2020	36/6	1	No	O	NA	R (25OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12314421 16-55/ C4591001 1231 12314429	INJ&P	Fall/ Fall from his own height#	4	03MAR2021	20/5	1	No	O	NA/TC	R (07MAR2021)	N/N
16-55/ C4591001 1231 12314434	INJ&P	Chest injury/ Right lower thoracic trauma#	4	07MAR2021	24/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12314434	VASC	Hypertension/ arterial hypertension	1	01SEP2020	6/85	2	No	O	NA/TC	R (24NOV2020)	N/N
16-55/ C4591001 1231 12314435	GENRL	Asthenia/ asthenia	1	27AUG2020	1/1	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C4591001 1231 12314436	GENRL	Pyrexia/ fever	2	15SEP2020	1/2	3	No	O	NA	R (16SEP2020)	N/N
16-55/ C4591001 1231 12314450	INFEC	Anal fistula infection/ anal fistula acute infection	1	15SEP2020	20/5	2	No	O	NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1231 12314464	EAR	Tinnitus/ tinnitus bilateral, intermittent	1	10SEP2020	15/38	1	No	O	NA	R (17OCT2020)	N/N
	CARD	Palpitations/ PALPITATIONS	2	16SEP2020	1/13	1	No	O	NA	R (28SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12314474	GASTR	Dental caries/ Dental Cavities	2	10OCT2020	25/8	1	No	O	NA/TC/TCN	R (17OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site.	1	27AUG2020	1/1	2	Yes		NA	R (27AUG2020)	N/N	
16-55/ C4591001 1231 12314477	INFEC	Periodontitis/ Right lower molar periodontitis	1	28AUG2020	2/7	2	No	O	NA/TC	R (03SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N	
16-55/ C4591001 1231 12314482		Injection site pain/ Injection site pain	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N	
	MUSC	Myalgia/ Generalized muscle pain	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N	
	RESP	Rhinorrhoea/ rhinorrhea	2	23SEP2020	6/11	1	No	O	NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001 1231 12314486	INJ&P	Penis injury/ PENIS INJURY	2	15SEP2020	1/8	1	No	O	NA/TCN	R (22SEP2020)	N/N	
16-55/ C4591001 1231 12314486	RESP	Rhinitis allergic/ Allergic rhinitis	2	07OCT2020	23/3	1	No	O	NA	R (09OCT2020)	N/N	
16-55/ C4591001 1231 12314494	GASTR	Food poisoning/ Food poisoning	2	03FEB2021	141/5	3	No	O	NA/TC	R (07FEB2021)	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12314499	INFEC	Rhinitis/ Rhinitis	2	28SEP2020	13/3	1	No	O	NA/TC	R (30SEP2020)	N/N	
	MUSC	Back pain/ low back pain	2	30SEP2020	15/6	1	No	O	NA	R (05OCT2020)	N/N	
	MUSC	Pain in extremity/ Nonspecific upper limb pain.	2	18OCT2020	33/2	2	No	O	NA/TC	R (19OCT2020)	N/N	
	REPRO	Metrorrhagia/ Metrorrhagia	2	11NOV2020	57/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1231 12314511	GENRL	Pyrexia/ Fever	1	28AUG2020	2/3	2	Yes		NA/TC	R (30AUG2020)	N/N	
	GASTR	Stomatitis/ Stomatitis	1	07SEP2020	12/6	1	No	O	NA	R (12SEP2020)	N/N	
16-55/ C4591001 1231 12314513	NERV	Headache/ Headache	2	15SEP2020	1/15	1	Yes		NA/TC	R (29SEP2020)	N/N	
16-55/ C4591001 1231 12314515	GENRL	Axillary pain/ Regional pain (left axillary hollow)	2	29OCT2020	45/3	1	No	O	NA	R (31OCT2020)	N/N	
16-55/ C4591001 1231 12314526	NERV	Dizziness/ Dizziness	2	06OCT2020	20/1	1	No	O	NA	R (06OCT2020)	N/N	
16-55/ C4591001	INFEC	Herpes zoster/ HERPES ZOSTER RIGHT THORACIC of one dermatome	2	01NOV2020	48/46	2	No	O	NA/TC	R (16DEC2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12314528	MUSC	Myalgia/ Generalized muscle pain	2	17SEP2020	2/2	3	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1231 12314529	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	30SEP2020	3/C		No	O	NA	UNK	N/N
1231 12314531	INFEC	Urinary tract infection/ Complicated urinary infection	2	08JAN2021	103/47	3	No	O	NA/TC	R (23FEB2021)	Y/N
16-55/ C4591001 1231 12314542	MUSC	Arthralgia/ Arthralgia	1	01SEP2020	6/50	1	No	O	NA/TC	R (20OCT2020)	N/N
16-55/ C4591001 1231 12314547	METAB	Vitamin B12 deficiency/ vitamin B12 deficiency	2	01NOV2020	48/124	1	No	O	NA/TC	RS (04MAR2021)	N/N
16-55/ C4591001 1231 12314550	INJ&P	Epicondylitis/ Medial epicondylitis	2	16OCT2020	31/120	2	No	O	NA/TC/TCN	R (12FEB2021)	N/N
1231 12314553	NERV	Neuropathy peripheral/ Right upper limb neuropathy	2	16OCT2020	31/26	2	No	O	NA/TC	R (10NOV2020)	N/N
16-55/ C4591001 1231 12314553	INFEC	Furuncle/ furunculosis	1	29AUG2020	3/16	2	No	O	NA/TC	R (13SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12314554	MUSC	Neck pain/ right cervicalgia	1	07SEP2020	12/2	1	No	O	NA	R (08SEP2020)	N/N	
16-55/ C4591001 1231 12314562	BLOOD	Lymphadenopathy/ left submandibular adenopathy.	2	03OCT2020	18/11	1	No	O	NA/TC	R (13OCT2020)	N/N	
16-55/ C4591001 1231 12314573	VASC	Haematoma/ hematoma 8 cm in diameter, external face of right leg	2	17OCT2020	33/6	1	No	O	NA/TC	R (22OCT2020)	N/N	
16-55/ C4591001 1231 12314574	INJ&P	Limb injury/ Right leg, external side trauma.	1	11SEP2020	16/1	1	No	O	NA	R (11SEP2020)	N/N	
	NERV	Paraesthesia/ Paresthesia on the outer side of the right leg	1	11SEP2020	16/78	1	No	O	NA/TCN	R (27NOV2020)	N/N	
16-55/ C4591001 1231 12314575	RESP	Asthma/ asthma attack	1	05SEP2020	10/2	2	No	O	NA/TC	R (06SEP2020)	N/N	
	GENRL	Injection site pain/ Burning at injection site	1	08OCT2020	43/1	1	Yes		NA	R (08OCT2020)	N/N	
	MUSC	Myalgia/ myalgia	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N	
16-55/ C4591001 1231 12314582	NERV	Trigeminal neuralgia/ Trigeminal neuralgia	2	17OCT2020	31/10	2	No	O	NA/TC	R (26OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12314583	GASTR	Abdominal pain upper/ Epigastralgia	2	15OCT2020	31/5	1	No	O	NA	R (19OCT2020)	N/N	
	GASTR	Pancreatitis acute/ acute pancreatitis	2	30NOV2020	77/15	2	No	O	NA/TC	R (14DEC2020)	Y/N	
16-55/ C4591001 1231 12314586	INFEC	Tooth infection/ odontogenic infection	2	08FEB2021	147/30	1	No	O	NA/TC/TCN	R (09MAR2021)	N/N	
16-55/ C4591001 1231 12314602	SKIN	Rash/ Rash in torso and arms.	1	01SEP2020	6/10	1	No	O	NA	R (10SEP2020)	N/N	
16-55/ C4591001 1231 12314633	INFEC	Orchitis/ Epididymitis orchitis	2	21OCT2020	37/40	2	No	O	NA/TC	R (29NOV2020)	N/N	
16-55/ C4591001 1231 12314639	GASTR	Abdominal pain upper/ Epigastralgia#	4	04MAR2021	15/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1231 12314649	CARD	Tachycardia/ resting tachycardia	1	29AUG2020	3/1	1	No	O	NA	R (29AUG2020)	N/N	
16-55/ C4591001 1231 12314674	GENRL	Injection site pain/ Local pain at injection site	1	29AUG2020	2/2	1	Yes		NA/TC	R (30AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12314678	MUSC	Back pain/ Low back pain	2	05OCT2020	20/4	1	No	O	NA/TC	R (08OCT2020)	N/N	
16-55/ C4591001 1231 12314679	CARD	Tachycardia/ tachycardia	1	29AUG2020	2/3	1	No	O	NA	R (31AUG2020)	N/N	
	MUSC	Neck pain/ Neck pain	1	01SEP2020	5/3	1	No	O	NA/TC/TCN	R (03SEP2020)	N/N	
	RENAL	Renal colic/ Renal colic	2	21NOV2020	18/4	3	No	O	NA/TC	R (24NOV2020)	N/N	
16-55/ C4591001 1231 12314693	EAR	Vertigo/ Vertigo	2	25JAN2021	130/41	1	No	O	NA/TC/TCN	R (06MAR2021)	N/N	
16-55/ C4591001 1231 12314699	GENRL	Asthenia/ asthenia	1	05SEP2020	9/3	2	No	O	NA/TC	R (07SEP2020)	N/N	
	NERV	Headache/ headache	2	16SEP2020	1/24	1	Yes		NA/TC	R (09OCT2020)	N/N	
16-55/ C4591001 1231 12314712	GENRL	Pyrexia/ fever	2	17SEP2020	2/2	3	Yes		NA/TC	R (18SEP2020)	N/N	
16-55/ C4591001 1231 12314719	GASTR	Diarrhoea/ loose stools	2	30SEP2020	15/3	1	No	O	NA	R (02OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12314730	INFEC	Folliculitis/ Left Groin Folliculitis	2	04OCT2020	19/8	1	No	O	NA/TC	R (11OCT2020)	N/N	
16-55/ C4591001 1231 12314731	INJ&P	Meniscus injury/ Right knee meniscus tear	2	22SEP2020	7/46	2	No	O	NA/TC/TCN	R (06NOV2020)	N/N	
16-55/ C4591001 1231 12314751	INFEC	Mastitis/ Left mastitis	2	05MAR2021	171/C	2	No	O	NA/TC/TCN	N	N/N	
16-55/ C4591001 1231 12314756	EAR	Ear pain/ Right otalgia	2	14OCT2020	29/14	1	No	O	NA/TC	R (27OCT2020)	N/N	
16-55/ C4591001 1231 12314764	NERV	Headache/ headache	2	15OCT2020	30/1	1	No	O	NA/TC	R (15OCT2020)	N/N	
16-55/ C4591001 1231 12314768	GENRL	Pyrexia/ fever	2	18SEP2020	2/1	3	Yes		NA/TC/TCN	R (18SEP2020)	N/N	
16-55/ C4591001 1231 12314771	GASTR	Gastritis/ Gastritis	2	08OCT2020	23/11	1	No	O	NA/TC	R (18OCT2020)	N/N	
16-55/ C4591001 1231 12314774	EYE	Chalazion/ chalazion	2	24SEP2020	9/3	1	No	O	NA/TC	R (26SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12314790	GASTR	Nausea/ Nausea	2	30SEP2020	15/2	2	No	O	NA/TC	R (01OCT2020)	N/N	
16-55/ C4591001 1231 12314804	INFEC	Gingivitis/ Gingivitis	1	03SEP2020	7/8	2	No	O	NA/TC	R (10SEP2020)	N/N	
	VASC	Hypertension/ Arterial Hypertension	1	16SEP2020	20/1	2	No	O	NA/TC	R (16SEP2020)	N/N	
	GASTR	Vomiting/ vomits	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N	
	GENRL	Asthenia/ asthenia	2	03OCT2020	2/2	1	No	O	NA	R (04OCT2020)	N/N	
	NERV	Headache/ Headache	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N	
16-55/ C4591001 1231 12314813	MUSC	Back pain/ Low back pain	2	21SEP2020	5/22	2	No	O	NA/TC/TCN	R (12OCT2020)	N/N	
		Intervertebral disc protrusion/ Worsening of herniated disc	2	21SEP2020	5/107	3	No	O	NA/TC/TCN	R (05JAN2021)	Y/N	
16-55/ C4591001 1231 12314816	INJ&P	Ligament injury/ grade 1 injury to the internal collateral ligament of the right knee	2	25SEP2020	10/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1231 12314817	INFEC	Tooth infection/ Dental infection	2	03OCT2020	18/44	1	No	O	NA	R (15NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12314833	INFEC	Appendicitis/ Acute Appendicitis	2	16OCT2020	29/9	3	No	O	NA/TC/TCN	R (24OCT2020)	Y/N	
	INFEC	Abdominal abscess/ Intra-abdominal Abscess	2	29OCT2020	42/37	3	No	O	NA/TC/TCN	R (04DEC2020)	Y/N	
	INFEC	Postoperative wound infection/ infection in surgical wound	2	30OCT2020	43/36	2	No	O	NA/TC/TCN	R (04DEC2020)	N/N	
16-55/ C4591001 1231 12314836	NERV	Headache/ headache	2	20OCT2020	35/1	1	No	O	NA	R (20OCT2020)	N/N	
	INFEC	Tooth infection/ Odontogenic infection#	3	02MAR2021	12/4	1	No	O	NA/TC	R (05MAR2021)	N/N	
16-55/ C4591001 1231 12314847	SKIN	Rash/ skin rash on chest and neck	2	08OCT2020	23/7	1	No	O	NA/TC	R (14OCT2020)	N/N	
16-55/ C4591001 1231 12314852	GENRL	Fatigue/ Fatigue	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N	
		Injection site pain/ Pain at injection site	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N	
16-55/ C4591001 1231 12314857	MUSC	Neck pain/ Cervicalgia	1	16SEP2020	20/5	1	No	O	NA/TC	R (20SEP2020)	N/N	
	METAB	Dyslipidaemia/ Dyslipidemia	2	20JAN2021	97/C	1	No	O	NA/TC/TCN	RG	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12314870	GASTR	Toothache/ odontogenic pain	2	01OCT2020	16/1	1	No	O	NA/TCN	R (01OCT2020)	N/N	
16-55/ C4591001 1231 12314873	GENRL	Injection site pain/ Injection site pain (left arm)	1	29AUG2020	2/3	1	Yes		NA	R (31AUG2020)	N/N	
	EAR	Vertigo/ Vertigo	2	19SEP2020	2/25	2	No	O	NA/TCN	R (13OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site	2	19SEP2020	2/62	1	Yes		NA	R (19NOV2020)	N/N	
	INFEC	Oral herpes/ Worsening of herpes labialis	2	23OCT2020	36/10	1	No	O	NA/TC	R (01NOV2020)	N/N	
16-55/ C4591001 1231 12314877	GASTR	Toothache/ exacerbation of dental pain	2	04OCT2020	19/6	2	No	O	NA/TC/TCN	R (09OCT2020)	N/N	
16-55/ C4591001 1231 12314878	GENRL	Chills/ INTERMITENT CHILLS	1	05SEP2020	9/10	1	No	O	NA	R (14SEP2020)	N/N	
16-55/ C4591001 1231 12314883	GASTR	Vomiting/ vomiting	1	30AUG2020	3/1	3	Yes		NA	R (30AUG2020)	N/N	
16-55/ C4591001 1231 12314885	MUSC	Back pain/ low back pain	2	17OCT2020	32/50	2	No	O	NA/TC/TCN	R (05DEC2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12314889	GENRL	Asthenia/ asthenia	1	05SEP2020	9/1	1	No	O	NA	R (05SEP2020)	N/N	
16-55/ C4591001 1231 12314894	CARD	Myocarditis/ right retroatrial inflammation	2	21SEP2020	6/1	1	No	O	NA/TC	R (21SEP2020)	N/N	
16-55/ C4591001 1231 12314919	IMMUN	Hypersensitivity/ Face allergic reaction	2	10OCT2020	24/1	1	No	O	NA/TC	R (10OCT2020)	N/N	
16-55/ C4591001 1231 12314921	INJ&P	Burns second degree/ Second degree burn of the right arm and forearm.#	2	27JAN2021	134/C	3	No	O	NA/TC/TCN	RG	Y/N	
		Burns third degree/ Third degree burn on the right hand#	2	27JAN2021	134/C	3	No	O	NA/TC/TCN	RG	Y/N	
16-55/ C4591001 1231 12314928	GENRL	Pyrexia/ Fever (38.8 degrees C)	2	17SEP2020	2/2	3	Yes		NA/TC	R (18SEP2020)	N/N	
	MUSC	Myalgia/ MYALGIA GENERALIZED	2	17SEP2020	2/2	3	Yes		NA/TC	R (18SEP2020)	N/N	
	NERV	Headache/ HEADACHE	2	17SEP2020	2/2	3	Yes		NA/TC	R (18SEP2020)	N/N	
16-55/ C4591001 1231 12314931	EYE	Eye allergy/ eye allergy	1	01SEP2020	5/11	1	No	O	NA	R (11SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12314934	RESP	Rhinitis allergic/ Allergic rhinitis	2	15NOV2020	59/6	1	No	O	NA/TC	R (20NOV2020)	N/N	
16-55/ C4591001 1231 12314935	GENRL	Chest pain/ prechordalgia	1	31AUG2020	4/1	1	No	O	NA/TC	R (31AUG2020)	N/N	
16-55/ C4591001 1231 12314947	GENRL	Asthenia/ asthenia	1	04SEP2020	8/3	1	No	O	NA	R (06SEP2020)	N/N	
	NERV	Somnolence/ DROWSINESS	1	04SEP2020	8/3	1	No	O	NA	R (06SEP2020)	N/N	
16-55/ C4591001 1231 12314974	NERV	Headache/ Headache	2	01OCT2020	16/7	1	No	O	NA	R (07OCT2020)	N/N	
16-55/ C4591001 1231 12314980	BLOOD	Leukopenia/ Leukopenia	2	21OCT2020	36/24	1	No	O	NA	R (13NOV2020)	N/N	
16-55/ C4591001 1231 12314987	CARD	Cardio-respiratory arrest/ Non-traumatic cardiorespiratory arrest	2	05DEC2020	81/2	4	No	O	NA/W	F (06DEC2020)	Y/N	
16-55/ C4591001 1231 12314998	INJ&P	Vulvovaginal injury/ Vulvar injury	2	20SEP2020	4/C	1	No	O	NA/TCN	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12315054	GENRL	Injection site pain/ Pain at the injection site#	3	20JAN2021	2/5	1	Yes		NA	R (24JAN2021)	N/N
	MUSC	Myalgia/ Generalized myalgia#	3	20JAN2021	2/5	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1231 12315073	INFEC	Bartholinitis/ inflammation of the bartolin glands	2	15OCT2020	29/4	2	No	O	NA/TC/TCN	R (18OCT2020)	N/N
16-55/ C4591001 1231 12315087	GASTR	Toothache/ toothache	2	10OCT2020	23/1	1	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1231 12315089	MUSC	Back pain/ low back pain	1	29AUG2020	1/9	1	No	O	NA	R (06SEP2020)	N/N
	MUSC	Back pain/ Low back pain	2	23SEP2020	7/7	2	No	O	NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 1231 12315093	BLOOD	Lymphadenopathy/ Adenopathy in low left cervical region.	2	19SEP2020	3/5	1	No	O	NA	R (23SEP2020)	N/N
16-55/ C4591001 1231 12315094	MUSC	Neck pain/ Cervicalgia	2	23SEP2020	6/3	2	No	O	NA/TC	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site.#	3	20FEB2021	1/C	1	Yes		NA/TC	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Asthenia/ Asthenia#	3	21FEB2021	2/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1231 12315095	NERV	Paraesthesia/ Paresthesias in both hands	2	29SEP2020	13/45	1	No	O	NA/TC/TCN	R (12NOV2020)	N/N
16-55/ C4591001 1231 12315101	VASC	Hypertension/ Arterial hypertension	2	19SEP2020	3/1	1	No	O	NA/TC	R (19SEP2020)	N/N
	SKIN	Rash maculo-papular/ Maculo psular rash on chest	2	23SEP2020	7/38	1	No	O	NA	R (30OCT2020)	N/N
16-55/ C4591001 1231 12315167	MUSC	Intervertebral disc protrusion/ DISC PROTRUSION AT CERVICAL LEVEL	2	11OCT2020	25/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1231 12315176	INFEC	Tooth infection/ dental infection	1	10SEP2020	13/4	2	No	O	NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1231 12315185	REPRO	Amenorrhoea/ functional amenorrhea	1	16SEP2020	19/61	1	No	O	NA/TC	R (15NOV2020)	N/N
16-55/ C4591001 1231 12315186	GASTR	Abdominal pain/ abdominal pain	2	18SEP2020	2/2	3	No	O	NA/TC	R (19SEP2020)	N/N
	MUSC	Myalgia/ abdominal myalgia	2	18SEP2020	2/2	3	No	O	NA/TC	R (19SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Gastritis erosive/ worsening of antral erosive gastritis	2	24SEP2020	8/28	1	No	O	NA/TC/TCN	R (21OCT2020)	N/N
	METAB	Dyslipidaemia/ dyslipidemia	2	01DEC2020	76/C	1	No	O	NA	N	N/N
	NEOPL	Adenocarcinoma pancreas/ pancreatic ductal adenocarcinoma#	2	17FEB2021	154/C	3	No	O	NA/TC/TCN	RG	Y/N
16-55/ C4591001 1231 12315189	INFEC	Conjunctivitis/ Worsening of rhino conjunctivitis	1	01SEP2020	4/20	1	No	O	NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1231 12315190	RESP	Asthma/ bronchial asthma	2	03NOV2020	48/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12315197	INFEC	Tooth infection/ Odontogenic infection#	3	12MAR2021	15/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C4591001 1231 12315201	CARD	Palpitations/ PALPITATIONS	1	04SEP2020	7/6	1	No	O	NA/TCN	R (09SEP2020)	N/N
16-55/ C4591001 1231 12315202	GENRL	Asthenia/ asthenia	1	30AUG2020	2/5	1	No	O	NA	R (03SEP2020)	N/N
	MUSC	Myalgia/ myalgia	1	30AUG2020	2/5	1	No	O	NA	R (03SEP2020)	N/N
		Pain in extremity/ Severe pain in the left upper limb	1	30AUG2020	2/5	3	No	O	NA/TC	R (03SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12315204 16-55/ C4591001 1231 12315205 16-55/ C4591001 1231 12315206 16-55/ C4591001 1231 12315208 16-55/ C4591001 1231 12315225 16-55/ C4591001 1231 12315264 16-55/ C4591001	MUSC	Arthralgia/ generalized arthralgias	1	17SEP2020	20/7	1	No	O	NA	R (23SEP2020)	N/N
	NERV	Headache/ headache	2	28SEP2020	1/4	2	No	O	NA	R (01OCT2020)	N/N
	MUSC	Neck pain/ cervicalgia	1	14SEP2020	17/1	2	No	O	NA/TC/TCN	R (14SEP2020)	N/N
	GASTR	Rectal haemorrhage/ Proctorrhagia	2	03OCT2020	17/2	1	No	O	NA	R (04OCT2020)	N/N
	SURG	Endodontic procedure/ Endodontic treatment	2	22SEP2020	5/22	1	No	O	NA/TC/TCN	R (13OCT2020)	N/N
	PSYCH	Insomnia/ insomnia	2	22SEP2020	6/43	1	No	O	NA/TC	R (03NOV2020)	N/N
	GASTR	Dyspepsia/ Dyspepsia	2	16NOV2020	61/7	1	No	O	NA/TC/TCN	R (22NOV2020)	N/N
	GENRL	Oedema peripheral/ Left upper limb edema#	4	05FEB2021	1/9	1	Yes		NA/TC	R (13FEB2021)	N/N
	MUSC	Tendonitis/ Left elbow tendonitis#	3	09FEB2021	12/C	1	No	O	NA/TC/TCN	RG	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12315268 16-55/ C4591001	GENRL	Asthenia/ asthenia	1	06SEP2020	9/2	1	No	O	NA	R (07SEP2020)	N/N
1231 12315271 16-55/ C4591001	GASTR	Lip oedema/ Lip Edema	1	03SEP2020	6/1	1	No	O	NA/TC	R (03SEP2020)	N/N
1231 12315276	SKIN	Pruritus/ perioral pruritus	1	03SEP2020	6/1	1	No	O	NA/TC	R (03SEP2020)	N/N
	GASTR	Lip oedema/ Lip Edema	2	29SEP2020	12/1	1	No	O	NA/TC	R (29SEP2020)	N/N
	SKIN	Pruritus/ perioral pruritus	2	29SEP2020	12/1	1	No	O	NA/TC	R (29SEP2020)	N/N
	MUSC	Muscle spasms/ muscle cramps	2	18OCT2020	31/1	1	No	O	NA/TC	R (18OCT2020)	N/N
	MUSC	Pain in extremity/ pain in left deltoid region	2	28OCT2020	41/C	2	No	O	NA	N	N/N
	INV	Blood immunoglobulin E increased/ Elevation IG E	2	30OCT2020	43/C	1	No	O	NA	N	N/N
16-55/ C4591001	MUSC	Pain in extremity/ pain in soles and palms	2	25SEP2020	8/C	2	No	O	NA/TC	RG	N/N
1231 12315280 16-55/ C4591001	GENRL	Oedema peripheral/ left foot edema	2	22SEP2020	4/1	1	No	O	NA/TC	R (22SEP2020)	N/N
1231 12315286											

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12315287	EYE	Keratitis/ Keratitis	2	29SEP2020	13/16	1	No	O	NA/TC	R (14OCT2020)	N/N	
16-55/ C4591001 1231 12315291	EYE	Choroidal neovascularisation/ Myopic choroidal neovascular membrane of the left eye	1	06SEP2020	9/83	1	No	O	NA/TC	R (27NOV2020)	Y/N	
16-55/ C4591001 1231 12315298	MUSC	Myalgia/ myalgia	2	18SEP2020	2/2	3	No	O	NA/TC	R (19SEP2020)	N/N	
16-55/ C4591001 1231 12315299	SKIN	Rash papular/ Erythematous papules in the right malar region	2	20SEP2020	4/52	1	No	O	NA/TC	R (10NOV2020)	N/N	
16-55/ C4591001 1231 12315311	GENRL	Asthenia/ Asthenia#	3	23FEB2021	1/C	1	Yes		NA	RG	N/N	
16-55/ C4591001 1231 12315322	NERV	Injection site pain/ Injection site pain# Sciatica/ Worsening of Sciatica	3	23FEB2021	1/12	1	Yes		NA/TC	R (06MAR2021)	N/N	
	GENRL	Non-cardiac chest pain/ PRECORDIAL PAIN NON-CARDIAC	1	30SEP2020	33/1	2	No	O	NA	R (30SEP2020)	N/N	
16-55/ C4591001	VASC	Hot flush/ Hot flushes	2	03OCT2020	16/22	1	No	O	NA	R (24OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12315325 16-55/ C4591001	MUSC	Intervertebral disc protrusion/ Incipient disc herniation at L5	2	23SEP2020	7/11	2	No	O	NA/TCN	R (03OCT2020)	N/N	
1231 12315349 16-55/ C4591001	BLOOD	Lymphadenopathy/ Left axillary adenopathy	2	19SEP2020	3/101	1	No	O	NA	R (28DEC2020)	N/N	
1231 12315351	MUSC	Arthralgia/ Arthralgias	2	22SEP2020	6/98	2	No	O	NA	R (28DEC2020)	N/N	
16-55/ C4591001 1231 12315359	INJ&P	Facial bones fracture/ NASAL SEPTUM FRACTURE	1	01SEP2020	4/C	1	No	O	NA/TC	RG	N/N	
		Fall/ Fell from own height	1	01SEP2020	4/1	2	No	O	NA/TC/TCN	RS (01SEP2020)	N/N	
	REPRO	Amenorrhoea/ amenorrhoea	1	16SEP2020	19/69	1	No	O	NA	R (23NOV2020)	N/N	
16-55/ C4591001 1231 12315362	INFEC	Rash pustular/ pustular rash on the inner right thigh	2	28SEP2020	12/29	1	No	O	NA	R (26OCT2020)	N/N	
	GASTR	Abdominal pain upper/ Epigastric pain	2	01OCT2020	15/87	1	No	O	NA	R (26DEC2020)	N/N	
16-55/ C4591001 1231 12315370	PSYCH	Depression/ Depression	2	05OCT2020	19/36	1	No	O	NA/TC/TCN	R (09NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12315373	GENRL	Chest pain/ Nonspecific chest pain	2	23OCT2020	36/25	1	No	O	NA	R (16NOV2020)	N/N	
16-55/ C4591001 1231 12315400	EYE	Asthenopia/ Eye fatigue	1	03SEP2020	5/2	1	No	O	NA	R (04SEP2020)	N/N	
16-55/ C4591001 1231 12315401	GENRL	Asthenia/ asthenia	1	03SEP2020	5/3	1	Yes		NA/TC	R (05SEP2020)	N/N	
	PSYCH	Depression/ depression	2	25SEP2020	7/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1231 12315412	INV	Alanine aminotransferase increased/ Increased alanine aminotransferase 164 U/l (normal range 15-45 U/l)	2	05NOV2020	48/17	1	No	O	NA	R (21NOV2020)	N/N	
		Aspartate aminotransferase increased/ Increased aspartate aminotransferase 113 U/l (normal range 5-40 U/l) 05-nov- 2020	2	05NOV2020	48/17	1	No	O	NA	R (21NOV2020)	N/N	
16-55/ C4591001 1231 12315429	GENRL	Injection site pain/ pain at injection site	1	30AUG2020	1/18	2	Yes		P/TC/W	R (16SEP2020)	N/Y	
16-55/ C4591001 1231 12315441	PSYCH	Depression/ Depressive syndrome	1	10SEP2020	12/137	3	No	O	P/TC	RS (24JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12315446	NERV	Tension headache/ TENSION HEADACHE	1	14SEP2020	16/2	1	No	O	NA	R (15SEP2020)	N/N	
16-55/ C4591001 1231 12315450	INFEC	Tooth infection/ Left lower wisdom tooth infection	2	09OCT2020	18/8	1	No	O	NA/TCN	R (16OCT2020)	N/N	
	SURG	Wisdom teeth removal/ Dental piece extraction (lower left wisdom tooth)	2	16OCT2020	25/1	1	No	O	NA/TCN	R (16OCT2020)	N/N	
16-55/ C4591001 1231 12315453	REPRO	Mammary duct ectasia/ Breast ductal ectasia	2	07OCT2020	19/33	1	No	O	NA	R (08NOV2020)	N/N	
16-55/ C4591001 1231 12315460	NERV	Tension headache/ worsening of tensional headache	2	21SEP2020	3/47	1	No	O	NA	R (06NOV2020)	N/N	
16-55/ C4591001 1231 12315464	GASTR	Odynophagia/ Odynophagia	1	13SEP2020	15/5	1	No	O	NA	R (17SEP2020)	N/N	
	RESP	Rhinorrhoea/ Rhinorrhea	1	13SEP2020	15/5	1	No	O	NA	R (17SEP2020)	N/N	
16-55/ C4591001 1231 12315467	RESP	Rhinitis allergic/ Allergic rhinitis	2	13OCT2020	25/18	1	No	O	NA/TCN	R (30OCT2020)	N/N	
16-55/ C4591001	NERV	Headache/ HEADACHE	1	05SEP2020	7/1	1	No	O	NA/TC	R (05SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12315470 16-55/ C4591001	CARD	Angina unstable/ Unstable Angina Pectoris	2	14OCT2020	26/3	3	No	O	NA/TCN	R (16OCT2020)	Y/N
1231 12315473 16-55/ C4591001	MUSC	Back pain/ LOW BACK PAIN	1	17SEP2020	19/7	1	No	O	NA/TC	R (23SEP2020)	N/N
1231 12315477		Neck pain/ CERVICAL PAIN	1	17SEP2020	19/7	1	No	O	NA/TC	R (23SEP2020)	N/N
16-55/ C4591001	GASTR	Dyspepsia/ Pyrosis	2	20SEP2020	3/6	1	No	O	NA	R (25SEP2020)	N/N
1231 12315497	NERV	Headache/ headache	2	20SEP2020	3/4	2	No	O	NA/TC	R (23SEP2020)	N/N
16-55/ C4591001	RENAL	Nephrolithiasis/ Nephrolithiasis	2	05DEC2020	78/48	3	No	O	NA/TC	R (21JAN2021)	Y/N
1231 12315498											
16-55/ C4591001	GENRL	Injection site bruising/ bruise at injection site of left arm	1	30AUG2020	1/18	1	Yes		NA	R (16SEP2020)	N/Y
1231 12315499											
16-55/ C4591001	GASTR	Oral lichenoid reaction/ LICHENOID REACTION, in both jaw mucosa	2	22SEP2020	5/103	1	No	O	NA/TCN	RS (02JAN2021)	N/N
1231 12315504											

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12315514	VASC	Hypertension/ Arterial hypertension	2	04JAN2021	109/C	1	No	O	NA/TC/TCN	RG	N/N	
16-55/ C4591001 1231 12315516	NERV	Headache/ headache	1	30AUG2020	1/20	1	No	O	NA/TC	R (18SEP2020)	N/N	
16-55/ C4591001 1231 12315518	RESP	Rhinorrhoea/ rhinorrhea	1	17SEP2020	19/3	1	No	O	NA	R (19SEP2020)	N/N	
16-55/ C4591001 1231 12315528	METAB	Type 2 diabetes mellitus/ Worsening of your type 2 diabetes.	1	17SEP2020	19/2	2	No	O	NA/TC	R (18SEP2020)	N/N	
16-55/ C4591001 1231 12315542	BLOOD	Lymphadenopathy/ Left axillary adenomegaly	2	20SEP2020	2/6	2	No	O	NA/TC	R (25SEP2020)	N/N	
16-55/ C4591001 1231 12315546	GENRL	Asthenia/ Asthenia.	2	16OCT2020	28/8	1	No	O	NA	R (23OCT2020)	N/N	
16-55/ C4591001 1231 12315547	VASC	Hypertension/ Worsening of Hypertension	1	19SEP2020	20/1	1	No	O	NA	R (19SEP2020)	N/N	
16-55/ C4591001 1231 12315550	ENDO	Hyperprolactinaemia/ Hyperprolactinemia	1	15SEP2020	16/149	1	No	CD	NA/TC	R (10FEB2021)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12315559	GASTR	Flatulence/ meteorism (abdominal pain in the left iliac fossa)	2	04OCT2020	14/10	3	No	O	NA/TC	R (13OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	19SEP2020	1/2	1	No	O	NA/TC	R (20SEP2020)	N/N	
	MUSC	Myalgia/ generalized myalgia	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N	
	BLOOD	Lymphadenopathy/ Left axillar adenomegaly	2	20SEP2020	2/7	2	Yes		NA/TC	R (26SEP2020)	N/N	
16-55/ C4591001 1231 12315568	METAB	Dyslipidaemia/ dyslipidemia	1	17SEP2020	18/21	1	No	O	NA/TC/TCN	R (07OCT2020)	N/N	
16-55/ C4591001 1231 12315600	GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux	1	05SEP2020	6/26	1	No	O	NA/TC	R (30SEP2020)	N/N	
16-55/ C4591001 1231 12315601	MUSC	Back pain/ LOW BACK PAIN	1	13SEP2020	14/1	2	No	O	NA/TC	R (13SEP2020)	N/N	
	MUSC	Back pain/ Back pain	1	25OCT2020	56/2	2	No	O	NA/TC	R (26OCT2020)	N/N	
	INJ&P	Hand fracture/ Right fifth metacarpal fracture	2	18NOV2020	59/36	2	No	O	NA	R (23DEC2020)	N/N	
16-55/ C4591001	INFECTION	Road traffic accident/ Motorcycle accident	2	18NOV2020	59/1	2	No	O	NA	R (18NOV2020)	N/N	
		Gastroenteritis/ gastroenterocolitis	2	09JAN2021	113/3	2	No	O	NA/TC/TCN	R (11JAN2021)	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12315622	GASTR	Vomiting/ Vomiting#	3	21FEB2021	2/1	1	Yes		NA	R (21FEB2021)	N/N	
	GENRL	Injection site pain/ Pain at injection site.#	3	21FEB2021	2/1	1	Yes		NA/TC	R (21FEB2021)	N/N	
16-55/ C4591001 1231 12315626	NERV	Sciatica/ Lumbociatalgia	2	15OCT2020	27/12	1	No	O	NA/TC	R (26OCT2020)	N/N	
16-55/ C4591001 1231 12315627	MUSC	Arthralgia/ left omalgia	1	17SEP2020	18/15	1	No	O	NA/TC	R (01OCT2020)	N/N	
16-55/ C4591001 1231 12315636	GASTR	Gastritis/ Gastritis	2	23JAN2021	127/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1231 12315645	MUSC	Myalgia/ Low Back Myalgia	1	01SEP2020	2/2	2	Yes		NA/TC	R (02SEP2020)	N/N	
	REPRO	Erectile dysfunction/ FUNCTIONAL IMPOTENCE	1	10SEP2020	11/2	2	No	O	NA/TC	R (11SEP2020)	N/N	
16-55/ C4591001 1231 12315677	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	12DEC2020	85/62		No	O	NA	R (11FEB2021)	N/N	
16-55/ C4591001	SURG	Rhinoplasty/ COSMETIC RHINOPLASTY	1	07SEP2020	8/1	2	No	O	NA/TC	RS (07SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12315681	SKIN	Urticaria contact/ generalized contact urticaria	1	03OCT2020	34/16	1	No	O	NA/TC	R (18OCT2020)	N/N	
16-55/ C4591001 1232 12321010	GENRL	Pyrexia/ Fever	2	03SEP2020	2/2	2	Yes		NA	R (04SEP2020)	N/N	
	GENRL	Chills/ Chills	2	04SEP2020	3/2	2	Yes		NA	R (05SEP2020)	N/N	
	INFEC	Sinusitis/ Sinusitis	2	09SEP2020	8/3	1	No	CND	NA	R (11SEP2020)	N/N	
16-55/ C4591001 1232 12321053	NERV	Headache/ Headache	2	11SEP2020	2/4	1			NA	R (14SEP2020)	N/N	
	GENRL	Axillary pain/ Under arm pain	2	12SEP2020	3/2	1			NA	R (13SEP2020)	N/N	
		Injection site pain/ Pain in arm at injection site	2	12SEP2020	3/2	1			NA	R (13SEP2020)	N/N	
	EYE	Vision blurred/ Blurry vision	2	14SEP2020	5/9	1			NA	R (22SEP2020)	N/N	
16-55/ C4591001 1232 12321086	NERV	Syncope/ Syncopal*		25AUG2020	1/1	1	No	O	NA	R (25AUG2020)	N/N	
16-55/ C4591001 1232 12321159	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	28DEC2020	97/C	1	No	O	NA	UNK	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1232 12321173	BLOOD	Anaemia/ Worsening Anemia	2	16OCT2020	25/5	1	No	O	NA	R (20OCT2020)	N/N	
	REPRO	Vaginal haemorrhage/ abnormal vaginal bleeding	2	19OCT2020	28/1	1	No	O	NA	R (19OCT2020)	N/N	
16-55/ C4591001 1232 12321175	VASC	Hypertension/ high blood pressure	1	25SEP2020	23/29	2	No	O	P	R (23OCT2020)	N/N	
16-55/ C4591001 1232 12321213	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	01OCT2020	23/C		No	O	P	UNK	N/N	
16-55/ C4591001 1232 12321250	RESP	Cough/ cough	2	09OCT2020	12/3	1			NA	R (11OCT2020)	N/N	
		Respiratory tract congestion/ Chest congestion	2	09OCT2020	12/3	1			NA	R (11OCT2020)	N/N	
16-55/ C4591001 1232 12321293	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	1	22OCT2020	22/C		No	O	P	RG	N/N	
16-55/ C4591001 1232 12321299	VASC	Hypertension/ Hypertension*		06OCT2020	1/C	2	No	O	NA/W	UNK	N/N	
16-55/ C4591001	GENRL	Malaise/ General Malaise#	4	05JAN2021	1/3	1	Yes		NA/TC	R (07JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1235 12351007		Pyrexia/ Pyrexia#	4	05JAN2021	1/3	1	Yes		NA/TC	R (07JAN2021)	N/N
16-55/ C4591001 1235 12351009	GENRL	Pain/ body aches#	4	25JAN2021	1/2	2	Yes		NA/TC	R (26JAN2021)	N/N
16-55/ C4591001 1235 12351020	MUSC	Pain in extremity/ Left Arm Pain#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	MUSC	Arthralgia/ generalized Joint Pain#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
		Myalgia/ Generalized Myalgia#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1235 12351025	PSYCH	Depression/ anxiety/depression#	3	DEC2020	1/C	2	No	O	NA/TC	RG	N/N
	GENRL	Fatigue/ Fatigue#	4	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
		Pyrexia/ Pyrexia#	4	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
	MUSC	Myalgia/ Myalgia, generalized#	4	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
		Pain in extremity/ Right Arm Pain#	4	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1235 12351029	GENRL	Injection site pain/ injection site pain#	4	04JAN2021	1/3	1	Yes		NA	R (06JAN2021)	N/N
16-55/ C4591001 1235 12351030	RESP	Rhinorrhoea/ Rhinorrhea#	4	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1235 12351045	MUSC	Myalgia/ Generalized myalgia#	4	05JAN2021	1/2	1	Yes		NA/TC	R (06JAN2021)	N/N
	NERV	Headache/ Headache#	4	05JAN2021	1/1	1	Yes		NA/TC	R (05JAN2021)	N/N
16-55/ C4591001 1235 12351057	GENRL	Chills/ Chills#	4	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
		Pyrexia/ Pyrexia#	4	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
16-55/ C4591001 1235 12351060	GENRL	Chills/ Chills#	4	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N
		Fatigue/ Fatigue#	4	12JAN2021	1/3	2	Yes		NA	RS (14JAN2021)	N/N
		Pyrexia/ Fever#	4	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1235 12351074	MUSC	Myalgia/ Myalgia#	4	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N
	INFEC	Conjunctivitis/ Conjunctivitis	2	16OCT2020	11/6	1	Yes		NA/TC	R (21OCT2020)	N/N
		Pharyngitis/ Pharyngitis	2	16OCT2020	11/6	1	Yes		NA/TC	R (21OCT2020)	N/N
	NERV	Headache/ cephalgia	2	16OCT2020	11/6	1	Yes		NA/TC	R (21OCT2020)	N/N
	RESP	Nasal congestion/ Nasal Congestion	2	16OCT2020	11/6	1	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C4591001 1235 12351079	MUSC	Myalgia/ Myalgia#	4	20JAN2021	1/2	1	Yes		NA	RS (21JAN2021)	N/N
	NERV	Headache/ Headache#	4	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1235 12351083	GENRL	Chills/ Chills after Vaccine 2	2	07OCT2020	2/4	2	Yes		NA	R (10OCT2020)	N/N
		Fatigue/ Fatigue after Vaccine 2	2	07OCT2020	2/4	2	Yes		NA	R (10OCT2020)	N/N
	MUSC	Pain in extremity/ Left arm pain after Vaccine 2	2	07OCT2020	2/4	2	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1235 12351084	GENRL	Chills/ Rigors	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1235 12351098	MUSC	Myalgia/ Myalgia	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
	NERV	Headache/ Cephalgia	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
	GENRL	Chills/ Rigor	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1235 12351101	NERV	Headache/ Cephalgia	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Pain/ body aches	2	25OCT2020	18/2	1	No	O	NA/TC	R (26OCT2020)	N/N
	RESP	Cough/ cough	2	25OCT2020	18/2	1	No	O	NA/TC	R (26OCT2020)	N/N
16-55/ C4591001 1235 12351105		Nasal congestion/ nasal congestion	2	25OCT2020	18/2	1	No	O	NA/TC	R (26OCT2020)	N/N
	GENRL	Chills/ chills	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
		Pain/ body aches	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001		Pyrexia/ fever	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
	NERV	Headache/ mild headache	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
	GENRL	Injection site pain/ Muscle pain at injection site of left arm#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1235 12351108	GENRL	Chills/ chills	2	07OCT2020	1/2	2	Yes	NA/TC		R (08OCT2020)	N/N	
16-55/ C4591001 1235 12351110	GENRL	Pain/ body aches	2	07OCT2020	1/2	2	Yes	NA/TC		R (08OCT2020)	N/N	
16-55/ C4591001 1235 12351124	GENRL	Chills/ Chills#	4	12JAN2021	1/3	1	Yes	NA/TC		R (14JAN2021)	N/N	
		Fatigue/ Fatigue#	4	12JAN2021	1/3	1	Yes	NA/TC		R (14JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	12JAN2021	1/3	1	Yes	NA/TC		R (14JAN2021)	N/N	
16-55/ C4591001 1235 12351130	BLOOD	Lymphadenopathy/ Bilateral swollen mandibular lymph nodes#	4	15JAN2021	4/C	2	Yes	NA		N	N/N	
16-55/ C4591001 1235 12351131	MUSC	Myalgia/ Myalgia, generalized	2	14OCT2020	2/2	1	Yes	NA/TC		R (15OCT2020)	N/N	
16-55/ C4591001 1235 12351134	GENRL	Chills/ Chills#	4	07JAN2021	2/1	1	Yes	NA/TC		R (07JAN2021)	N/N	
		Fatigue/ Fatigue#	4	07JAN2021	2/1	1	Yes	NA		R (07JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Pain in extremity/ Right Arm Pain#	4	07JAN2021	2/1	1	Yes		NA/TC	R (07JAN2021)	N/N
16-55/ C4591001 1235 12351137	MUSC	Myalgia/ Myalgia	1	15OCT2020	24/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1235 12351143	GENRL	Chills/ chills	2	12OCT2020	1/4	1	Yes		NA/TC	R (15OCT2020)	N/N
		Pyrexia/ pyrexia	2	12OCT2020	1/4	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 1235 12351144	GENRL	Chills/ chills#	4	06JAN2021	1/3	2	Yes		NA/TC	R (08JAN2021)	N/N
		Injection site pain/ injection site soreness#	4	06JAN2021	1/3	1	Yes		NA/TC	R (08JAN2021)	N/N
		Pyrexia/ pyrexia#	4	06JAN2021	1/3	1	Yes		NA/TC	R (08JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	06JAN2021	1/3	1	Yes		NA/TC	R (08JAN2021)	N/N
	NERV	Headache/ headache#	4	06JAN2021	1/3	1	Yes		NA/TC	R (08JAN2021)	N/N
16-55/ C4591001 1235 12351146	GENRL	Injection site pain/ injection site pain#	4	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N
16-55/ C4591001	GENRL	Pyrexia/ pyrexia	2	15OCT2020	1/2	2	Yes		NA	R (16OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1235 12351151	MUSC	Pain in extremity/ left arm soreness#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
1235 12351152	GENRL	Fatigue/ Fatigue#	4	12JAN2021	1/2	1	Yes		NA/TC	R (13JAN2021)	N/N
1235 12351155	GENRL	Injection site pain/ right arm injection site soreness	2	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
1235 12351161	NERV	Pyrexia/ pyrexia	2	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
1235 12351162	NERV	Headache/ cephalalgia	2	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
1235 12351165	NERV	Headache/ cephalalgia#	4	08JAN2021	1/6	1	Yes		NA	R (13JAN2021)	N/N
1235 12351166	GENRL	Pyrexia/ Pyrexia	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N
1235 12351168	GENRL	Pyrexia/ Febrile	2	31OCT2020	2/2	2	Yes		NA/TC	R (01NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1235 12351169	MUSC	Myalgia/ Myalgia	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N
	GENRL	Pyrexia/ PYREXIA*		21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1235 12351175	MUSC	Myalgia/ MYALGIA	1	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	15OCT2020	2/1	2	Yes		NA	R (15OCT2020)	N/N
		Pain/ Body aches	1	15OCT2020	2/1	2	Yes		NA	R (15OCT2020)	N/N
	MUSC	Myalgia/ Right arm muscle soreness	1	15OCT2020	2/1	2	Yes		NA	R (15OCT2020)	N/N
	GASTR	Nausea/ nausea	2	05NOV2020	2/1	2	Yes		NA/TC	R (05NOV2020)	N/N
		Vomiting/ emesis	2	05NOV2020	2/1	2	Yes		NA/TC	R (05NOV2020)	N/N
	GENRL	Chills/ rigor	2	05NOV2020	2/1	2	Yes		NA/TC	R (05NOV2020)	N/N
	MUSC	Myalgia/ generalized myalgia	2	05NOV2020	2/1	2	Yes		NA/TC	R (05NOV2020)	N/N
	NERV	Headache/ cephalgia	2	05NOV2020	2/1	2	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1235 12351180	GENRL	Pyrexia/ fever 38.5 C	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1235 12351188 16-55/ C4591001 1235 12351189 16-55/ C4591001 1235 12351190 16-55/ C4591001 1235 12351191 16-55/ C4591001 1235 12351192	MUSC	Pain in extremity/ left arm soreness	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Pyrexia/ pyrexia	2	03NOV2020	1/3	2	Yes		NA	R (05NOV2020)	N/N
	MUSC	Pain in extremity/ sore arm#	2	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
	MUSC	Pain in extremity/ Arm pain#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N
	MUSC	Pain in extremity/ Arm soreness, Right#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Pyrexia/ pyrexia	2	07NOV2020	2/2	1	Yes		NA/TC	R (08NOV2020)	N/N
	NERV	Headache/ cephalgia	2	09NOV2020	4/1	1	Yes		NA/TC	R (09NOV2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	16OCT2020	1/2	2	Yes		NA	R (17OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	17OCT2020	2/2	2	Yes		NA	R (18OCT2020)	N/N
	MUSC	Myalgia/ Bilateral Shoulder Myalgia	1	17OCT2020	2/2	2	Yes		NA	R (18OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1235 12351193		Myalgia/ Right arm myalgia	1	17OCT2020	2/2	2	Yes		NA	R (18OCT2020)	N/N
	RESP	Upper-airway cough syndrome/ Post-nasal drip	2	09NOV2020	4/1	1	Yes		NA	R (09NOV2020)	N/N
	GENRL	Fatigue/ fatigue	1	19OCT2020	1/2	2	Yes		NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ Injection site soreness	2	09NOV2020	1/2	2	Yes		NA	R (10NOV2020)	N/N
	GENRL	Pyrexia/ Pyrexia	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	10NOV2020	2/3	1	Yes		NA	R (12NOV2020)	N/N
	MUSC	Pain in extremity/ left arm pain	1	19OCT2020	1/3	1	Yes		NA/TC	R (21OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Fatigue/ fatigue	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1235 12351209	MUSC	Myalgia/ myalgia	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	MUSC	Pain in extremity/ Sore left arm#	3	17DEC2020	1/3	1	Yes		NA/TC	R (19DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1235 12351214	GASTR	Nausea/ nausea#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Chills/ chills#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
		Pyrexia/ fever#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
	GASTR	Nausea/ Nausea	2	11NOV2020	2/3	2	Yes		NA/TC	R (13NOV2020)	N/N
	GENRL	Chills/ Chills	2	11NOV2020	2/3	2	Yes		NA/TC	R (13NOV2020)	N/N
		Pyrexia/ Pyrexia	2	11NOV2020	2/3	1	Yes		NA/TC	R (13NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	10NOV2020	1/3	2	Yes		NA	R (12NOV2020)	N/N
		Pyrexia/ Pyrexia	2	10NOV2020	1/3	2	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1235 12351217	MUSC	Myalgia/ generalized myalgia#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1235 12351218	GENRL	Fatigue/ Fatigue	1	23OCT2020	1/2	2	Yes		NA	R (24OCT2020)	N/N
	MUSC	Myalgia/ Left arm myalgia	1	23OCT2020	1/2	2	Yes		NA/TC	R (24OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1235 12351223	SKIN	Rash papular/ Rash to right upper arm, raised, tender, 5cm diameter	2	15NOV2020	4/1	1	Yes		NA	R (15NOV2020)	N/N
16-55/ C4591001 1235 12351228	GENRL	Pyrexia/ Pyrexia#	4	20JAN2021	1/2	1	Yes		NA/TC	R (21JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	20JAN2021	1/2	1	Yes		NA/TC	R (21JAN2021)	N/N
16-55/ C4591001 1235 12351230	GENRL	Fatigue/ fatigue	1	03NOV2020	1/2	1	Yes		NA	R (04NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	1	03NOV2020	1/2	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C4591001 1241 12411001	GENRL	Injection site pain/ Injection site pain	1	07AUG2020	1/1	1	Yes		NA	R (07AUG2020)	N/Y
	GENRL	Injection site pain/ Injection site pain	2	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/Y
	GASTR	Nausea/ Nausea#	3	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	22JAN2021	2/2	1	Yes		NA/TC	R (23JAN2021)	N/N
		Pyrexia/ Fever#	3	22JAN2021	2/2	1	Yes		NA/TC	R (23JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Nausea/ Nausea#	4	10FEB2021	1/3	3	Yes		NA/TC	R (12FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	1/3	3	Yes		NA	R (12FEB2021)	N/N
		Pyrexia/ Fever#	4	10FEB2021	1/3	1	Yes		NA/TC	R (12FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	10FEB2021	1/3	3	Yes		NA	R (12FEB2021)	N/N
	NERV	Headache/ Headache#	4	10FEB2021	1/3	3	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1241 12411002	GENRL	Injection site erythema/ Injection site erythema	1	07AUG2020	1/2	1	Yes		NA	R (08AUG2020)	N/Y
	GENRL	Chills/ Chills	2	26AUG2020	1/1	1	Yes		NA/TC	R (26AUG2020)	N/N
		Pyrexia/ Fever	2	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/N
	MUSC	Myalgia/ Myalgia	2	26AUG2020	1/2	2	Yes		NA	R (27AUG2020)	N/N
	GASTR	Vomiting/ Vomiting	2	27AUG2020	2/1	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C4591001 1241 12411003	NERV	Somnolence/ Somnolence	2	26AUG2020	1/C	1	No	O	NA	RG	N/N
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	07AUG2020	1/3	1	Yes		NA	R (09AUG2020)	N/Y

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411004	MUSC	Myalgia/ Myalgia	2	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
	NERV	Headache/ Intermittent Headache	2	26AUG2020	1/2	2	No	O	NA/TC	R (27AUG2020)	N/N
	GENRL	Chills/ Chills	2	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
		Pyrexia/ Fever	2	27AUG2020	2/2	1	Yes		NA/TC	R (28AUG2020)	N/N
16-55/ C4591001 1241 12411005	GASTR	Nausea/ Nausea	2	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ Chills	2	26AUG2020	1/3	1	Yes		NA/TC	R (28AUG2020)	N/N
		Injection site pain/ Injection site pain	2	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/Y
			2	26AUG2020	1/1	2	Yes		NA/TC	R (26AUG2020)	N/N
		Pyrexia/ Fever	2	26AUG2020	1/3	1	Yes		NA/TC	R (28AUG2020)	N/N
	NERV	Headache/ Headache	2	26AUG2020	1/3	1	Yes		NA/TC	R (28AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	18OCT2020	54/1	1	No	O	NA	R (18OCT2020)	N/N
16-55/ C4591001 1241 12411006	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/1	1	Yes		NA	R (21JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411007	GENRL	Injection site pain/ Injection site pain#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1241 12411007	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/1	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1241 12411010	GENRL	Injection site erythema/ Injection site erythema	1	07AUG2020	1/1	1	Yes		NA	R (07AUG2020)	N/Y
16-55/ C4591001 1241 12411011	MUSC	Myalgia/ Myalgia	2	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1241 12411012	GENRL	Fatigue/ Prostration#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1241 12411013	GENRL	Pyrexia/ Fever#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1241 12411013	GENRL	Injection site pain/ Injection site pain	1	10AUG2020	1/3	1	Yes		NA	R (12AUG2020)	N/Y
16-55/ C4591001 1241 12411014	GENRL	Injection site pain/ Injection site pain	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411016	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N	
16-55/ C4591001 1241 12411017	GENRL	Chills/ Chills#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N	
16-55/ C4591001 1241 12411018	NERV	Headache/ Headache#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N	
16-55/ C4591001 1241 12411019	RESP	Rhinitis allergic/ Allergic rhinitis	2	21SEP2020	22/1	1	No	O	NA	R (21SEP2020)	N/N	
16-55/ C4591001 1241 12411020	GENRL	Injection site pain/ Injection site pain	1	10AUG2020	1/3	1	Yes		NA	R (12AUG2020)	N/Y	
16-55/ C4591001 1241 12411021	NERV	Headache/ headache	1	27AUG2020	18/3	1	No	O	NA	R (29AUG2020)	N/N	
16-55/ C4591001 1241 12411022	GENRL	Chills/ Chills	1	12AUG2020	3/2	1	Yes		NA	R (13AUG2020)	N/N	
16-55/ C4591001	NERV	Headache/ Headache#	3	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N	
16-55/ C4591001	NERV	Headache/ Headache	1	28AUG2020	19/1	1	No	O	NA/TC	R (28AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411022	GENRL	Injection site pain/ Injection site pain#	4	15FEB2021	1/3	1	Yes		NA/TCN	R (17FEB2021)	N/N	
	GENRL	Pyrexia/ Fever#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N	
16-55/ C4591001 1241 12411023	ENDO	Hypogonadism/ Hypogonadism	1	19AUG2020	10/43	1	No	O	NA/TC	R (30SEP2020)	N/N	
	METAB	Dyslipidaemia/ Dyslipidemia	1	19AUG2020	10/93	1	No	O	NA/TC	R (19NOV2020)	N/N	
16-55/ C4591001 1241 12411024	NERV	Headache/ Headache	1	26AUG2020	17/1	2	No	O	NA/TC	R (26AUG2020)	N/N	
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/3	1	Yes		NA	R (12FEB2021)	N/N	
		Injection site pain/ Injection site pain#	4	10FEB2021	2/3	1	Yes		NA	R (12FEB2021)	N/N	
	NERV	Headache/ Headache#	4	10FEB2021	2/3	1	Yes		NA/TC	R (12FEB2021)	N/N	
16-55/ C4591001 1241 12411026	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N	
		Fatigue/ Fatigue#	4	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411027	NERV	Injection site pain/ Injection site pain#	4	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N	
		Pyrexia/ Fever#	4	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N	
		Headache/ Headache#	4	11FEB2021	2/1	2	Yes		NA	R (11FEB2021)	N/N	
	INFEC	Parasitic gastroenteritis/ Intestinal parasitosis	2	07SEP2020	8/24	1	No	O	NA/TC	R (30SEP2020)	N/N	
	METAB	Dyslipidaemia/ Dyslipidemia	2	12SEP2020	13/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1241 12411028	METAB	Vitamin D deficiency/ Hypovitaminosis D#	2	07FEB2021	161/C	2	No	O	NA/TC	RG	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N	
	GENRL	Pyrexia/ Fever#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N	
16-55/ C4591001 1241 12411029	INFEC	Tonsillitis/ Acute tonsillitis	1	11AUG2020	2/7	1	No	O	NA/TC	R (17AUG2020)	N/N	
	INFEC	Tonsillitis/ Acute tonsillitis	2	01SEP2020	2/9	1	No	O	NA/TC	R (09SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
		Pyrexia/ Fever#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1241 12411030	INFEC	Ear infection/ Otitis	1	20AUG2020	11/4	1	No	O	NA/TC	R (23AUG2020)	N/N
16-55/ C4591001 1241 12411031	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	2/1	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Asthenia/ Asthenia#	3	23JAN2021	3/1	1	Yes		NA	R (23JAN2021)	N/N
	NERV	Headache/ Headache#	3	23JAN2021	3/1	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1241 12411032	NERV	Dysgeusia/ Bitter taste in mouth	1	11AUG2020	1/1	1	Yes		NA	R (11AUG2020)	N/Y
	NERV	Dysgeusia/ Bitter taste in mouth	2	03SEP2020	1/1	1	Yes		NA	R (03SEP2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	2/1	1	Yes		NA	R (22JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	22JAN2021	2/1	1	Yes		NA	R (22JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/5	1	Yes		NA	R (14FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	10FEB2021	2/5	1	Yes		NA	R (14FEB2021)	N/N
	NERV	Headache/ Headache#	4	10FEB2021	2/5	1	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1241 12411034	SURG	Sclerotherapy/ Sclerotherapy	2	23SEP2020	22/1	1	No	O	NA	R (23SEP2020)	N/N
16-55/ C4591001 1241 12411037	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1241 12411040	NERV	Headache/ Headache	2	28SEP2020	28/1	1	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C4591001 1241 12411042	GENRL	Chills/ Chills#	3	26JAN2021	2/2	2	Yes		NA	R (27JAN2021)	N/N
		Fatigue/ Fatigue#	3	26JAN2021	2/2	2	Yes		NA	R (27JAN2021)	N/N
		Fatigue/ Prostration#	3	26JAN2021	2/2	2	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	26JAN2021	2/2	2	Yes		NA	R (27JAN2021)	N/N
		Pyrexia/ Fever#	3	26JAN2021	2/2	2	Yes		NA	R (27JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411043	NERV	Headache/ Headache#	3	26JAN2021	2/2	2	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/3	1	Yes		NA/TC	R (18FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	16FEB2021	2/3	1	Yes		NA/TC	R (18FEB2021)	N/N
		Pyrexia/ Fever#	4	16FEB2021	2/3	1	Yes		NA/TC	R (18FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	2/3	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411044	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	2/4	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	11AUG2020	1/1	2	Yes		NA	R (11AUG2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/6	1	Yes		NA	R (27JAN2021)	N/N
GENRL	GASTR	Diarrhoea/ Diarrhea#	3	23JAN2021	2/6	2	Yes		NA/TC	R (28JAN2021)	N/N
		Nausea/ Nausea#	3	23JAN2021	2/6	2	Yes		NA/TC	R (28JAN2021)	N/N
		Chills/ Chills#	3	23JAN2021	2/6	2	Yes		NA/TC	R (28JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411045	MUSC	Pyrexia/ Fever#	3	23JAN2021	2/6	2	Yes		NA/TC	R (28JAN2021)	N/N
		Myalgia/ Myalgia#	3	23JAN2021	2/6	2	Yes		NA/TC	R (28JAN2021)	N/N
		Headache/ Headache#	3	23JAN2021	2/6	2	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	2/3	1	Yes		NA	R (25FEB2021)	N/N
	INFEC	Oral herpes/ Lip herpes	1	18AUG2020	8/5	1	No	O	NA/TC	R (22AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
	NERV	Headache/ Headache#	3	23JAN2021	2/1	1	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12411047	NERV	Pyrexia/ Fever#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
		Headache/ Headache	1	29AUG2020	19/2	2	No	O	NA/TC	R (30AUG2020)	N/N
16-55/ C4591001 1241 12411048	GENRL	Fatigue/ Fatigue#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411050	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N	
		Fatigue/ Fatigue#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N	
		Injection site pain/ Injection site pain#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N	
	NERV	Headache/ Headache#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N	
		SURG	Metabolic surgery/ Bariatric surgery#	2	08MAR2021	188/1	2	No	O	NA/TCN	R (08MAR2021)	N/N
	16-55/ C4591001 1241 12411051	BLOOD	Lymphadenopathy/ Left Axillary lymphadenopathy	2	03SEP2020	2/4	1	Yes		NA	R (06SEP2020)	N/N
		INFEC	Oral candidiasis/ Oral thrush	2	06SEP2020	5/6	1	Yes		NA	R (11SEP2020)	N/N
		INFEC	Cystitis/ Cystitis	2	07OCT2020	36/8	2	No	O	NA/TC	R (14OCT2020)	N/N
	16-55/ C4591001 1241 12411053	GASTR	Dyspepsia/ Dyspepsia#	3	31JAN2021	7/13	3	No	O	NA/TC	R (12FEB2021)	N/N
			Gastroesophageal reflux disease/ Non-erosive reflux esophagitis#	3	31JAN2021	7/C	3	No	O	NA/TC/TCN	RG	Y/N
16-55/ C4591001 1241 12411059	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411060	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1241 12411062	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
	NERV	Headache/ Headache	2	22SEP2020	21/3	2	No	O	NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1241 12411064	GENRL	Fatigue/ FATIGUE#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1241 12411069	GENRL	Chills/ Chills#	4	24FEB2021	2/1	1	Yes		NA/TC	R (24FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	24FEB2021	2/1	1	Yes		NA/TC	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	4	24FEB2021	2/1	1	Yes		NA/TC	R (24FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/3	2	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001	SURG	Gingival operation/ Gingivoplasty	2	21SEP2020	20/1	1	No	O	NA/TC	R (21SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411070	VASC	Thrombophlebitis superficial/ Left great saphenous thrombophlebitis	2	12OCT2020	41/40	2	No	O	NA/TC	R (20NOV2020)	N/N
16-55/ C4591001 1241 12411071	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1241 12411072	MUSC	Neck pain/ Cervicalgia	2	01NOV2020	61/20	2	No	O	NA/TC/TCN	R (20NOV2020)	N/N
16-55/ C4591001 1241 12411073	GENRL	Injection site pain/ Injection site pain#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12411075	MUSC	Myalgia/ myalgia#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12411077	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1241 12411077	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/1	1	Yes		NA	R (22FEB2021)	N/Y
16-55/ C4591001 1241 12411077	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/1	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1241 12411077	MUSC	Myalgia/ Myalgia#	3	22JAN2021	2/1	1	Yes		NA	R (22JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411078	GENRL	Pyrexia/ Fever#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	18FEB2021	2/3	1	Yes		NA/TC	R (20FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/3	1	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/3	1	Yes		NA/TC	R (20FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/4	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Chills/ Chills#	4	19FEB2021	2/4	1	Yes		NA	R (22FEB2021)	N/N
	MUSC	Injection site pain/ Injection site pain#	4	19FEB2021	2/4	1	Yes		NA	R (22FEB2021)	N/N
16-55/ C4591001	MUSC	Myalgia/ Myalgia#	4	19FEB2021	2/4	1	Yes		NA	R (22FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411091	SURG	Hysterectomy/ Hysterectomy#	3	06FEB2021	17/1	1	No	O	NA/TC	R (06FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	11FEB2021	1/5	1	Yes		NA	R (15FEB2021)	N/N	
16-55/ C4591001 1241 12411093	REPRO	Dysmenorrhoea/ Menstrual cramps	2	30SEP2020	28/3	2	No	O	NA/TC	R (02OCT2020)	N/N	
16-55/ C4591001 1241 12411094	INJ&P	Thermal burn/ Burn in right upper limb	2	12DEC2020	101/9	2	No	O	NA/TC	R (20DEC2020)	N/N	
16-55/ C4591001 1241 12411098	GENRL	Injection site pain/ Injection site pain#	4	15FEB2021	1/3	1	Yes		NA/TC	R (17FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N	
16-55/ C4591001 1241 12411106	INFEC	Otitis media acute/ Acute otitis media	1	21AUG2020	9/10	2	No	O	NA/TC	R (30AUG2020)	N/N	
16-55/ C4591001 1241 12411108	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/Y	
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411109	GENRL	Fatigue/ Fatigue#	3	12FEB2021	2/3	1	Yes		NA/TC	R (14FEB2021)	N/N	
16-55/ C4591001 1241 12411111	NERV	Injection site pain/ Injection site pain#	3	12FEB2021	2/3	2	Yes		NA/TC/TCN	R (14FEB2021)	N/N	
	NERV	Headache/ Headache#	3	12FEB2021	2/3	1	Yes		NA/TC	R (14FEB2021)	N/N	
16-55/ C4591001 1241 12411113	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N	
	MUSC	Pyrexia/ Fever#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N	
16-55/ C4591001 1241 12411114	INFEC	Vaginal infection/ Colpitis	1	28AUG2020	15/68	1	No	O	NA/TC	R (03NOV2020)	N/N	
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	10FEB2021	2/4	1	Yes		NA	R (13FEB2021)	N/N	
	GENRL	Pyrexia/ Fever#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	2/3	1	Yes		NA	R (04FEB2021)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411118	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411120	INFEC	Urinary tract infection/ Urinary tract infection#	2	01MAR2021	179/3	1	No	O	NA/TC	R (03MAR2021)	N/N
16-55/ C4591001 1241 12411122	GENRL	Asthenia/ Asthenia#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1241 12411125	GENRL	Injection site pain/ Injection site pain	1	14AUG2020	1/2	1	Yes		NA	R (15AUG2020)	N/Y
16-55/ C4591001 1241 12411127	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N
		Pyrexia/ Fever#	3	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N
	NERV	Headache/ Headache#	3	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	2/4	1	Yes		NA/TC	R (26FEB2021)	N/N
		Pyrexia/ Fever#	4	23FEB2021	2/4	1	Yes		NA/TC	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	4	23FEB2021	2/4	1	Yes		NA/TC	R (26FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411131	SURG	Tooth extraction/ Dental extraction#	3	25FEB2021	22/1	1	No	O	NA/TCN	R (25FEB2021)	N/N
16-55/ C4591001 1241 12411132	GENRL	Fatigue/ Intermittent fatigue	1	18OCT2020	66/6	1	No	O	NA	R (23OCT2020)	N/N
16-55/ C4591001 1241 12411135	INFEC	Urinary tract infection/ Urinary tract infection	2	05SEP2020	2/10	2	No	O	NA/TC	R (14SEP2020)	N/N
	MUSC	Arthralgia/ Arthralgia	2	05SEP2020	2/8	2	Yes		NA/TC	R (12SEP2020)	N/N
		Myalgia/ Myalgia	2	05SEP2020	2/8	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1241 12411136	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
		Pyrexia/ Fever#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411137	GENRL	Injection site pain/ Injection site pain	1	14AUG2020	1/1	1	Yes		NA	R (14AUG2020)	N/Y
	GENRL	Fatigue/ Fatigue#	4	13FEB2021	2/2	1	Yes		NA/TC	R (14FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411138	GENRL	Pyrexia/ Fever#	4	13FEB2021	2/2	1	Yes		NA/TC	R (14FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	4	15FEB2021	1/1	1	Yes		NA	R (15FEB2021)	N/N
	GENRL	Asthenia/ Asthenia#	4	15FEB2021	1/3	2	Yes		NA/TC	R (17FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	15FEB2021	1/1	1	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1241 12411141	MUSC	Pyrexia/ Fever#	4	15FEB2021	1/3	2	Yes		NA/TC	R (17FEB2021)	N/N
		Myalgia/ Myalgia#	4	15FEB2021	1/3	2	Yes		NA/TC	R (17FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
		Pyrexia/ Fever#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1241 12411142	GENRL	Pyrexia/ Fever#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411145	GENRL	Pyrexia/ Fever#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
	SKIN	Rash/ Generalised Skin rash	2	10DEC2020	93/37	1	No	O	NA/TC	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Fatigue/ Prostration#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/3	1	Yes		NA/TCN	R (28JAN2021)	N/N
	1241 12411156	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/2	2	Yes		NA/TC	R (18FEB2021)

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411157	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1241 12411163	GENRL	Chills/ Chills#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
		Pyrexia/ Fever#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	NERV	Headache/ Headache#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	4	17FEB2021	2/4	1	Yes		NA/TC	R (20FEB2021)	N/N
	GENRL	Pain/ Body pain#	4	17FEB2021	2/4	1	Yes		NA/TC	R (20FEB2021)	N/N
		Pyrexia/ Fever#	4	17FEB2021	2/4	1	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	4	17FEB2021	2/4	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1241 12411165	INV	Blood iron decreased/ Reduction of serum iron	2	JAN2021	116/C	1	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411167	GENRL	Chills/ Chills#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411170	NERV	Fatigue/ Prostration#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
		Headache/ Headache#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Chills/ Chills#	4	11FEB2021	2/2	2	Yes		NA/TC	R (12FEB2021)	N/N
		Pyrexia/ Fever#	4	11FEB2021	2/2	2	Yes		NA/TC	R (12FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/2	2	Yes		NA/TC	R (12FEB2021)	N/N
	NERV	Headache/ Headache#	4	11FEB2021	2/2	2	Yes		NA/TC	R (12FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N
		Pyrexia/ Fever#	3	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N
		Pyrexia/ Fever#	4	17FEB2021	2/2	2	Yes		NA/TC	R (18FEB2021)	N/N
MUSC		Myalgia/ Myalgia#	4	17FEB2021	2/2	2	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411171	MUSC	Myalgia/ Myalgia#	3	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001	INFEC	Folliculitis/ Folliculitis in the left armpit	1	02SEP2020	17/9	1	No	O	NA	R (10SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411175 16-55/ C4591001 1241 12411178	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
1241 12411178	GENRL	Fatigue/ Fatigue#	4	19FEB2021	2/3	1	Yes		NA	R (21FEB2021)	N/N
1241 12411178		Injection site pain/ Injection site pain#	4	19FEB2021	2/3	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1241 12411179	GENRL	Asthenia/ Asthenia#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
1241 12411179		Injection site pain/ Injection site pain#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
1241 12411183	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
1241 12411183	NERV	Headache/ Headache#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411183	GENRL	Injection site pain/ Injection site plain#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
1241 12411183	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411184	GASTR	Nausea/ Nausea#	3	22JAN2021	1/1	2	Yes		NA/TC	R (22JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411188	GENRL	Vomiting/ Vomiting#	3	22JAN2021	1/1	2	Yes		NA/TC	R (22JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	22JAN2021	1/2	2	Yes		NA/TC	R (23JAN2021)	N/N
	NERV	Headache/ Headache#	3	22JAN2021	1/2	2	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/1	2	Yes		NA/TC	R (11FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1241 12411195	GENRL	Injection site pain/ Injection site pain#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411197	INJ&P	Injection site pain/ Injection site pain#	4	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
		Ligament sprain/ Left ankle sprain	2	24SEP2020	17/7	2	No	O	NA/TC	R (30SEP2020)	N/N
	INFEC	Tooth infection/ Dental inflammation	2	28SEP2020	21/15	1	No	O	NA/TC	R (12OCT2020)	N/N
	BLOOD	Lymphadenopathy/ Ipsilateral axillary lymphadenopathy#	3	22JAN2021	1/3	2	Yes		NA	R (24JAN2021)	N/N
	GENRL	Chills/ Chills#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
		Fatigue/ Fatigue#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	22JAN2021	1/3	2	Yes		NA	R (24JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
		Pyrexia/ Fever#	4	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12411198	MUSC	Myalgia/ Myalgia#	4	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
	INFEC	Fungal skin infection/ Fungal dermatitis	2	10SEP2020	3/60	1	No	O	NA/TC	R (08NOV2020)	N/N
	INFEC	Folliculitis/ Folliculitis in the armpits	2	15OCT2020	38/25	1	No	O	NA/TC	R (08NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411205	GENRL	Injection site pain/ Injection site pain#	4	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1241 12411206	REPRO	Breast hyperplasia/ Atypical intraductal hyperplasia in left breast	2	29SEP2020	21/2	2	No	O	NA/TC	R (30SEP2020)	Y/N
16-55/ C4591001 1241 12411208	GENRL	Injection site pain/ Injection site pain#	3	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy#	3	10FEB2021	6/C		No	O	P	UNK	N/N
16-55/ C4591001 1241 12411214	RESP	Cough/ Cough	2	24SEP2020	16/2	1	No	O	NA	R (25SEP2020)	N/N
16-55/ C4591001 1241 12411220	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	2/3	1	Yes		NA	R (31JAN2021)	N/N
		Injection site swelling/ Injection site swelling#	3	29JAN2021	2/3	1	Yes		NA	R (31JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1241 12411223	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GASTR	Vomiting/ Vomiting#	4	17FEB2021	2/3	2	Yes		NA/TC	R (19FEB2021)	N/N	
	GENRL	Pyrexia/ Fever#	4	17FEB2021	2/3	2	Yes		NA/TC	R (19FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/3	2	Yes		NA/TC	R (19FEB2021)	N/N	
16-55/ C4591001 1241 12411224	IMMUN	Food allergy/ Worsening Allergic reaction to shrimp	1	19AUG2020	2/1	1	No	O	NA/TC	R (19AUG2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	20FEB2021	2/1	1	Yes		NA/TC	R (20FEB2021)	N/N	
	NERV	Headache/ Headache#	3	20FEB2021	2/1	1	Yes		NA/TC	R (20FEB2021)	N/N	
16-55/ C4591001 1241 12411226	GENRL	Injection site pain/ Injection site pain#	3	06FEB2021	2/4	1	Yes		NA	R (09FEB2021)	N/N	
16-55/ C4591001 1241 12411228	MUSC	Myalgia/ Myalgia#	3	27JAN2021	2/2	2	Yes		NA/TC	R (28JAN2021)	N/N	
16-55/ C4591001 1241 12411230	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N	
16-55/ C4591001 1241 12411231	NERV	Headache/ Worsening Recurrent headache	2	02OCT2020	23/5	2	No	O	NA/TC	R (06OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411232	GENRL	Pyrexia/ Fever#	3	27JAN2021	1/2	1	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Chills/ Chills#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
		Pyrexia/ Fever#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411236	NERV	Dizziness/ Dizziness	1	08SEP2020	22/2	1	No	O	NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1241 12411242	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/6	1	Yes		NA	R (14SEP2020)	N/Y
16-55/ C4591001 1241 12411243	RESP	Rhinitis allergic/ Allergic rhinitis	2	11SEP2020	3/1	1	No	O	NA/TC	R (11SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Asthenia/ Asthenia#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411248	MUSC	Pyrexia/ Fever#	4	22FEB2021	1/1	1	Yes		NA/TC	R (22FEB2021)	N/N	
		Myalgia/ Myalgia#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/4	1	Yes		NA/TC	R (25JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	3	23JAN2021	2/1	1	Yes		NA/TC	R (23JAN2021)	N/N	
16-55/ C4591001 1241 12411250	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/1	1	Yes		NA/TC	R (11FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N	
	GENRL	Pyrexia/ Fever#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N	
16-55/ C4591001 1241 12411253	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N	
	GENRL	Chills/ Chills#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N	
16-55/ C4591001 1241 12411255	REPRO	Injection site pain/ Injection site pain#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N	
		Dysmenorrhoea/ Menstrual cramps	1	05SEP2020	19/1	1	No	O	NA/TC	R (05SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411257	NERV	Headache/ Headache#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1241 12411261	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/1	1	Yes		NA	R (19AUG2020)	N/Y
	GENRL	Pyrexia/ Fever#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411262	MUSC	Arthritis/ Right knee arthritis	1	06SEP2020	19/21	2	No	O	NA/TC	R (26SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	14SEP2020	1/6	2	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1241 12411263	GENRL	Chills/ Chills#	3	04FEB2021	1/4	2	Yes		NA/TC	R (07FEB2021)	N/N
		Fatigue/ Fatigue#	3	04FEB2021	1/4	2	Yes		NA/TC	R (07FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	04FEB2021	1/4	2	Yes		NA/TC	R (07FEB2021)	N/N
		Pyrexia/ Fever#	3	04FEB2021	1/4	2	Yes		NA	R (07FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411267	MUSC	Myalgia/ Myalgia#	3	04FEB2021	1/4	2	Yes		NA/TC	R (07FEB2021)	N/N	
	NERV	Headache/ Headache#	3	04FEB2021	1/4	2	Yes		NA/TC	R (07FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/4	1	Yes		NA	R (06FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	24FEB2021	2/3	1	Yes		NA	R (26FEB2021)	N/N	
	16-55/ C4591001 1241 12411268	GENRL	Injection site pain/ Injection site pain	2	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N	
	NERV	Headache/ Headache#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N	
16-55/ C4591001 1241 12411269	SKIN	Hyperhidrosis/ Sweating#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	19FEB2021	2/1	1	Yes		NA/TC	R (19FEB2021)	N/N	
	INJ&P	Fall/ Fall from own height#	4	06MAR2021	17/1	3	No	O	NA	R (06MAR2021)	Y/N	
16-55/ C4591001	GENRL	Scapula fracture/ Fracture of the anterior border of the right glenoid#	4	06MAR2021	17/C	3	No	O	NA/TCN	N	Y/N	
		Fatigue/ Fatigue	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411270		Pain/ Body pain	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N	
	NERV	Headache/ Headache	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N	
16-55/ C4591001 1241 12411272	NERV	Headache/ Headache	1	19AUG2020	1/3	2	Yes		NA	R (21AUG2020)	N/N	
	GENRL	Pyrexia/ Fever	1	20AUG2020	2/2	2	Yes		NA	R (21AUG2020)	N/N	
16-55/ C4591001 1241 12411273	GENRL	Injection site pain/ Injection site pain	2	23OCT2020	1/1	1	Yes		NA	R (23OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N	
16-55/ C4591001 1241 12411274	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	2/4	2	Yes		NA	R (23AUG2020)	N/N	
16-55/ C4591001 1241 12411277	GENRL	Injection site pain/ Injection site pain#	3	26FEB2021	2/3	1	Yes		NA	R (28FEB2021)	N/N	
16-55/ C4591001 1241 12411278	GENRL	Pyrexia/ Fever	2	09SEP2020	2/1	1	Yes		NA/TC	R (09SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411279	GASTR	Abdominal pain/ Abdominal pain	2	12SEP2020	5/1	2	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/N
	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	10SEP2020	23/35		No	O	P	R (14OCT2020)	N/N
	REPRO	Vaginal haemorrhage/ Vaginal bleeding	1	05OCT2020	48/10	1	No	O	NA/TC	R (14OCT2020)	N/N
	PREG	Retained products of conception/ RETAINED PRODUCTS OF CONCEPTION	1	14OCT2020	57/1	3	No	O	NA/TC	R (14OCT2020)	Y/N
	GENRL	Chills/ Chills#	3	16FEB2021	1/4	1	Yes		NA	R (19FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	16FEB2021	1/4	1	Yes		NA	R (19FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	16FEB2021	1/4	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	2	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	2/3	2	Yes		NA	R (22AUG2020)	N/N
16-55/ C4591001 1241 12411280	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/Y
16-55/ C4591001 1241 12411281	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/Y
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411282		Fatigue/ Prostration#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1241 12411286	GASTR	Diarrhoea/ diarrhea	1	20AUG2020	2/4	1	Yes		NA	R (23AUG2020)	N/N
	MUSC	Myalgia/ Myalgia	1	20AUG2020	2/1	2	Yes		NA/TC	R (20AUG2020)	N/N
	IMMUN	Drug hypersensitivity/ Drug allergy	1	10SEP2020	23/1	3	No	CD	NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1241 12411287	GENRL	Fatigue/ Fatigue	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		Injection site pain/ Injection site pain	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1241 12411288	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/2	1	Yes		NA/TCN	R (05FEB2021)	N/N
16-55/ C4591001 1241 12411289	NERV	Headache/ Headache#	3	28JAN2021	2/3	2	Yes		NA/TC	R (30JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411290	NERV	Headache/ Headache#	4	18FEB2021	2/3	2	Yes		NA/TC	R (20FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
	RESP	Rhinitis allergic/ Headache due to allergic rhinitis	1	20AUG2020	2/2	1	No	O	NA/TC	R (21AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	21AUG2020	3/1	1	No	O	NA	R (21AUG2020)	N/N
		Vomiting/ Vomiting	1	21AUG2020	3/1	1	No	O	NA	R (21AUG2020)	N/N
16-55/ C4591001 1241 12411292	NERV	Paraesthesia/ Tingling in the left upper limb	1	21AUG2020	3/1	2	Yes		NA	R (21AUG2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
	NERV	Migraine/ Migraine crisis	2	07OCT2020	28/12	2	No	O	NA	R (18OCT2020)	N/N
	GENRL	Chills/ Chills#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
		Fatigue/ Fatigue#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411293		Pyrexia/ Fever#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/2	1	Yes		NA	R (20AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411294	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1241 12411295	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1241 12411299	GENRL	Chills/ Chills#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1241 12411300	NERV	Headache/ Headache#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411301	REPRO	Dysmenorrhoea/ menstrual cramps*		19AUG2020	1/3	2	No	O	NA/TC	R (21AUG2020)	N/N
16-55/ C4591001 1241 12411303	GASTR	Nausea/ Nausea	2	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ Headache	2	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411305	GENRL	Somnolence/ Drowsiness	2	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N	
		Chills/ Chills	2	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N	
	GENRL	Pyrexia/ Fever	2	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N	
16-55/ C4591001 1241 12411307	GASTR	Nausea/ Nausea	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N	
	GENRL	Injection site erythema/ Injection site erythema	2	11SEP2020	2/8	1	Yes		NA	R (18SEP2020)	N/N	
	NERV	Paraesthesia/ Tingling in the body	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N	
16-55/ C4591001 1241 12411308	GENRL	Injection site pain/ Injection site pain#	4	24FEB2021	2/2	1	Yes		NA	R (25FEB2021)	N/N	
	NERV	Headache/ Headache	1	19AUG2020	1/5	1	Yes		NA/TC	R (23AUG2020)	N/N	
	GENRL	Chills/ Chills#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N	
16-55/ C4591001 1241 12411309	GENRL	Chills/ Chills#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411311	GENRL	Pyrexia/ Fever#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
		Injection site pain/ Injection site pain	2	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1241 12411312	GENRL	Pyrexia/ Fever	1	20AUG2020	2/1	2	Yes		NA/TC	R (20AUG2020)	N/N
16-55/ C4591001 1241 12411313	MUSC	Myalgia/ Myalgia	1	20AUG2020	2/1	2	Yes		NA/TC	R (20AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1241 12411314	NERV	Headache/ Headache	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Fatigue/ Prostration#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
		Pyrexia/ Fever#	3	28JAN2021	2/1	1	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411315	NERV	Headache/ Headache	1	06SEP2020	19/1	1	No	O	NA/TC	R (06SEP2020)	N/N
16-55/ C4591001 1241 12411317	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/Y
	INFEC	Varicella/ varicella	1	01SEP2020	14/4	1	No	O	NA/TC	R (04SEP2020)	N/N
16-55/ C4591001 1241 12411319	INFEC	Gastroenteritis/ Food gastroenteritis	1	10SEP2020	23/1	1	No	O	NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		Injection site warmth/ Injection site heat	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/7	1	Yes		NA	R (08FEB2021)	N/N
		Pyrexia/ Fever#	3	02FEB2021	1/7	1	Yes		NA	R (08FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	02FEB2021	1/7	1	Yes		NA	R (08FEB2021)	N/N
	NERV	Headache/ Headache#	3	02FEB2021	1/7	1	Yes		NA/TC	R (08FEB2021)	N/N
16-55/ C4591001 1241 12411324	GENRL	Chills/ Chills#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411326	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	1/2	2	Yes		NA	R (21AUG2020)	N/N
		Injection site swelling/ Injection site swelling	1	20AUG2020	1/2	2	Yes		NA	R (21AUG2020)	N/N
	NERV	Headache/ Headache	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N
	INJ&P	Animal bite/ Dog bite in the cervical region	2	20DEC2020	103/1	1	No	O	NA/TCN	R (20DEC2020)	N/N
16-55/ C4591001 1241 12411330	GENRL	Pyrexia/ Fever#	4	25FEB2021	2/1	1	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1241 12411333	GENRL	Injection site pain/ Injection site pain	2	11SEP2020	1/3	2	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1241 12411334	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	10FEB2021	1/2	2	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1241 12411335	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411336	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
		Pyrexia/ Fever#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	NERV	Headache/ Headache#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	24FEB2021	2/3	1	Yes		NA/TC	R (26FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	24FEB2021	2/3	1	Yes		NA/TC	R (26FEB2021)	N/N
16-55/ C4591001 1241 12411337	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/1	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1241 12411339	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	1/3	1	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Chills/ Chills	2	11SEP2020	2/3	1	Yes		NA/TC	R (13SEP2020)	N/N
		Fatigue/ Fatigue	2	11SEP2020	2/4	2	Yes		NA/TC	R (14SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	11SEP2020	2/4	2	Yes		NA/TC	R (14SEP2020)	N/N
	NERV	Headache/ Headache	2	11SEP2020	2/4	2	Yes		NA/TC	R (14SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411341	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1241 12411342	GENRL	Injection site pain/ Injection site pain	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1241 12411343	GENRL	Injection site pain/ Injection site pain	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
	MUSC	Back pain/ Backache	2	12SEP2020	2/3	2	Yes		NA/TC	R (14SEP2020)	N/N
		Pain in extremity/ Legs pain	2	12SEP2020	2/3	2	Yes		NA/TC	R (14SEP2020)	N/N
	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy	2	30OCT2020	50/C		No	O	NA	UNK	N/N
16-55/ C4591001 1241 12411344	GENRL	Asthenia/ Asthenia	2	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411345	GENRL	Chills/ chills	1	20AUG2020	1/1	1	Yes		NA	R (20AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411346	NERV	Headache/ Headache	1	20AUG2020	1/2	1	Yes		NA/TC	R (21AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411347	NERV	Headache/ Headache	1	09SEP2020	21/1	1	No	O	NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1241 12411348	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Left axillary lymphadenopathy#	3	02FEB2021	2/3	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	3	03FEB2021	3/4	1	Yes		NA/TC	R (06FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
	NERV	Headache/ Headache#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
	NERV	Headache/ Headache	1	10SEP2020	22/1	1	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411349		Injection site pain/ Injection site pain#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N	
16-55/ C4591001 1241 12411351	GENRL	Fatigue/ Fatigue#	4	24FEB2021	2/2	1	Yes		NA	R (25FEB2021)	N/N	
		Pyrexia/ Fever#	4	24FEB2021	2/2	1	Yes		NA	R (25FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	24FEB2021	2/2	1	Yes		NA	R (25FEB2021)	N/N	
16-55/ C4591001 1241 12411356	GENRL	Pyrexia/ Fever	2	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N	
16-55/ C4591001 1241 12411360	GASTR	Nausea/ Nausea#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N	
16-55/ C4591001 1241 12411362	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N	
16-55/ C4591001 1241 12411363	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/4	1	Yes		NA	R (28JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411367	MUSC	Myalgia/ Myalgia#	3	25JAN2021	1/4	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1241 12411368	GENRL	Fatigue/ Fatigue#	3	20FEB2021	2/1	1	Yes		NA/TC/TCN	R (20FEB2021)	N/N
	GENRL	Chills/ Chills	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1241 12411369		Fatigue/ Fatigue	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
		Injection site pain/ Injection site pain	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
		Pyrexia/ Fever	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Headache/ Headache	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
	MUSC	Myalgia/ Myalgia#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
	NERV	Headache/ Headache#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Chills/ Chills#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411370	NERV	Headache/ Headache#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
	GENRL	Chills/ Chills	2	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
		Fatigue/ Fatigue	2	11SEP2020	1/3	2	Yes		NA/TC	R (13SEP2020)	N/N
		Injection site pain/ Injection site pain	2	11SEP2020	1/3	2	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1241 12411372	NERV	Headache/ Headache	1	04SEP2020	16/1	1	No	O	NA/TC	R (04SEP2020)	N/N
16-55/ C4591001 1241 12411373	GENRL	Fatigue/ Fatigue#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1241 12411376	GASTR	Toothache/ Toothache	2	18SEP2020	8/1	1	No	O	NA/TC	R (18SEP2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411377		Injection site pain/ Injection site pain	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		Pain/ Body pain	2	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N
		Pyrexia/ Fever	2	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Headache/ headache	2	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1241 12411378	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/1	1	Yes		NA/TC	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1241 12411379	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411381	GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux disease	2	20SEP2020	12/4	1	No	O	NA/TC	R (23SEP2020)	N/N
	GENRL	Pyrexia/ Fever#	3	05FEB2021	4/2	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411383		Pyrexia/ Fever	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N	
16-55/ C4591001 1241 12411384	GENRL	Injection site pain/ Injection site pain	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N	
		Malaise/ Malaise	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N	
	NERV	Tension headache/ Tension headache	2	09OCT2020	29/1	1	No	O	NA/TC	R (09OCT2020)	N/N	
16-55/ C4591001 1241 12411385	REPRO	Dysmenorrhoea/ dysmenorrhea	1	05SEP2020	17/1	1	No	O	NA/TC/TCN	R (05SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N	
	BLOOD	Lymphadenopathy/ Lymph node enlargement in the left armpit#	4	11FEB2021	2/3	1	Yes		NA/TC	R (13FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N	
16-55/ C4591001 1241 12411386	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	1/1	1	Yes		NA	R (20AUG2020)	N/Y	
16-55/ C4591001 1241 12411387	GENRL	Fatigue/ Fatigue	2	16SEP2020	1/3	2	Yes		NA/TCN	R (18SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411388	GENRL	Chills/ Chills	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N	
		Pyrexia/ Fever	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N	
		Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N	
		MUSC	Myalgia/ Myalgia#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
		MUSC	Myalgia/ Myalgia#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
	16-55/ C4591001 1241 12411389	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
			Pyrexia/ Fever#	3	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
		NERV	Headache/ Headache#	3	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1241 12411390	NERV	Headache/ Headache	1	07SEP2020	19/1	2	No	O	NA/TC	R (07SEP2020)	N/N	
	GENRL	Chills/ Chills	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411393	MUSC	Myalgia/ Myalgia	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	21AUG2020	1/2	2	Yes		NA/TC	R (22AUG2020)	N/N
16-55/ C4591001 1241 12411395	GENRL	Injection site pain/ Injection site pain	2	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Pyrexia/ Fever#	3	04FEB2021	1/2	1	Yes		NA/TC	R (05FEB2021)	N/N
16-55/ C4591001 1241 12411398	MUSC	Myalgia/ Myalgia#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1241 12411399	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411401	GENRL	Injection site pain/ Injection site pain#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/Y	
16-55/ C4591001 1241 12411402	GENRL	Chills/ Chills	2	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N	
		Fatigue/ Prostration	2	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N	
		Injection site pain/ Injection site pain	2	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N	
16-55/ C4591001 1241 12411408	MUSC	Myalgia/ Myalgia	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N	
16-55/ C4591001 1241 12411409	GENRL	Fatigue/ Fatigue	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N	
		Fatigue/ Prostration	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	
		Injection site swelling/ Injection site swelling#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	
16-55/ C4591001 1241 12411410	BLOOD	Lymphadenopathy/ Left axillary lymph node enlargement#	3	26JAN2021	2/4	1	Yes		NA	R (29JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	2/4	1	Yes		NA	R (29JAN2021)	N/N
	NERV	Headache/ Headache#	3	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	BLOOD	Lymphadenopathy/ Left axillary lymphadenopathy#	4	16FEB2021	2/4	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	2/4	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411411	GENRL	Injection site pruritus/ Injection site itching	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1241 12411413	GENRL	Chills/ Chills	2	16SEP2020	1/1	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1241 12411415	GENRL	Injection site pain/ Injection site pain#	3	19FEB2021	1/3	2	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1241 12411416	GASTR	Nausea/ Nausea	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ Headache	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411417	MUSC	Myalgia/ Myalgia#	3	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	2/4	1	Yes		NA/TC	R (19FEB2021)	N/N	
		Pyrexia/ Fever#	4	16FEB2021	2/4	1	Yes		NA/TC	R (19FEB2021)	N/N	
16-55/ C4591001 1241 12411418	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N	
16-55/ C4591001 1241 12411420	GASTR	Nausea/ Nausea#	3	27JAN2021	3/2	1	Yes		NA/TC	R (28JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	3/2	1	Yes		NA	R (28JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	3	27JAN2021	3/2	1	Yes		NA/TC	R (28JAN2021)	N/N	
	NERV	Headache/ Headache#	3	27JAN2021	3/2	1	Yes		NA/TC	R (28JAN2021)	N/N	
	GASTR	Abdominal pain/ Abdominal pain#	3	29JAN2021	5/3	2	Yes		NA	R (31JAN2021)	N/N	
		Diarrhoea/ Diarrhea#	3	29JAN2021	5/3	2	Yes		NA	R (31JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	3	29JAN2021	5/3	2	Yes		NA	R (31JAN2021)	N/N	
	GASTR	Diarrhoea/ Diarrhea#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411422	GENRL	Pyrexia/ Fever#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	GENRL	Fatigue/ Prostration#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1241 12411423		Injection site pain/ Injection site pain#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1241 12411424	NERV	Headache/ Headache	2	15SEP2020	2/1	1	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1241 12411426	GENRL	Fatigue/ Fatigue#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
		Pyrexia/ Fever#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411431	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/4	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	1/3	1	Yes		NA	R (18FEB2021)	N/Y
16-55/ C4591001 1241 12411432	INFEC	Vulvovaginal candidiasis/ Vaginal candidiasis	1	07SEP2020	15/21	1	No	O	NA/TC	R (27SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1241 12411435	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/Y
	NERV	Headache/ Headache	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1241 12411437	GENRL	Pyrexia/ Fever	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ Headache	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411438	GENRL	Chills/ Chills	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1241 12411439	GENRL	Pyrexia/ Fever	2	15SEP2020	2/2	2	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1241 12411440	GENRL	Fatigue/ Prostration#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Chills/ Chills#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
		Fatigue/ Fatigue#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	11FEB2021	2/1	1	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1241 12411441	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1241 12411443	GENRL	Injection site erythema/ Erythema at the injection site	2	15SEP2020	2/5	2	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Injection site pain	2	15SEP2020	2/5	2	Yes		NA	R (19SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411444	NERV	Injection site swelling/ Swelling the injection site	2	15SEP2020	2/5	2	Yes		NA	R (19SEP2020)	N/N
		Tension headache/ Tension headache	1	10SEP2020	18/1	1	No	O	NA/TC	R (10SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	15SEP2020	2/1	2	Yes		NA/TC	R (15SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	15SEP2020	2/1	2	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1241 12411445	INJ&P	Skin laceration/ Cutting injury in left hand	2	19SEP2020	6/1	2	No	O	NA/TC	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	2/3	2	Yes		NA	R (28JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1241 12411449	NERV	Injection site pain/ Injection site pain	2	14SEP2020	1/1	1	Yes		NA/TC	R (14SEP2020)	N/N
		Headache/ headache	2	14SEP2020	1/1	1	Yes		NA	R (14SEP2020)	N/Y
16-55/ C4591001 1241 12411450	GENRL	Fatigue/ Fatigue#	3	23JAN2021	2/1	1	Yes		NA/TC	R (23JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411451	NERV	Injection site pain/ Injection site pain#	3	23JAN2021	2/1	1	Yes	NA/TC	R	(23JAN2021)	N/N	
		Headache/ Headache#	3	23JAN2021	2/1	1	Yes	NA/TC	R	(23JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/1	1	Yes	NA	R	(11FEB2021)	N/N	
		Injection site pain/ Injection site pain#	4	11FEB2021	2/1	1	Yes	NA	R	(11FEB2021)	N/N	
	NERV	Headache/ Headache#	4	11FEB2021	2/1	1	Yes	NA/TC	R	(11FEB2021)	N/N	
		Injection site erythema/ Injection site redness	2	15SEP2020	2/3	2	Yes	NA/TCN	R	(17SEP2020)	N/N	
	16-55/ C4591001 1241 12411452	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/3	2	Yes	NA/TCN	R	(17SEP2020)	N/N
			Injection site swelling/ Injection site swelling	2	15SEP2020	2/3	2	Yes	NA/TCN	R	(17SEP2020)	N/N
			Pyrexia/ Fever	2	15SEP2020	2/1	1	Yes	NA/TC	R	(15SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain*		24AUG2020	1/8	2	Yes	NA	R	(31AUG2020)	N/N
Injection site swelling/ Injection site swelling			1	25AUG2020	2/2	2	Yes	NA	R	(26AUG2020)	N/N	
MUSC			Myalgia/ Myalgia	1	26AUG2020	3/6	2	Yes	NA	R	(31AUG2020)	N/N
GENRL	Chills/ Chills	1	30AUG2020	7/1	1	Yes	NA	R	(30AUG2020)	N/N		

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/6	2	Yes		NA/TC	R (20SEP2020)	N/N	
		Pyrexia/ Fever	2	15SEP2020	2/4	2	Yes		NA/TC	R (18SEP2020)	N/N	
16-55/ C4591001 1241 12411453	GENRL	Injection site pain/ Injection site pain	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N	
16-55/ C4591001 1241 12411454	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N	
	NERV	Headache/ Headache#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N	
		Injection site pain/ Injection site pain#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N	
16-55/ C4591001 1241 12411455	GENRL	Fatigue/ Fatigue#	3	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N	
		Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N	
16-55/ C4591001	GASTR	Nausea/ Nausea	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411456	GENRL	Chills/ Chills	2	14SEP2020	1/2	1	Yes	NA/TC	R	(15SEP2020)	N/N
		Fatigue/ Prostration	2	14SEP2020	1/2	1	Yes	NA/TC	R	(15SEP2020)	N/N
		Pyrexia/ Fever	2	14SEP2020	1/2	1	Yes	NA/TC	R	(15SEP2020)	N/N
	NERV	Headache/ headache	2	14SEP2020	1/2	1	Yes	NA/TC	R	(15SEP2020)	N/N
16-55/ C4591001 1241 12411457	GENRL	Fatigue/ Prostration#	3	30JAN2021	2/2	1	Yes	NA/TC	R	(31JAN2021)	N/N
		Pyrexia/ Subfebrile#	3	30JAN2021	2/2	1	Yes	NA/TC	R	(31JAN2021)	N/N
16-55/ C4591001 1241 12411459	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/2	1	Yes	NA	R	(03FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	02FEB2021	1/2	1	Yes	NA	R	(03FEB2021)	N/N
	NERV	Headache/ Headache#	3	02FEB2021	1/2	1	Yes	NA	R	(03FEB2021)	N/N
16-55/ C4591001 1241 12411460	GENRL	Injection site pain/ Injection site pain#	3	23JAN2021	2/2	1	Yes	NA	R	(24JAN2021)	N/N
16-55/ C4591001	GASTR	Nausea/ Nausea	2	15SEP2020	2/2	1	Yes	NA/TC	R	(16SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411461	GENRL	Pyrexia/ Fever	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N	
16-55/ C4591001 1241 12411462	GENRL	Chills/ Chills	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N	
		Fatigue/ Fatigue	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N	
		Pyrexia/ Fever	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N	
16-55/ C4591001 1241 12411464	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/Y	
		Injection site swelling/ Injection site swelling	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/Y	
	GASTR	Abdominal pain/ Abdominal pain	2	14SEP2020	1/5	1	Yes		NA/TC	R (18SEP2020)	N/N	
		Diarrhoea/ Diarrhea	2	14SEP2020	1/5	1	Yes		NA/TC	R (18SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/Y	
	MUSC	Myalgia/ Myalgia#	3	29JAN2021	2/1	1	Yes		NA	R (29JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/Y	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411465	GENRL	Fatigue/ Prostration#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
	METAB	Food intolerance/ Gastrointestinal food intolerance	1	31AUG2020	8/1	1	No	O	NA/TC	R (31AUG2020)	N/N
	GENRL	Chills/ Chills	2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N
		Pain/ Body pain	2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N
		Pyrexia/ Fever	2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	24SEP2020	9/1	2	No	O	NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
GENRL	Injection site pain/ Injection site pain#	4	15FEB2021	1/2	1	Yes		NA/TC	R (16FEB2021)	N/N	
GENRL	Pyrexia/ Fever#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N	
GENRL	Fatigue/ Fatigue#	4	17FEB2021	3/3	1	Yes		NA/TC	R (19FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	3/3	1	Yes		NA/TC	R (19FEB2021)	N/N	
16-55/ C4591001 1241 12411467	INFEC	Urinary tract infection/ Urinary tract infection#	2	20FEB2021	158/9	1	No	O	NA/TC	R (28FEB2021)	N/N	
16-55/ C4591001 1241 12411468	GENRL	Chills/ Chills#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N	
		Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N	
	BLOOD	Lymphadenopathy/ Left axillary lymphadenopathy#	4	16FEB2021	2/5	1	Yes		NA	R (20FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N	
16-55/ C4591001 1241 12411469	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	2/4	1	Yes		NA	R (07FEB2021)	N/N	
16-55/ C4591001 1241 12411470	GENRL	Chills/ Chills	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N	
		Pyrexia/ Fever	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N	
16-55/ C4591001 1241 12411471	GENRL	Injection site pain/ Injection site pain	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/Y	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411472	GASTR	Nausea/ Nausea	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
		Fatigue/ Fatigue	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
		Injection site pain/ Injection site pain	2	15SEP2020	1/7	2	Yes		NA/TC	R (21SEP2020)	N/N
		Injection site swelling/ Injection site swelling	2	15SEP2020	1/7	2	Yes		NA/TC	R (21SEP2020)	N/N
		Pyrexia/ Fever	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
	BLOOD	Lymphadenopathy/ Reactive axillary lymph node in the left arm	2	16SEP2020	2/11	2	Yes		NA/TC	R (26SEP2020)	N/N
	INFEC	Mumps/ Left mumps#	2	FEB2021	140/C	1	No	O	NA	RG	N/N
	Fatigue/ Fatigue#	3	25JAN2021	1/3	2	Yes		NA	R (27JAN2021)	N/N	
	Injection site pain/ Injection site pain#	3	25JAN2021	1/3	2	Yes		NA/TC	R (27JAN2021)	N/N	
MUSC	Arthralgia/ Arthralgia#	3	25JAN2021	1/3	2	Yes		NA/TC	R (27JAN2021)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411473	NERV	Myalgia/ Myalgia#	3	25JAN2021	1/3	2	Yes		NA/TC	R (27JAN2021)	N/N
		Headache/ Headache#	3	25JAN2021	1/3	2	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	3	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	15FEB2021	1/4	1	Yes		NA/TC	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	15FEB2021	1/4	1	Yes		NA/TC	R (18FEB2021)	N/N
	NERV	Headache/ Headache#	4	15FEB2021	1/4	1	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	2/3	1	Yes		NA	R (31JAN2021)	N/N
	NERV	Headache/ Headache#	3	29JAN2021	2/1	1	Yes		NA/TC	R (29JAN2021)	N/N
	GENRL	Chills/ Chills#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
			Fatigue/ Fatigue#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)
		Injection site pain/ Injection site pain#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
		Pyrexia/ Fever#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411475	GENRL	Pyrexia/ Fever	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1241 12411476	NERV	Dizziness/ Dizziness	1	29AUG2020	5/1	1	No	O	NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/Y
	GENRL	Fatigue/ Fatigue#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1241 12411477	NERV	Headache/ Headache	1	25AUG2020	1/1	2	Yes		NA/TC	R (25AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	26AUG2020	2/2	2	Yes		NA	R (27AUG2020)	N/N
		Injection site swelling/ Injection site swelling	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
	MUSC	Myalgia/ Myalgia	1	26AUG2020	2/2	2	Yes		NA	R (27AUG2020)	N/N
	GENRL	Chills/ Chills	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Fatigue/ Fatigue	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411478	GENRL	Injection site pain/ Injection site pain	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Injection site pain#	3	04FEB2021	2/1	2	Yes		NA	R (04FEB2021)	N/N
	GENRL	Chills/ Chills#	4	24FEB2021	1/1	1	Yes		NA/TC	R (24FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	24FEB2021	1/C	1	Yes		NA/TC	N	N/N
16-55/ C4591001 1241 12411480	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/Y
16-55/ C4591001 1241 12411482	NERV	Headache/ headache	1	25AUG2020	1/1	2	Yes		NA/TC	R (25AUG2020)	N/N
16-55/ C4591001 1241 12411482	GENRL	Injection site oedema/ Edema at the injection site	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Injection site pain/ injection site pain	1	26AUG2020	2/2	2	Yes		NA	R (27AUG2020)	N/N
	MUSC	Myalgia/ Myalgia	1	26AUG2020	2/2	2	Yes		NA	R (27AUG2020)	N/N
	GENRL	Fatigue/ Fatigue#	2	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Injection site pain/ Injection site pain#	2	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
NERV	Headache/ Headache#	2	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411483	GENRL	Chills/ Chills	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
		Fatigue/ Fatigue	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
		Injection site pain/ Injection site pain	2	15SEP2020	1/3	1	Yes		NA/TC	R (17SEP2020)	N/N
		Pain/ Body pain	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
		Pyrexia/ Fever	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ Headache	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)
16-55/ C4591001 1241 12411484	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	17FEB2021	1/3	1	Yes		NA/TC	R (19FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	1/3	1	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	17FEB2021	1/3	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411487	NERV	Tension headache/ Tension headache	1	12SEP2020	19/1	1	No	O	NA/TC	R (12SEP2020)	N/N
16-55/ C4591001	GASTR	Dyspepsia/ Pyrosis	1	07SEP2020	14/5	1	No	O	NA/TC	R (11SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411488	NERV	Headache/ Headache#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1241 12411489	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1241 12411490	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/4	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411490	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1241 12411490	GENRL	Injection site pain/ Injection site pain#	4	11FEB2021	1/5	1	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1241 12411493	BLOOD	Lymphadenopathy/ Left axillary lymph node enlargement#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411493	GENRL	Pyrexia/ Fever#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411493	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411494	GASTR	Diarrhoea/ Diarrhea#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1241 12411494	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INJ&P	Limb injury/ Foot injury with nail#	3	15FEB2021	12/1	1	No	O	NA/TCN	R (15FEB2021)	N/N
16-55/ C4591001 1241 12411495	GENRL	Pyrexia/ Fever	2	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1241 12411497	GENRL	Injection site pain/ Injection site pain	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	2/1	2	Yes		NA/TC	R (15SEP2020)	N/N
		Fatigue/ Fatigue	2	15SEP2020	2/1	2	Yes		NA/TC	R (15SEP2020)	N/N
		Pyrexia/ Fever	2	15SEP2020	2/1	2	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1241 12411499	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/4	2	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1241 12411500	GASTR	Diarrhoea/ Diarrhea	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1241 12411501	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		Malaise/ Malaise	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411502	MUSC	Myalgia/ Myalgia	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ Headache	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1241 12411503	GENRL	Pyrexia/ Fever	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/Y
16-55/ C4591001 1241 12411504	GASTR	Nausea/ Nausea	2	16SEP2020	2/3	3	Yes		NA	R (18SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1241 12411504	MUSC	Myalgia/ Myalgia	2	16SEP2020	2/3	3	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	2/3	3	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1241 12411505	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1241 12411505	NERV	Headache/ Headache	1	10SEP2020	17/1	1	No	O	NA/TC	R (10SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
		Pyrexia/ Fever	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1241 12411506	GENRL	Pyrexia/ Fever#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1241 12411509	MUSC	Myalgia/ Myalgia#	3	30JAN2021	2/1	2	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1241 12411510	NERV	Headache/ Headache	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Injection site swelling/ Injection site swelling	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1241 12411512	GENRL	Chills/ Chills	1	02SEP2020	2/1	1	Yes		NA/TC	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	2/2	1	Yes		NA/TC	R (03FEB2021)	N/N
	NERV	Headache/ Headache#	3	02FEB2021	2/2	1	Yes		NA/TC	R (03FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411513	NERV	Pyrexia/ Fever#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
		Headache/ Headache#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
	MUSC	Myalgia/ Myalgia	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
	NERV	Headache/ headache	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1241 12411514	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	2/2	2	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1241 12411515	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy#	3	05FEB2021	10/C		No	O	P	UNK	N/N
	GENRL	Injection site pain/ Injection site pain	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1241 12411516	GENRL	Injection site pain/ Injection site pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411519	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	NERV	Headache/ Headache#	3	01FEB2021	1/3	2	Yes		NA/TC	R (03FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/3	1	Yes		NA/TC	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	4	22FEB2021	1/4	1	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1241 12411520	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
		Pyrexia/ Fever#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
	NERV	Headache/ Headache#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1241 12411526	GENRL	Injection site pain/ Injection site pain#	3	18FEB2021	1/C	1	Yes		NA	N	N/N
	GENRL	Fatigue/ Fatigue#	3	19FEB2021	2/2	2	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	3	19FEB2021	2/2	2	Yes		NA/TC	R (20FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411527	GENRL	Pyrexia/ Fever	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1241 12411528	GENRL	Injection site pain/ Injection site pain	1	01SEP2020	1/1	1	Yes		NA	R (01SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	1	01SEP2020	1/1	1	Yes		NA	R (01SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	29JAN2021	2/2	1	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	19FEB2021	2/5	1	Yes		NA/TC	R (23FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	19FEB2021	2/5	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1241 12411530	GENRL	Chills/ Chills	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N
		Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N
		Injection site pain/ Injection site pain	2	24SEP2020	2/4	2	Yes		NA/TC	R (27SEP2020)	N/N
		Pyrexia/ Fever	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411531	NERV	Headache/ Headache	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N	
	GENRL	Fatigue/ Prostration#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N	
		Fatigue/ Prostration#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N	
		Injection site pain/ Injection site pain#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N	
	GENRL	Pyrexia/ Fever	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N	
	16-55/ C4591001 1241 12411535	INFEC	Influenza/ Flu syndrome	1	14SEP2020	13/4	1	No	O	NA	R (17SEP2020)	N/N
	16-55/ C4591001 1241 12411536	NERV	Headache/ Headache#	3	28JAN2021	2/1	1	Yes		NA/TC	R (28JAN2021)	N/N
16-55/ C4591001 1241 12411538	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411542	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
		Injection site pain/ Injection site pain	1	03SEP2020	2/4	2	Yes		NA/TC	R (06SEP2020)	N/N	
	GASTR	Diarrhoea/ Diarrhea	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N	
	GENRL	Chills/ Chills	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N	
		Fatigue/ Fatigue	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N	
		Pyrexia/ Fever	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N	
	NERV	Headache/ Headache	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N	
	16-55/ C4591001 1241 12411544	GENRL	Injection site pain/ Injection site pain#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
	16-55/ C4591001 1241 12411546	MUSC	Myalgia/ Myalgia#	3	22JAN2021	1/5	1	Yes		NA/TC	R (26JAN2021)	N/N
	NERV	Headache/ Headache#	3	22JAN2021	1/5	1	Yes		NA/TC	R (26JAN2021)	N/N	
16-55/ C4591001	GENRL	Chills/ Chills#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411547		Fatigue/ Fatigue#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N	
		Injection site pain/ Injection site pain#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	3	06FEB2021	2/3	1	Yes		NA/TC	R (08FEB2021)	N/N	
16-55/ C4591001 1241 12411548	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/Y	
16-55/ C4591001 1241 12411552	GENRL	Fatigue/ Fatigue#	3	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N	
		Injection site pain/ Injection site pain#	3	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N	
	NERV	Headache/ Headache#	3	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	22FEB2021	1/2	2	Yes		NA/TC	R (23FEB2021)	N/N	
	NERV	Headache/ Headache#	4	22FEB2021	1/2	2	Yes		NA/TC	R (23FEB2021)	N/N	
16-55/ C4591001 1241 12411555	GASTR	Diarrhoea/ Diarrhea#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
		Pyrexia/ Fever#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
		Fatigue/ Fatigue#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
		Pyrexia/ Fever#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411556	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	2/2	2	Yes		NA	R (04SEP2020)	N/N
	NERV	Headache/ Headache	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1241 12411557	GENRL	Chills/ Chills	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1241 12411558	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ Prostration	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411561	MUSC	Myalgia/ Myalgia	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	25SEP2020	4/6	1	Yes		NA/TC	R (30SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	26SEP2020	5/1	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/5	1	Yes		NA	R (05FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Left axillary lymph node enlargement#	4	22FEB2021	1/5	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	2/3	1	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1241 12411562	GENRL	Fatigue/ Fatigue#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
		Pyrexia/ Fever#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	2/5	1	Yes		NA	R (27FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411564	GENRL	Pyrexia/ Fever#	4	23FEB2021	2/2	1	Yes		NA/TC	R (24FEB2021)	N/N
		Injection site pain/ Injection site pain	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		Fatigue/ Fatigue	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
		Nausea/ Nausea	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
		Chills/ Chills	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
		Fatigue/ Fatigue	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
		Headache/ Headache	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1241 12411565	SURG	Mammoplasty/ Breast implant prosthesis	2	15DEC2020	85/1	1	No	O	NA/TC	R (15DEC2020)	N/N
16-55/ C4591001 1241 12411566	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/3	2	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1241 12411566	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Chills/ Chills#	4	19FEB2021	2/4	1	Yes		NA	R (22FEB2021)	N/N
		Fatigue/ Fatigue#	4	19FEB2021	2/4	1	Yes		NA	R (22FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411567	GENRL	Injection site pain/ Injection site pain#	4	19FEB2021	2/4	1	Yes		NA	R (22FEB2021)	N/N	
		Injection site pain/ Injection site pain	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N	
		Injection site pain/ Injection site pain#	3	01FEB2021	1/2	2	Yes		NA/TC/TCN	R (02FEB2021)	N/N	
		Fatigue/ Fatigue#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N	
16-55/ C4591001 1241 12411568	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/2	1	Yes		NA/TCN	R (23FEB2021)	N/N	
		Injection site pain/ Injection site pain	1	04SEP2020	3/1	1	Yes		NA	R (04SEP2020)	N/N	
		Lymphadenopathy/ Right axillary lymph node enlargement#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N	
		Pyrexia/ Fever#	4	18FEB2021	2/3	1	Yes		NA/TC	R (20FEB2021)	N/N	
16-55/ C4591001 1241 12411569	GENRL	Headache/ Headache#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N	
		Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
		Injection site erythema/ Injection site redness	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N	
		Injection site pain/ Injection site pain	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411570	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N	
	INFEC	Cystitis/ Cystitis	2	24OCT2020	31/11	1	No	O	NA/TC	R (03NOV2020)	N/N	
16-55/ C4591001 1241 12411572	GENRL	Chills/ Chills	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N	
	NERV	Headache/ Headache	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N	
16-55/ C4591001 1241 12411574	GASTR	Odynophagia/ Odynophagia	1	03SEP2020	1/1	1	No	O	NA	R (03SEP2020)	N/Y	
	GENRL	Pyrexia/ Fever#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N	
16-55/ C4591001 1241 12411575	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 1241 12411576	EYE	Eye pain/ Pain in the eyes	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Chills/ Chills	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411577	GENRL	Pyrexia/ Fever	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N	
		Injection site pain/ Injection site pain#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N	
16-55/ C4591001 1241 12411578	GENRL	Pyrexia/ Fever	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001 1241 12411580	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N	
16-55/ C4591001 1241 12411581	MUSC	Myalgia/ Myalgia	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N	
	GENRL	Pyrexia/ Fever	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
	GENRL	Chills/ Chills#	3	23FEB2021	1/4	1	Yes		NA/TC	R (26FEB2021)	N/N	
			Fatigue/ Fatigue#	3	23FEB2021	1/4	1	Yes		NA/TC	R (26FEB2021)	N/N
			Pyrexia/ Fever#	3	23FEB2021	1/4	1	Yes		NA/TC	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	3	23FEB2021	1/4	1	Yes		NA/TC	R (26FEB2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411582	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ myalgia	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1241 12411583	NERV	Tension headache/ Tension headache	2	21OCT2020	29/1	1	No	O	NA/TCN	R (21OCT2020)	N/N
	GENRL	Chills/ Chills#	3	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
	NERV	Headache/ Headache#	3	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12411586	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	2/1	2	Yes		NA/TC	R (04SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	1	04SEP2020	2/1	2	Yes		NA/TC	R (04SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	22SEP2020	1/4	2	Yes		NA/TC	R (25SEP2020)	N/N
		Vomiting/ Vomiting	2	22SEP2020	1/4	2	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22SEP2020	1/4	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1241 12411587	GENRL	Injection site pain/ Injection site pain#	3	10FEB2021	1/4	1	Yes		NA	R (13FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411589	INFEC	Tinea cruris/ Ringworm in the inguinal region	1	04SEP2020	2/4	1	No	O	NA/TCN	R (07SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1241 12411590	GENRL	Pyrexia/ Fever#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411592	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1241 12411595	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
	METAB	Decreased appetite/ Inapetence	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411596	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	NERV	Headache/ Headache#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	2/3	1	Yes		NA	R (25FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411599	GENRL	Chills/ Chills	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		Fatigue/ Fatigue	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		Injection site pain/ Injection site pain	2	22SEP2020	1/3	2	Yes		NA/TC	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001	INFEC	Rhinitis/ Worsening Recurrent rhinitis	1	21SEP2020	19/2	1	No	O	NA/TC	R (22SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Investigational Vaccine Dose/ Subject	Action: Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411600	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/1	1	Yes	NA	R (18FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	18FEB2021	2/1	1	Yes	NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411601	GENRL	Injection site pain/ Injection site pain#	3	30JAN2021	2/2	1	Yes	NA	R (31JAN2021)	N/N
16-55/ C4591001 1241 12411603	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/4	1	Yes	NA	R (25SEP2020)	N/Y
16-55/ C4591001 1241 12411604	GENRL	Fatigue/ Fatigue#	3	01FEB2021	1/3	1	Yes	NA	R (03FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	01FEB2021	1/3	1	Yes	NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/2	1	Yes	NA/TC/TCN	R (23FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	23FEB2021	2/2	1	Yes	NA/TC	R (24FEB2021)	N/N
		Injection site erythema/ Injection site redness#	4	23FEB2021	2/2	1	Yes	NA/TC/TCN	R (24FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	2/2	1	Yes	NA/TC	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	4	23FEB2021	2/2	1	Yes	NA/TC	R (24FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411605	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1241 12411607	GENRL	Chills/ Chills	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	26SEP2020	2/4	2	Yes		NA/TC	R (29SEP2020)	N/N
	NERV	Headache/ Headache	2	26SEP2020	2/4	2	Yes		NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 1241 12411608	GENRL	Pyrexia/ Fever#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
	NERV	Headache/ Headache#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1241 12411610	GENRL	Fatigue/ Fatigue#	3	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/4	1	Yes		NA	R (28FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	25FEB2021	2/4	2	Yes		NA	R (28FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411611	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	18FEB2021	2/1	2	Yes		NA/TC	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/1	2	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411613	GENRL	Chills/ Chills	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N
		Injection site pain/ Injection site pain	1	05SEP2020	2/1	2	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1241 12411616	NERV	Sciatica/ Left sciatic nerve inflammation	2	16OCT2020	24/39	2	No	O	NA/TC/TCN	R (23NOV2020)	N/N
16-55/ C4591001 1241 12411617	GENRL	Fatigue/ Fatigue#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
		Fatigue/ Prostration#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Chills/ Chills#	4	13FEB2021	2/2	1	Yes		NA/TC	R (14FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411619	GENRL	Fatigue/ Fatigue#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N	
		Injection site pain/ Injection site pain#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N	
		Injection site pain/ Injection site pain	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 1241 12411624	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N	
	NERV	Injection site pain/ Injection site pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N	
16-55/ C4591001 1241 12411625	GENRL	Headache/ Headache#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N	
	GENRL	Pyrexia/ Fever#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N	
	GASTR	Diarrhoea/ Diarrhea	1	21SEP2020	18/2	1	No	O	NA	R (22SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/2	1	Yes		NA/TC	R (03FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411626	MUSC	Myalgia/ Myalgia#	4	25FEB2021	2/1	1	Yes		NA/TC	R (25FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/1	1	Yes		NA/TC	R (25FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	05SEP2020	2/2	2	Yes		NA/TC	R (06SEP2020)	N/N
16-55/ C4591001 1241 12411630		Pyrexia/ Fever	1	05SEP2020	2/2	2	Yes		NA/TC/TCN	R (06SEP2020)	N/N
	MUSC	Myalgia/ Myalgia#	3	23JAN2021	2/2	1	Yes		NA/TC	R (24JAN2021)	N/N
	NERV	Headache/ Headache#	3	23JAN2021	2/2	1	Yes		NA/TC	R (24JAN2021)	N/N
16-55/ C4591001 1241 12411632	MUSC	Myalgia/ Myalgia#	4	15FEB2021	1/3	1	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	15FEB2021	1/3	1	Yes		NA	R (17FEB2021)	N/N
	GENRL	Pyrexia/ Fever	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
	NERV	Headache/ Headache	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C4591001	INFEC	Furuncle/ Furunculosis in buttocks	2	07OCT2020	14/8	1	No	O	NA/TC	R (14OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411633	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	2/4	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1241 12411635	NERV	Headache/ Headache	1	20SEP2020	17/2	1	No	O	NA/TC	R (21SEP2020)	N/N
	GENRL	Fatigue/ Prostration#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1241 12411636	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		Injection site pruritus/ Injection site itching	2	24SEP2020	1/3	1	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1241 12411637	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Somnolence/ Drowsiness	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	1/1	1	Yes		NA	R (04SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411638	GENRL	Pyrexia/ Fever	2	26SEP2020	3/1	1	Yes		NA/TC	R (26SEP2020)	N/N	
16-55/ C4591001 1241 12411639	RESP	Nasal congestion/ Nasal congestion	2	06OCT2020	13/2	1	No	O	NA	R (07OCT2020)	N/N	
16-55/ C4591001 1241 12411640	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N	
16-55/ C4591001 1241 12411641	INJ&P	Skin laceration/ Second left finger cut	2	11OCT2020	19/1	2	No	O	NA/TC	R (11OCT2020)	N/N	
16-55/ C4591001 1241 12411645	GENRL	Chills/ Chills	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N	
	NERV	Somnolence/ Drowsiness	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N	
16-55/ C4591001 1241 12411646	GENRL	Chills/ Chills#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N	
		Injection site pain/ Injection site pain#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411648	MUSC	Myalgia/ Myalgia#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Pyrexia/ Fever	2	25SEP2020	2/1	1	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/4	1	Yes		NA	R (07FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/Y
	INFEC	Pelvic inflammatory disease/ Pelvic inflammatory disease	1	14SEP2020	11/26	2	No	O	NA/TC	R (09OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
		Pyrexia/ Fever#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	24FEB2021	2/3	2	Yes		NA/TC	R (26FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	24FEB2021	2/3	2	Yes		NA/TC	R (26FEB2021)	N/N
		Pyrexia/ Fever#	4	24FEB2021	2/3	2	Yes		NA/TC	R (26FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411653	MUSC	Myalgia/ Myalgia#	4	24FEB2021	2/3	2	Yes		NA/TC	R (26FEB2021)	N/N
	GENRL	Injection site rash/ Injection site macular papular rash	1	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C4591001 1241 12411654	NERV	Headache/ Headache	1	08SEP2020	1/2	2	Yes		NA/TC	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1241 12411654	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1241 12411655	GENRL	Fatigue/ Fatigue#	3	04FEB2021	2/2	2	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1241 12411656		Injection site pain/ Injection site pain#	3	04FEB2021	2/2	2	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1241 12411656		Pyrexia/ Fever	1	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N
	NERV	Headache/ Headache	1	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N
	GENRL	Asthenia/ Asthenia	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411657	EYE	Injection site pain/ Injection site pain	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N	
		Eye pain/ Retrorbital pain#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N	
		Fatigue/ Fatigue#	3	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N	
		Pyrexia/ Fever#	3	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N	
		Chills/ Chills#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N	
		Fatigue/ Prostration#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N	
GENRL	Pyrexia/ Fever#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N		
	Chills/ Chills	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N		
	Myalgia/ Myalgia	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N		
16-55/ C4591001 1241 12411659	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N	
		Pyrexia/ Fever#	3	02FEB2021	1/3	1	Yes		NA/TC	R (04FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411661	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411661	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1241 12411663	GENRL	Pyrexia/ Fever	2	01OCT2020	3/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1241 12411664	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1241 12411665	NERV	Headache/ Headache	1	11SEP2020	2/3	1	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1241 12411666	MUSC	Myalgia/ Myalgia#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411666	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1241 12411667	GENRL	Chills/ Chills	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
	METAB	Decreased appetite/ Hyporexia	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411672	MUSC	Myalgia/ Myalgia	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		Vomiting/ Vomiting	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1241 12411673	NERV	Headache/ Headache	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1241 12411674		Pyrexia/ Fever#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1241 12411678	MUSC	Myalgia/ Myalgia	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
	NERV	Headache/ Headache	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001	REPRO	Uterine inflammation/ Uterine inflammation	1	01OCT2020	18/5	2	No	O	NA/TCN	R (05OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411679	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy	2	01NOV2020	28/C		No	O	NA	UNK	N/N
	MUSC	Back pain/ Backache	2	15NOV2020	42/2	2	No	O	NA/TC	R (16NOV2020)	N/N
16-55/ C4591001 1241 12411680	GENRL	Asthenia/ Asthenia	2	05OCT2020	1/4	1	Yes		NA	R (08OCT2020)	N/N
		Chills/ Chills	2	05OCT2020	1/4	1	Yes		NA/TC	R (08OCT2020)	N/N
		Pyrexia/ Fever	2	05OCT2020	1/4	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1241 12411681	GENRL	Chills/ Chills	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		Fatigue/ Fatigue	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		Injection site pain/ Injection site pain	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		Pyrexia/ Fever	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1241 12411683	GENRL	Fatigue/ Fatigue	1	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411684	MUSC	Injection site pain/ Injection site pain	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
		Myalgia/ Myalgia#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	24FEB2021	2/1	1	Yes		NA/TC	R (24FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	24FEB2021	2/1	1	Yes		NA/TC	R (24FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N	
		Fatigue/ Fatigue#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N	
		MUSC	Myalgia/ Myalgia#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
	16-55/ C4591001 1241 12411685	GENRL	Injection site pain/ Injection site pain	1	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/Y
	GENRL	Fatigue/ fatigue	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N	
MUSC	Injection site pain/ Injection site pain	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/Y		
	Myalgia/ Muscle pain	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N		
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411686	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/4	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1241 12411688	GENRL	Pyrexia/ Fever	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1241 12411690	GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/Y
16-55/ C4591001 1241 12411692	GENRL	Pyrexia/ Fever	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1241 12411694	NERV	Headache/ Headache#	3	30JAN2021	2/1	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1241 12411695	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1241 12411696	GENRL	Injection site pain/ Injection site pain#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
1241 12411697											

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411698	NERV	Headache/ Headache#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1241 12411699	MUSC	Myalgia/ Myalgia#	4	23FEB2021	1/2	1	Yes		NA/TC	R (24FEB2021)	N/N
	GENRL	Chest discomfort/ Chest discomfort	1	25SEP2020	11/2	1	No	O	NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1241 12411700	GENRL	Pyrexia/ Fever	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1241 12411702		Pyrexia/ Fever	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411707	NERV	Headache/ headache	2	05OCT2020	1/1	1	Yes		NA	R (05OCT2020)	N/N
16-55/ C4591001 1241 12411708	INJ&P	Injury/ Injury secondary to trauma	1	04OCT2020	19/23	1	No	O	NA/TC	R (26OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ Fever#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411709	GENRL	Pyrexia/ Fever	2	06OCT2020	2/3	1	Yes		NA/TC	R (08OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	06OCT2020	2/3	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1241 12411710	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Prostration#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411713	GENRL	Pyrexia/ Fever#	4	19FEB2021	2/1	1	Yes		NA/TC	R (19FEB2021)	N/N	
		Injection site pain/ Injection site pain	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
16-55/ C4591001 1241 12411714	GENRL	Pyrexia/ Fever	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N	
		Injection site pain/ Injection site pain	1	17SEP2020	2/4	1	Yes		NA	R (20SEP2020)	N/N	
16-55/ C4591001 1241 12411715	GENRL	Fatigue/ Fatigue	2	05OCT2020	1/1	1	Yes		NA	R (05OCT2020)	N/N	
		Injection site pain/ Injection site pain#	3	01FEB2021	1/4	1	Yes		NA	R (04FEB2021)	N/N	
16-55/ C4591001 1241 12411716	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/2	1	Yes		NA/TCN	R (23FEB2021)	N/N	
		Fatigue/ Fatigue	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N	
16-55/ C4591001	NERV	Headache/ Headache	1	16SEP2020	1/1	1	Yes		NA/TC	R (16SEP2020)	N/N	
		Headache/ headache	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N	
16-55/ C4591001	GASTR	Aphthous ulcer/ Oral aphthae	1	17SEP2020	2/4	1	Yes		NA/TC	R (20SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411719		Diarrhoea/ Diarrhea	1	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Asthenia/ Asthenia	1	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		Injection site pain/ Injection site pain	1	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
	NERV	Headache/ Headache	1	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/4	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1241 12411720	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		Pyrexia/ Fever#	4	25FEB2021	2/1	1	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1241 12411724	GENRL	Injection site pain/ Injection site pain#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1241 12411725	GENRL	Asthenia/ Asthenia	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411726	GENRL	Fatigue/ Prostration#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
16-55/ C4591001 1241 12411727	SKIN	Rash/ Skin rash	1	16SEP2020	1/4	2	Yes		NA/TC	R (19SEP2020)	N/N
	MUSC	Arthralgia/ Arthralgia	1	17SEP2020	2/3	2	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1241 12411730	MUSC	Myalgia/ Myalgia	2	08OCT2020	4/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	4/1	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1241 12411731	GENRL	Fatigue/ Fatigue	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
		Injection site pain/ Injection site pain	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	1/1	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	27JAN2021	1/1	1	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ Headache#	3	27JAN2021	1/1	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	18FEB2021	1/2	2	Yes		NA/TC	R (19FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	1/2	2	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	1/2	2	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411733	MUSC	Back pain/ Backache	2	01NOV2020	27/5	1	No	O	NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1241 12411735	GENRL	Fatigue/ Fatigue#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1241 12411736	GASTR	Diarrhoea/ Diarrhea	1	16SEP2020	1/3	2	Yes		NA/TC	R (18SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411740	GENRL	Vomiting/ Vomiting	1	16SEP2020	1/3	2	Yes		NA/TC	R (18SEP2020)	N/N
		Injection site swelling/ Injection site swelling	2	05OCT2020	1/4	1	Yes		NA	R (08OCT2020)	N/Y
	GASTR	Diarrhoea/ Diarrhea	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Chills/ Chills	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Pyrexia/ Fever#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12411741	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1241 12411744	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12411747	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411750	MUSC	Back pain/ Backache	1	21SEP2020	6/4	1	No	O	NA/TC	R (24SEP2020)	N/N
	GENRL	Chills/ Chills#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	23FEB2021	1/2	2	Yes		NA	R (24FEB2021)	N/N
		Fatigue/ Fatigue#	4	23FEB2021	1/2	2	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	23FEB2021	1/2	2	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411756	MUSC	Myalgia/ Myalgia	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1241 12411757	GENRL	Pyrexia/ fever	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1241 12411758	GENRL	Chills/ Chills	1	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
		Injection site pain/ Injection site pain	1	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ Headache	1	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Chills/ Chills	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411760	MUSC	Myalgia/ Myalgia	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N	
		Pyrexia/ Fever#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N	
	GENRL	Pyrexia/ Fever#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N	
16-55/ C4591001 1241 12411762	GENRL	Fatigue/ Fatigue#	3	29JAN2021	2/1	2	Yes		NA/TC	R (29JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	3	29JAN2021	2/1	2	Yes		NA/TC	R (29JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N	
16-55/ C4591001 1241 12411764	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	1/4	1	Yes		NA/TC	R (06FEB2021)	N/N	
16-55/ C4591001 1241 12411765	GENRL	Injection site pain/ Injection site pain#	3	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Pyrexia/ Fever#	3	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
		Myalgia/ Myalgia#	3	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
16-55/ C4591001 1241 12411766	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy	1	17SEP2020	2/C		No	O	P	UNK	N/N
16-55/ C4591001 1241 12411768	GENRL	Fatigue/ Fatigue#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411769	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ Injection site pain	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1241 12411771	GENRL	Chills/ Chills	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
		Fatigue/ Fatigue	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
		Pyrexia/ Fever	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411774	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	07OCT2020	1/4	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411775	GENRL	Fatigue/ Fatigue	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/Y
	GENRL	Fatigue/ Fatigue#	3	02FEB2021	1/3	2	Yes		NA/TC	R (04FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	02FEB2021	1/3	2	Yes		NA/TC	R (04FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	02FEB2021	1/3	2	Yes		NA/TC	R (04FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411776	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Chills/ Chills#	4	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
		Fatigue/ Fatigue#	4	12FEB2021	2/1	1	Yes		NA/TC	R (12FEB2021)	N/N
		Pyrexia/ Fever#	4	12FEB2021	2/1	1	Yes		NA/TC	R (12FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411777	NERV	Headache/ Headache#	4	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1241 12411779	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1241 12411781	GASTR	Diarrhoea/ Diarrhea	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	1/2	1	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Chills/ Chills#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N
	GENRL	Fatigue/ Prostration#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
	GENRL	Pyrexia/ Subfebrile#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411782	GENRL	Pyrexia/ Fever	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1241 12411784	GENRL	Injection site pain/ Injection site pain	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Chills/ Chills#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Chills/ Chills#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		Pyrexia/ Fever#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1241 12411785	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1241 12411786	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/3	1	Yes		NA/TCN	R (18SEP2020)	N/N
	GENRL	Pyrexia/ Fever	1	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411790	IMMUN	Drug hypersensitivity/ Allergic reaction to dipyrone	1	17SEP2020	2/1	3	No	CD	NA/TC	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	10OCT2020	2/1	2	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Chills/ Chills	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411798	GENRL	Injection site pain/ Injection site pain#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12411799	GENRL	Chills/ Chills	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		Fatigue/ Fatigue	1	17SEP2020	1/1	2	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1241 12411800	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1241 12411801	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1241 12411803	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Chills/ Chills	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
		Fatigue/ Fatigue	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
		Injection site pain/ Injection site pain	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411804	GENRL	Chills/ Chills#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N	
16-55/ C4591001 1241 12411805	GENRL	Injection site pain/ Injection site pain	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N	
16-55/ C4591001 1241 12411806	MUSC	Myalgia/ Myalgia#	4	20FEB2021	2/1	1	Yes		NA	R (20FEB2021)	N/N	
16-55/ C4591001 1241 12411807	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N	
	NERV	Headache/ Headache	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	
16-55/ C4591001 1241 12411808	GENRL	Fatigue/ Fatigue#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N	
		Injection site pain/ Injection site pain#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N	
16-55/ C4591001 1241 12411809	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411810	NERV	Headache/ Headache#	3	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		Pyrexia/ Fever#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1241 12411812	NERV	Headache/ Headache#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ Headache	1	18SEP2020	2/2	3	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1241 12411813	GENRL	Chills/ Chills	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
		Pain/ Body pain	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
		Pyrexia/ Fever	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	1	17SEP2020	1/1	1	Yes		NA/TC	R (17SEP2020)	N/N
	NERV	Headache/ Headache	1	17SEP2020	1/1	1	Yes		NA/TC	R (17SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411814	MUSC	Myalgia/ Myalgia	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
	INJ&P	Limb injury/ Right foot trauma	1	05OCT2020	19/14	1	No	O	NA/TC	R (18OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411815	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1241 12411816	GENRL	Pyrexia/ Fever#	4	25FEB2021	2/1	1	Yes		NA/TC	R (25FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1241 12411817											



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Chills/ Chills	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	
		Fatigue/ Fatigue	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia	1	18SEP2020	2/2	2	Yes		NA/TC	R (19SEP2020)	N/N	
	GASTR	Nausea/ Nausea	2	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N	
	GENRL	Asthenia/ Asthenia	2	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N	
		Chills/ Chills	2	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N	
		Pyrexia/ Fever	2	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	09OCT2020	2/12	2	Yes		NA	R (20OCT2020)	N/N	
	NERV	Headache/ Headache	2	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N	
16-55/ C4591001 1241 12411818	GENRL	Pyrexia/ fever	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N	
16-55/ C4591001 1241 12411820	GENRL	Injection site pain/ Injection site pain#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N	
16-55/ C4591001 1241 12411823	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411824	GENRL	Chills/ Chills	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		Injection site pain/ Injection site pain	2	09OCT2020	2/3	1	Yes		NA	R (11OCT2020)	N/N
		Pyrexia/ Fever	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411827	GENRL	Fatigue/ Prostration#	3	26JAN2021	2/5	1	Yes		NA	R (30JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
		Pyrexia/ Fever#	3	26JAN2021	2/5	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1241 12411828	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1241 12411830	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1241 12411834	GENRL	Injection site pain/ injection site pain	1	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411835	GENRL	Fatigue/ Prostration	2	09OCT2020	2/3	2	Yes		NA	R (11OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
		Fatigue/ Fatigue#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
		Pyrexia/ Fever#	4	23FEB2021	1/3	1	Yes		NA/TC	R (25FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Chills/ Chills	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
		Fatigue/ Fatigue	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
	NERV	Headache/ Headache	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411839	GENRL	Chills/ Chills	1	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
		Injection site pain/ Injection site pain	1	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411845	GENRL	Pyrexia/ Fever	1	18SEP2020	2/2	1	Yes		NA/TC/TCN	R (19SEP2020)	N/N
		Pyrexia/ Fever	2	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1241 12411846	INJ&P	Limb injury/ Left hand injury#	3	12MAR2021	15/1	2	No	O	NA/TC	R (12MAR2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	3	03FEB2021	1/2	1	Yes		NA/TC	R (04FEB2021)	N/N
16-55/ C4591001 1241 12411847	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1241 12411849	GENRL	Chills/ Chills	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411850	MUSC	Pyrexia/ Fever	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
		Myalgia/ Myalgia	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
	NERV	Injection site pain/ Injection site pain	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
		Headache/ Headache	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1241 12411854	NERV	Headache/ Headache	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/5	1	Yes		NA/TCN	R (21SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	1	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001	MUSC	Myalgia/ Myalgia	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	2/2	1	Yes		NA/TC	R (30JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411855	MUSC	Myalgia/ Myalgia#	3	29JAN2021	2/2	1	Yes		NA/TC	R (30JAN2021)	N/N	
	NERV	Headache/ Headache#	3	29JAN2021	2/2	1	Yes		NA/TC	R (30JAN2021)	N/N	
16-55/ C4591001 1241 12411856	NERV	Headache/ Headache	1	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N	
	GENRL	Injection site bruising/ Injection site bruise	2	09OCT2020	1/5	2	Yes		NA	R (13OCT2020)	N/N	
		Injection site pain/ Injection site pain	2	09OCT2020	1/5	2	Yes		NA	R (13OCT2020)	N/N	
	GASTR	Nausea/ Nausea	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N	
	GENRL	Chills/ Chills	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N	
		Pyrexia/ Fever	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N	
	NERV	Headache/ Headache	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N	
16-55/ C4591001 1241 12411857	GENRL	Fatigue/ Prostration	2	09OCT2020	2/1	2	Yes		NA	R (09OCT2020)	N/N	
		Pyrexia/ Fever	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/2	2	Yes		NA	R (06FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411858 16-55/ C4591001 1241 12411860	GENRL	Pyrexia/ Fever#	3	26JAN2021	2/3	1	Yes		NA/TC	R (28JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	26JAN2021	2/3	1	Yes		NA/TC	R (28JAN2021)	N/N
	NERV	Headache/ Headache#	3	26JAN2021	2/3	1	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	15FEB2021	1/3	1	Yes		NA/TC	R (17FEB2021)	N/N
		Pyrexia/ Fever#	4	15FEB2021	1/2	1	Yes		NA/TC	R (16FEB2021)	N/N
16-55/ C4591001 1241 12411861	GENRL	Chills/ Chills	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ Fever	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ Headache	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
	NERV	Headache/ Headache	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411862	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411863 16-55/ C4591001 1241 12411864 16-55/ C4591001 1241 12411865 16-55/ C4591001 1241 12411866 16-55/ C4591001 1241 12411867	BLOOD	Lymphadenopathy/ Axillary lymph nodes enlargement in left arm	2	06OCT2020	1/4	1	Yes		NA/TC	R (09OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	1/4	1	Yes		NA/TC	R (09OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/1	2	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ Headache#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/4	1	Yes		NA	R (07FEB2021)	N/N
	NERV	Headache/ Headache	1	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/Y
	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411868	SKIN	Erythema nodosum/ Erythema nodosum on the inner face of the right thigh#	4	16FEB2021	1/21	1	Yes		NA/TC	R (08MAR2021)	N/N
16-55/ C4591001 1241 12411869	GENRL	Chills/ chills	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1241 12411872	GENRL	Injection site pain/ Injection site pain	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		Pyrexia/ Fever	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
	NERV	Headache/ Headache	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411873	GENRL	Fatigue/ Fatigue#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411874	GENRL	Chills/ Chills#	4	19FEB2021	1/2	1	Yes	NA/TC		R (20FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	19FEB2021	1/2	1	Yes	NA		R (20FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	19FEB2021	1/2	1	Yes	NA/TC		R (20FEB2021)	N/N
16-55/ C4591001 1241 12411875	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/2	1	Yes	NA		R (19SEP2020)	N/N
16-55/ C4591001 1241 12411877	GENRL	Asthenia/ Asthenia	1	18SEP2020	1/1	1	Yes	NA		R (18SEP2020)	N/N
		Injection site pain/ Injection site pain and burning sensation	1	18SEP2020	1/1	1	Yes	NA		R (18SEP2020)	N/Y
16-55/ C4591001 1241 12411878	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/2	1	Yes	NA		R (05FEB2021)	N/N
16-55/ C4591001 1241 12411879	GENRL	Chills/ Chills	2	09OCT2020	1/1	1	Yes	NA		R (09OCT2020)	N/N
		Injection site pain/ Injection site pain	2	09OCT2020	1/2	1	Yes	NA		R (10OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	1	Yes	NA		R (06FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411881	GENRL	Chills/ Chills	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	09OCT2020	1/3	1	Yes		NA/TC	R (11OCT2020)	N/N
1241 12411882		Injection site pain/ Injection site pain	2	09OCT2020	1/3	1	Yes		NA/TC	R (11OCT2020)	N/N
		Pyrexia/ Fever	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
1241 12411884	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/2	1	Yes		NA/TC	R (19SEP2020)	N/N
1241 12411886	GENRL	Asthenia/ Asthenia	1	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N
		Pyrexia/ Fever	1	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N
	GENRL	Fatigue/ Prostration	2	10OCT2020	2/1	2	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001	NEOPL	Teratoma/ High grade immature teratoma	2	18JAN2021	102/10	3	No	O	NA	R (27JAN2021)	Y/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411887	GENRL	Injection site pain/ Injection site pain#	3	10FEB2021	1/2	1	Yes	NA	NA	R (11FEB2021)	N/N
16-55/ C4591001 1241 12411888	GENRL	Fatigue/ Fatigue	1	19SEP2020	2/3	1	Yes	NA/TC	NA/TC	R (21SEP2020)	N/N
		Injection site pain/ Injection site pain	1	19SEP2020	2/3	1	Yes	NA/TC	NA/TC	R (21SEP2020)	N/N
	NERV	Headache/ Headache	1	19SEP2020	2/3	1	Yes	NA/TC	NA/TC	R (21SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	10OCT2020	2/1	1	Yes	NA/TC	NA/TC	R (10OCT2020)	N/N
	NERV	Headache/ Headache	2	10OCT2020	2/1	2	Yes	NA/TC	NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411889	GENRL	Chills/ Chills	1	18SEP2020	1/2	1	Yes	NA	NA	R (19SEP2020)	N/N
		Injection site pain/ Injection site pain	1	18SEP2020	1/3	2	Yes	NA	NA	R (20SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	19SEP2020	2/2	1	Yes	NA	NA	R (20SEP2020)	N/N
16-55/ C4591001 1241 12411892	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/1	1	Yes	NA	NA	R (05FEB2021)	N/N
16-55/ C4591001	GENRL	Asthenia/ Asthenia	1	18SEP2020	1/3	2	Yes	NA	NA	R (20SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411893	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/5	2	Yes	NA	R	(22SEP2020)	N/N	
		Chills/ Chills	2	09OCT2020	1/2	2	Yes	NA/TC	R	(10OCT2020)	N/N	
		Fatigue/ Fatigue	2	09OCT2020	1/2	2	Yes	NA/TC	R	(10OCT2020)	N/N	
		Injection site pain/ Injection site pain	2	09OCT2020	1/3	1	Yes	NA/TC	R	(11OCT2020)	N/N	
		Pyrexia/ Fever	2	09OCT2020	1/2	2	Yes	NA/TC	R	(10OCT2020)	N/N	
	NERV	Headache/ Headache	2	09OCT2020	1/2	2	Yes	NA/TC	R	(10OCT2020)	N/N	
16-55/ C4591001 1241 12411894	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	1/4	1	Yes	NA/TC	R	(20FEB2021)	N/N	
	NERV	Pyrexia/ Fever#	4	17FEB2021	1/2	2	Yes	NA/TC	R	(18FEB2021)	N/N	
		Headache/ Headache#	4	17FEB2021	1/2	1	Yes	NA/TC	R	(18FEB2021)	N/N	
16-55/ C4591001 1241 12411895	GENRL	Fatigue/ Prostration	2	16OCT2020	3/1	1	Yes	NA	R	(16OCT2020)	N/N	
	GENRL	Pyrexia/ Fever	2	16OCT2020	3/1	1	Yes	NA	R	(16OCT2020)	N/N	
16-55/ C4591001		Chills/ Chills#	3	11FEB2021	1/2	1	Yes	NA	R	(12FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411897		Fatigue/ Fatigue#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12411898	RESP	Rhinorrhoea/ Rhinorrhea	1	07OCT2020	20/2	1	No	O	NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1241 12411899	GENRL	Chills/ Chills	2	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
		Pyrexia/ Fever	2	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411900	GENRL	Fatigue/ Fatigue#	3	06FEB2021	3/2	1	Yes		NA/TC	R (07FEB2021)	N/N
		Pyrexia/ Fever#	3	06FEB2021	3/2	1	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1241 12411904	GENRL	Chills/ Chills	2	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N
		Fatigue/ Fatigue	2	10OCT2020	2/6	2	Yes		NA	R (15OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411906	GENRL	Fatigue/ Prostration	2	10OCT2020	2/6	2	Yes		NA	R (15OCT2020)	N/N
		Injection site pain/ Injection site pain	2	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N
		Injection site pain/ Injection site pain#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411911	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	3	05FEB2021	2/2	2	Yes		NA/TC	R (06FEB2021)	N/N
	MUSC	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	2	Yes		NA/TC	R (06FEB2021)	N/N
Myalgia/ Myalgia#		3	05FEB2021	2/2	2	Yes		NA/TC	R (06FEB2021)	N/N	
16-55/ C4591001 1241 12411912	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/2	2	Yes		NA	R (23JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	1/2	1	Yes		NA/TC	R (11FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	10FEB2021	1/2	1	Yes		NA/TC/TCN	R (11FEB2021)	N/N
NERV	Headache/ Headache#	4	10FEB2021	1/2	1	Yes		NA/TC	R (11FEB2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411914	GENRL	Chills/ Chills	1	22SEP2020	5/4	1	Yes		NA	R (25SEP2020)	N/N	
		Fatigue/ Fatigue	1	22SEP2020	5/4	1	Yes		NA	R (25SEP2020)	N/N	
	GENRL	Fatigue/ Prostration#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N	
		Injection site pain/ Injection site pain#	4	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N	
		Pyrexia/ Fever#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N	
16-55/ C4591001	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy	2	15DEC2020	68/C		No	O	NA	UNK	N/N	
1241 12411915	GENRL	Chills/ Chills#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N	
16-55/ C4591001		Injection site pain/ Injection site pain#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N	
1241 12411917	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N	
16-55/ C4591001		Chills/ Chills	1	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411920	NERV	Headache/ Headache	1	19SEP2020	2/1	1	Yes	NA/TC/TCN	R (19SEP2020)	N/N	
	GENRL	Chills/ chills	2	09OCT2020	1/1	1	Yes	NA	R (09OCT2020)	N/N	
16-55/ C4591001 1241 12411921	GENRL	Injection site erythema/ Injection site redness	1	19SEP2020	2/3	1	Yes	NA	R (21SEP2020)	N/N	
	GENRL	Pyrexia/ Fever	2	10OCT2020	2/2	1	Yes	NA	R (11OCT2020)	N/N	
	NERV	Headache/ Headache	2	10OCT2020	2/2	1	Yes	NA	R (11OCT2020)	N/N	
16-55/ C4591001 1241 12411924	GENRL	Pyrexia/ Fever	2	09OCT2020	1/2	1	Yes	NA/TC	R (10OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	10OCT2020	2/1	2	Yes	NA/TCN	R (10OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	10OCT2020	2/1	2	Yes	NA/TCN	R (10OCT2020)	N/N	
16-55/ C4591001 1241 12411925	GENRL	Fatigue/ Fatigue#	3	04FEB2021	1/2	1	Yes	NA/TC	R (05FEB2021)	N/N	
		Injection site pain/ Injection site pain#	3	04FEB2021	1/2	1	Yes	NA/TC	R (05FEB2021)	N/N	
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes	NA	R (07FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411926 16-55/ C4591001 1241 12411927	GENRL	Chills/ Chills	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N	
		Pyrexia/ Fever	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N	
	NERV	Headache/ Headache	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N	
16-55/ C4591001 1241 12411930	NERV	Headache/ Headache#	4	15FEB2021	1/2	1	Yes		NA/TC	R (16FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N	
	BLOOD	Lymphadenopathy/ Left axillary lymphadenopathy#	4	17FEB2021	3/3	1	Yes		NA/TC	R (19FEB2021)	N/N	
16-55/ C4591001 1241 12411931	MUSC	Myalgia/ Myalgia	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N	
16-55/ C4591001 1241 12411932	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N	
16-55/ C4591001 1241 12411935	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411936	MUSC	Myalgia/ Myalgia#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Axillary pain/ Left armpit pain	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
		Injection site pain/ Injection site pain	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1241 12411937	NERV	Headache/ Headache	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	08OCT2020	2/3	1	Yes		NA	R (10OCT2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	2/3	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411939	GASTR	Diarrhoea/ Diarrhea	2	09OCT2020	3/3	1	Yes		NA	R (11OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1241 12411940	GENRL	Injection site pain/ Injection site pain#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
		Pyrexia/ Fever#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411942	GENRL	Pyrexia/ fever	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411943	GENRL	Fatigue/ Fatigue	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
		Injection site pain/ Injection site pain	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1241 12411944	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/4	1	Yes		NA/TC	R (08FEB2021)	N/N
16-55/ C4591001 1241 12411945	GENRL	Pyrexia/ Fever	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
16-55/ C4591001 1241 12411947	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/Y
16-55/ C4591001 1241 12411948	GENRL	Injection site pain/ Injection site pain	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
		Injection site swelling/ Injection site swelling	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411949	MUSC	Myalgia/ Myalgia	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N	
16-55/ C4591001 1241 12411950	GENRL	Fatigue/ Fatigue#	4	15FEB2021	1/2	2	Yes		NA/TCN	R (16FEB2021)	N/N	
	GENRL	Asthenia/ Asthenia	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N	
16-55/ C4591001 1241 12411951		Chills/ Chills	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N	
		Pyrexia/ Fever	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N	
	NERV	Headache/ Headache	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N	
	GENRL	Chills/ Chill	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N	
16-55/ C4591001 1241 12411952	NERV	Headache/ Headache	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N	
	INFEC	Helicobacter gastritis/ Helicobacter pylori gastritis	2	13OCT2020	7/25	1	No	O	NA/TC	R (06NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411953	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/4	2	Yes		NA	R (04FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	2/4	1	Yes		NA	R (26FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	2/4	1	Yes		NA	R (26FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	3	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N	
	NERV	Headache/ Headache#	3	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	07OCT2020	1/4	1	Yes		NA	R (10OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N	
	NERV	Headache/ Headache	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	2/2	2	Yes		NA	R (09OCT2020)	N/N	
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411958		Injection site pain/ Injection site pain#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N	
16-55/ C4591001 1241 12411960	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N	
		Pyrexia/ Fever#	4	17FEB2021	2/1	1	Yes		NA/TC	R (17FEB2021)	N/N	
16-55/ C4591001 1241 12411961	GENRL	Fatigue/ Prostration	2	08OCT2020	2/1	2	Yes		NA	R (08OCT2020)	N/N	
16-55/ C4591001 1241 12411962	GENRL	Injection site pain/ Injection site pain	1	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia	1	19SEP2020	2/3	2	Yes		NA/TC	R (21SEP2020)	N/N	
	NERV	Headache/ Headache	1	19SEP2020	2/3	2	Yes		NA/TC	R (21SEP2020)	N/N	
	RESP	Nasal obstruction/ Nasal obstruction	1	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N	
		Rhinorrhoea/ Runny nose	1	19SEP2020	2/3	2	Yes		NA/TC	R (21SEP2020)	N/N	
16-55/ C4591001	GASTR	Vomiting/ Vomiting due to medication	1	25SEP2020	5/2	1	No	CD	NA	R (26SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411965	MUSC	Back pain/ Backache (Exacerbation of pre-existing condition)	1	25SEP2020	5/9	2	No	O	NA/TC	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Chills/ Chills#	3	23JAN2021	2/1	2	Yes		NA	R (23JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	23JAN2021	2/1	2	Yes		NA	R (23JAN2021)	N/N
	GENRL	Chills/ Chills#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1241 12411967	GENRL	Injection site pain/ Injection site pain	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	NERV	Headache/ Headache	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	13OCT2020	1/3	2	Yes		NA/TC	R (15OCT2020)	N/N
		Injection site pain/ Injection site pain	2	13OCT2020	1/3	2	Yes		NA/TC	R (15OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411968	NERV	Headache/ Headache	2	13OCT2020	1/3	2	Yes		NA/TC	R (15OCT2020)	N/N
	BLOOD	Lymphadenopathy/ Reactional Left axillary lymph node	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/4	1	Yes		NA	R (08FEB2021)	N/N
	GENRL	Chills/ Chills#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/4	1	Yes		NA	R (04FEB2021)	N/Y
	GENRL	Pyrexia/ Fever#	3	03FEB2021	3/1	1	Yes		NA/TC	R (03FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	22FEB2021	1/5	1	Yes		NA/TC	R (26FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/5	1	Yes		NA	R (26FEB2021)	N/Y
	GENRL	Pyrexia/ Fever#	4	22FEB2021	1/5	1	Yes		NA/TC	R (26FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	22FEB2021	1/5	1	Yes		NA/TC	R (26FEB2021)	N/N
16-55/ C4591001 1241 12411970	NERV	Headache/ Headache#	4	22FEB2021	1/5	1	Yes		NA	R (26FEB2021)	N/Y
	GENRL	Injection site pain/ Injection site pain	1	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411972	GENRL	Pyrexia/ Fever	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	NERV	Headache/ Headache	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
	GASTR	Nausea/ Nausea	1	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
		Vomiting/ Vomiting	1	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
	NERV	Headache/ Headache	1	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Pyrexia/ Fever#	3	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
	NERV	Headache/ Headache#	3	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411973	GENRL	Pyrexia/ Fever#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	06FEB2021	2/2	1	Yes		NA/TC	R (07FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411974	GENRL	Fatigue/ Fatigue	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N	
		Pyrexia/ Fever	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N	
	NERV	Headache/ Headache	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N	
16-55/ C4591001 1241 12411978	GENRL	Injection site pain/ Injection site pain	1	21SEP2020	1/4	1	Yes		NA	R (24SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia	1	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
	NERV	Headache/ Headache	1	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
	GENRL	Pyrexia/ Fever	2	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/N	
	INFEC	Cellulitis/ Cellulitis on the right foot	2	27DEC2020	76/C	2	No	O	NA/TC	N	Y/N	
16-55/ C4591001 1241 12411980	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N	
16-55/ C4591001 1241 12411982	GENRL	Fatigue/ Fatigue	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411983	GENRL	Pyrexia/ Fever	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1241 12411983	GENRL	Fatigue/ Fatigue	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1241 12411984	GENRL	Pyrexia/ Fever	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1241 12411986	MUSC	Myalgia/ Myalgia#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1241 12411987	GENRL	Pyrexia/ Fever#	3	06FEB2021	2/1	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1241 12411988	GENRL	Pyrexia/ Fever	1	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C4591001 1241 12411990	GENRL	Injection site pain/ Injection site pain	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1241 12411991	GENRL	Pyrexia/ Fever#	3	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411993	GENRL	Pyrexia/ Fever#	4	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N
	NERV	Headache/ Headache#	4	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N
	GENRL	Fatigue/ Prostration	1	21SEP2020	1/1	2	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1241 12411994		Pyrexia/ Fever	1	21SEP2020	1/1	2	Yes		NA	R (21SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1241 12411996	NERV	Headache/ Headache	1	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
	NERV	Headache/ Headache	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411997	GENRL	Fatigue/ Prostration#	4	17FEB2021	2/1	1	Yes	NA/TC		R (17FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/1	1	Yes	NA/TC		R (17FEB2021)	N/N
16-55/ C4591001 1241 12411998	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/3	2	Yes	NA		R (13FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/3	2	Yes	NA/TC		R (13FEB2021)	N/N
	NERV	Headache/ Headache#	4	11FEB2021	2/3	2	Yes	NA/TC		R (13FEB2021)	N/N
16-55/ C4591001 1241 12412002	GENRL	Injection site pain/ Injection site pain	2	13OCT2020	1/2	1	Yes	NA		R (14OCT2020)	N/Y
		Pyrexia/ Fever	2	13OCT2020	1/2	1	Yes	NA		R (14OCT2020)	N/Y
	NERV	Headache/ Headache	2	13OCT2020	1/2	1	Yes	NA		R (14OCT2020)	N/Y
16-55/ C4591001 1241 12412003	GENRL	Asthenia/ Asthenia#	3	05FEB2021	2/1	1	Yes	NA/TC		R (05FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	05FEB2021	2/1	1	Yes	NA/TC		R (05FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	22SEP2020	2/2	1	Yes	NA		R (23SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412004	GENRL	Pyrexia/ Fever	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1241 12412006	GENRL	Injection site pain/ Injection site tenderness#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1241 12412007	GENRL	Pyrexia/ Fever#	3	05FEB2021	2/2	1	Yes		NA/TC	R (06FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	05FEB2021	2/2	1	Yes		NA/TC	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	3	05FEB2021	2/2	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1241 12412008	MUSC	Myalgia/ Myalgia	1	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	14OCT2020	2/3	2	Yes		NA/TC	R (16OCT2020)	N/N
		Pyrexia/ Fever	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	14OCT2020	2/3	2	Yes		NA/TC	R (16OCT2020)	N/N
	NERV	Headache/ Headache	2	14OCT2020	2/3	2	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001	GENRL	Pain/ Body pain	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Investigational Vaccine Dose/ Subject	Action: Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412009	MUSC	Myalgia/ Myalgia	2	14OCT2020	2/1	1	Yes	NA	R (14OCT2020)	N/N
16-55/ C4591001 1241 12412010	SKIN	Skin lesion/ Hypochromic skin lesions	1	30SEP2020	10/21	1	Yes	NA	R (20OCT2020)	N/N
16-55/ C4591001 1241 12412013	GASTR	Nausea/ Nausea	1	22SEP2020	2/2	2	Yes	NA/TC	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	22SEP2020	2/2	2	Yes	NA/TC	R (23SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	1	22SEP2020	2/2	2	Yes	NA/TC	R (23SEP2020)	N/N
	NERV	Headache/ Headache	1	22SEP2020	2/2	2	Yes	NA/TC	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes	NA	R (27JAN2021)	N/N
	GENRL	Chills/ Chills#	4	16FEB2021	1/3	1	Yes	NA	R (18FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	16FEB2021	1/3	1	Yes	NA	R (18FEB2021)	N/Y
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	1/3	1	Yes	NA/TC	R (18FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	1/3	1	Yes	NA	R (18FEB2021)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever#	3	05FEB2021	2/2	1	Yes	NA/TC	R (06FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412015	MUSC	Myalgia/ Myalgia#	3	05FEB2021	2/2	1	Yes	NA/TC		R (06FEB2021)	N/N
16-55/ C4591001 1241 12412016	GENRL	Pyrexia/ Fever	2	22OCT2020	2/1	1	Yes	NA/TC		R (22OCT2020)	N/N
16-55/ C4591001 1241 12412018	NERV	Headache/ Headache	2	22OCT2020	2/1	1	Yes	NA/TC		R (22OCT2020)	N/N
16-55/ C4591001 1241 12412018	GENRL	Fatigue/ Fatigue#	3	04FEB2021	1/3	1	Yes	NA		R (06FEB2021)	N/N
16-55/ C4591001 1241 12412020	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/5	1	Yes	NA		R (08FEB2021)	N/N
16-55/ C4591001 1241 12412020	GENRL	Injection site pain/ Injection Site pain	1	28SEP2020	1/3	1	Yes	NA		R (30SEP2020)	N/N
16-55/ C4591001 1241 12412022	GENRL	Fatigue/ Prostration#	4	18FEB2021	2/1	1	Yes	NA		R (18FEB2021)	N/N
16-55/ C4591001 1241 12412023	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/1	1	Yes	NA		R (18FEB2021)	N/N
16-55/ C4591001 1241 12412023	GENRL	Chills/ Chills#	3	03FEB2021	1/1	1	Yes	NA/TC		R (03FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412024	GENRL	Fatigue/ Prostration#	3	03FEB2021	1/1	1	Yes	NA	R	(03FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	04FEB2021	2/3	1	Yes	NA	R	(06FEB2021)	N/N
	GENRL	Chills/ Chills#	4	25FEB2021	2/1	1	Yes	NA/TC	R	(25FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	25FEB2021	2/2	1	Yes	NA	R	(26FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	2	22OCT2020	1/2	2	Yes	NA/TC	R	(23OCT2020)	N/N
	GENRL	Chills/ Chills	2	23OCT2020	2/2	2	Yes	NA/TC	R	(24OCT2020)	N/N
	NERV	Headache/ Headache	2	23OCT2020	2/2	2	Yes	NA/TC	R	(24OCT2020)	N/N
	16-55/ C4591001 1241 12412025	GENRL	Injection site pain/ Injection site pain#	3	06FEB2021	2/2	2	Yes	NA/TC	R	(07FEB2021)
MUSC	Myalgia/ Myalgia#	3	06FEB2021	2/2	2	Yes	NA/TC	R	(07FEB2021)	N/N	
NERV	Headache/ Headache#	3	06FEB2021	2/2	2	Yes	NA/TC	R	(07FEB2021)	N/N	
16-55/ C4591001 1241 12412026	GENRL	Fatigue/ Fatigue	2	12NOV2020	3/8	1	Yes	NA	R	(19NOV2020)	N/N
GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes	NA	R	(27JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Investigational Vaccine Dose/ Subject	Action: Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache#	3	26JAN2021	1/2	2	Yes	NA/TC	R (27JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	1/3	1	Yes	NA	R (18FEB2021)	N/N
		Pyrexia/ Fever#	4	16FEB2021	1/3	1	Yes	NA/TC	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	1/3	1	Yes	NA/TC	R (18FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	1/3	1	Yes	NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412027	GENRL	Injection site pain/ Injection site pain	2	24OCT2020	2/3	2	Yes	NA	R (26OCT2020)	N/N
16-55/ C4591001 1241 12412028	GENRL	Fatigue/ Fatigue	1	30SEP2020	1/2	1	Yes	NA	R (01OCT2020)	N/N
		Injection site pain/ Injection site pain	1	30SEP2020	1/2	1	Yes	NA	R (01OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22OCT2020	1/6	2	Yes	NA/TC	R (27OCT2020)	N/N
	NERV	Headache/ Headache	2	22OCT2020	1/6	2	Yes	NA/TC	R (27OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	23OCT2020	2/2	2	Yes	NA/TC	R (24OCT2020)	N/N
16-55/ C4591001 1241 12412029	GENRL	Injection site pain/ Injection site pain	1	30SEP2020	1/2	2	Yes	NA	R (01OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412031	GENRL	Fatigue/ Fatigue	2	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
		Pain/ Body pain	2	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
		Pyrexia/ Fever	2	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1241 12412032	GENRL	Fatigue/ Fatigue#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
		Fatigue/ Prostration#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
	SKIN	Pruritus/ Itching in the body	1	02OCT2020	3/19	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Rash/ Left elbow rash	1	02OCT2020	3/19	1	Yes		NA	R (20OCT2020)	N/N
Rash/ Right trunk rash		1	02OCT2020	3/19	1	Yes		NA	R (20OCT2020)	N/N	
Fatigue/ Fatigue#		3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N	
Injection site pain/ Injection site pain#		3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N	
16-55/ C4591001 1241 12412034	GENRL	Injection site pain/ Injection site pain	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12412035	GENRL	Fatigue/ Fatigue	2	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N	
		Injection site pain/ Injection site pain	2	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N	
	GASTR	Odynophagia/ Odinophagy	1	13OCT2020	14/4	1	No	O	NA	R (16OCT2020)	N/N	
	GENRL	Pyrexia/ Fever	2	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N	
16-55/ C4591001 1241 12412037	BLOOD	Lymphadenopathy/ Left axillary lymph node enlargement	2	25OCT2020	3/3	1	Yes		NA	R (27OCT2020)	N/N	
	GASTR	Nausea/ Nausea	1	30SEP2020	1/3	2	Yes		NA/TC	R (02OCT2020)	N/N	
	GASTR	Nausea/ Nausea	2	21OCT2020	1/3	2	Yes		NA	R (23OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	21OCT2020	1/3	2	Yes		NA	R (23OCT2020)	N/N	
16-55/ C4591001 1241 12412038		Injection site pain/ Injection site pain	2	21OCT2020	1/3	2	Yes		NA	R (23OCT2020)	N/N	
		Pyrexia/ Fever	2	21OCT2020	1/2	2	Yes		NA/TC	R (22OCT2020)	N/N	
	NERV	Headache/ Headache	2	21OCT2020	1/3	2	Yes		NA	R (23OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12412041	MUSC	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N	
		Myalgia/ Myalgia#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N	
		Injection site pain/ Injection site pain#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N	
	NERV	Headache/ Headache#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N	
		Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N	
	16-55/ C4591001 1241 12412043	GENRL	Injection site pain/ Injection site pain	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	22OCT2020	1/2	1	Yes		NA/TC	R (23OCT2020)	N/N
			Pyrexia/ Fever	2	22OCT2020	1/2	1	Yes		NA/TC	R (23OCT2020)	N/N
	16-55/ C4591001 1241 12412045	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
MUSC		Pyrexia/ Fever#	3	05FEB2021	1/3	1	Yes		NA/TC	R (07FEB2021)	N/N	
		Myalgia/ Myalgia#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412046	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1241 12412048	GENRL	Injection site pain/ Injection site pain	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1241 12412049	GENRL	Pyrexia/ Fever	2	21OCT2020	1/1	1	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C4591001 1241 12412050	GASTR	Diarrhoea/ Diarrhea	2	22OCT2020	2/7	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1241 12412051	INJ&P	Injury/ Blunt trauma#	2	30JAN2021	102/25	2	No	O	NA	R (23FEB2021)	N/N
16-55/ C4591001 1241 12412052	GENRL	Chills/ Chills	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
		Fatigue/ Fatigue	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
		Pyrexia/ Fever	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12412053	SKIN	Rash/ Skin rash in arms	2	12NOV2020	23/2	1	No	O	NA	R (13NOV2020)	N/N	
	INJ&P	Clavicle fracture/ Fracture of right clavicle#	2	31JAN2021	103/4	3	No	O	NA/TC/TCN	R (03FEB2021)	Y/N	
		Rib fracture/ Fracture of ribs#	2	31JAN2021	103/4	3	No	O	NA/TC/TCN	R (03FEB2021)	Y/N	
		Road traffic accident/ Motor Vehicle Accident#	2	31JAN2021	103/1	3	No	O	NA	R (31JAN2021)	Y/N	
16-55/ C4591001 1241 12412055	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/4	1	Yes		NA	R (28FEB2021)	N/N	
	BLOOD	Injection site pain/ Injection site pain#	4	25FEB2021	2/4	1	Yes		NA	R (28FEB2021)	N/N	
		Lymphadenopathy/ Left axillary lymphadenopathy#	4	26FEB2021	3/6	1	Yes		NA	R (03MAR2021)	N/N	
16-55/ C4591001 1241 12412056	GENRL	Chills/ Chills	1	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N	
	MUSC	Injection site pain/ Injection site pain	1	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N	
		Myalgia/ Myalgia	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N	
	NERV	Headache/ Headache	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N	
	GASTR	Toothache/ Toothache	1	02OCT2020	3/1	1	No	O	NA/TC	R (02OCT2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412057	GENRL	Fatigue/ Fatigue	2	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1241 12412059	MUSC	Myalgia/ Myalgia	2	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
	NERV	Headache/ Headache	2	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001 1241 12412060	GENRL	Injection site pain/ Injection site pain	1	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/Y
	GASTR	Nausea/ Nausea	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	MUSC	Arthralgia/ Polyarthralgia	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	NERV	Headache/ Headache	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Chills/ Chills#	4	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N
		Fatigue/ Fatigue#	4	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N
	NERV	Headache/ Headache#	4	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412061	GENRL	Injection site pain/ Injection site pain#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
	NERV	Headache/ Headache#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1241 12412062	GENRL	Injection site pain/ Injection site pain	1	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001 1241 12412063	GENRL	Chills/ Chills	2	20OCT2020	1/3	2	Yes		NA	R (22OCT2020)	N/N
		Fatigue/ Prostration	2	20OCT2020	1/3	2	Yes		NA	R (22OCT2020)	N/N
		Injection site pain/ Injection site pain	2	20OCT2020	1/4	1	Yes		NA	R (23OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	20OCT2020	1/3	2	Yes		NA	R (22OCT2020)	N/N
	NERV	Headache/ Headache	2	20OCT2020	1/3	2	Yes		NA	R (22OCT2020)	N/N
	SKIN	Hyperhidrosis/ Sweating	2	20OCT2020	1/3	2	Yes		NA	R (22OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12412064		Injection site pain/ Injection site pain#	3	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	3	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N	
	NERV	Headache/ Headache#	3	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N	
16-55/ C4591001 1241 12412067	GENRL	Injection site pain/ Injection site burning	1	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N	
	GENRL	Pyrexia/ Fever#	3	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N	
16-55/ C4591001 1241 12412070	GENRL	Injection site pain/ Injection site pain	1	01OCT2020	1/4	1	Yes		NA	R (04OCT2020)	N/N	
	NERV	Headache/ Headache	1	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N	
	GENRL	Chills/ Chills	2	20OCT2020	1/2	1	Yes		NA/TC	R (21OCT2020)	N/N	
		Fatigue/ Fatigue	2	20OCT2020	1/2	1	Yes		NA/TC	R (21OCT2020)	N/N	
		Pyrexia/ Fever	2	20OCT2020	1/2	1	Yes		NA/TC	R (21OCT2020)	N/N	
	NERV	Headache/ Headache	2	20OCT2020	1/2	1	Yes		NA/TC	R (21OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412071	NERV	Headache/ Headache	1	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	23OCT2020	2/4	1	Yes		NA	R (26OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/4	1	Yes		NA	R (28FEB2021)	N/N
		Pyrexia/ Fever#	4	25FEB2021	2/4	1	Yes		NA/TC	R (28FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	25FEB2021	2/4	1	Yes		NA/TC	R (28FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/4	1	Yes		NA/TC	R (28FEB2021)	N/N
16-55/ C4591001 1241 12412072	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1241 12412073	GENRL	Injection site pain/ Injection site pain	2	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1241 12412074	MUSC	Myalgia/ Myalgia	2	22OCT2020	2/3	2	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1241 12412078	GENRL	Injection site pain/ Injection site pain	1	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412080	GENRL	Injection site pain/ Injection site pain	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1241 12412081	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N
	GASTR	Nausea/ Nausea	2	22OCT2020	1/2	2	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1241 12412083	GENRL	Injection site erythema/ Injection site redness	2	22OCT2020	1/5	2	Yes		NA/TC	R (26OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	22OCT2020	1/5	2	Yes		NA/TC	R (26OCT2020)	N/N
	GENRL	Injection site swelling/ Injection site swelling	2	22OCT2020	1/5	2	Yes		NA/TC	R (26OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	22OCT2020	1/2	2	Yes		NA/TC	R (23OCT2020)	N/N
	NERV	Headache/ Headache	2	22OCT2020	1/2	2	Yes		NA/TC	R (23OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
	NERV	Headache/ Headache	1	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Pain/ Body pain	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N	
	INV	Body temperature increased/ Subfebrile temperature	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N	
	NERV	Headache/ Headache	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N	
16-55/ C4591001 1241 12412086	GENRL	Pyrexia/ Fever#	3	06FEB2021	2/1	1	Yes		NA/TC	R (06FEB2021)	N/N	
16-55/ C4591001 1241 12412087	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	2/6	1	Yes		NA	R (14FEB2021)	N/N	
16-55/ C4591001 1241 12412088	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N	
16-55/ C4591001 1241 12412091	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N	
16-55/ C4591001 1241 12412093	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N	
16-55/ C4591001 1241 12412094	NERV	Headache/ Headache	1	03OCT2020	3/3	1	Yes		NA/TC	R (05OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412095	GASTR	Diarrhoea/ Diarrhea	1	06OCT2020	6/1	1	Yes		NA	R (06OCT2020)	N/N
	NERV	Headache/ Headache	2	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1241 12412096	GENRL	Chills/ Chills#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Chills/ Chills	2	23OCT2020	2/2	2	Yes		NA/TC	R (24OCT2020)	N/N
16-55/ C4591001 1241 12412097	GENRL	Injection site pain/ Injection site pain	2	23OCT2020	2/2	1	Yes		NA/TC	R (24OCT2020)	N/N
		Fatigue/ Fatigue#	4	11FEB2021	1/2	1	Yes		NA/TC/TCN	R (12FEB2021)	N/N
16-55/ C4591001 1241 12412098	GENRL	Pyrexia/ Fever#	4	11FEB2021	1/2	1	Yes		NA/TC	R (12FEB2021)	N/N
		Fatigue/ Fatigue	2	24OCT2020	2/1	1	Yes		NA/TCN	R (24OCT2020)	N/N
		Injection site pain/ Injection site pain	2	24OCT2020	2/1	1	Yes		NA/TCN	R (24OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12412099	GENRL	Pyrexia/ Fever	2	24OCT2020	2/1	1	Yes		NA/TCN	R (24OCT2020)	N/N	
		Fatigue/ Prostration#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N	
		Injection site pain/ Injection site pain#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N	
		Pyrexia/ Subfebrile#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N	
		Fatigue/ Prostration#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N	
		Pyrexia/ Fever#	4	25FEB2021	2/1	1	Yes		NA/TC	R (25FEB2021)	N/N	
16-55/ C4591001 1241 12412100	MUSC	Myalgia/ Myalgia#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N	
	INFEC	Urinary tract infection/ Urinary tract infection	1	20OCT2020	20/9	2	No	O	NA/TC	R (28OCT2020)	N/N	
16-55/ C4591001 1241 12412101	GENRL	Injection site pain/ Injection site pain	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	10FEB2021	1/2	1	Yes		NA/TC	R (11FEB2021)	N/N	
16-55/ C4591001	GENRL	Asthenia/ Asthenia	1	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12412102		Injection site pain/ Injection site pain	1	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N	
	GENRL	Pyrexia/ Fever	2	22OCT2020	2/2	2	Yes		NA/TC	R (23OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	22OCT2020	2/2	2	Yes		NA/TC	R (23OCT2020)	N/N	
16-55/ C4591001 1241 12412103	MUSC	Myalgia/ Myalgia#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N	
16-55/ C4591001 1241 12412104	GENRL	Fatigue/ Fatigue	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N	
		Injection site pain/ Injection site pain	2	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N	
16-55/ C4591001 1241 12412105	GENRL	Injection site pain/ Injection site pain	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N	
	GASTR	Nausea/ Nausea	2	21OCT2020	1/3	2	Yes		NA/TC	R (23OCT2020)	N/N	
	GENRL	Chills/ Chills	2	21OCT2020	1/3	2	Yes		NA/TC	R (23OCT2020)	N/N	
		Injection site pain/ Injection site pain	2	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12412107	MUSC	Pyrexia/ Fever	2	21OCT2020	1/3	2	Yes		NA/TC	R (23OCT2020)	N/N	
		Myalgia/ Myalgia	2	21OCT2020	1/3	2	Yes		NA/TC	R (23OCT2020)	N/N	
	NERV	Headache/ Headache	2	21OCT2020	1/3	2	Yes		NA/TC	R (23OCT2020)	N/N	
	GASTR	Dyspepsia/ Dyspepsia	1	20OCT2020	19/1	1	No	O	NA/TC	R (20OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N	
		Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes		NA/TC	R (07FEB2021)	N/N	
16-55/ C4591001 1241 12412108	GENRL	Injection site pain/ Injection site pain#	3	06FEB2021	2/2	1	Yes		NA/TC	R (07FEB2021)	N/N	
		Injection site pain/ Injection site pain#	3	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/2	2	Yes		NA/TC	R (18FEB2021)	N/N	
16-55/ C4591001 1241 12412109	GENRL	Fatigue/ Fatigue	2	26OCT2020	1/2	2	Yes		NA/TC	R (27OCT2020)	N/N	
	BLOOD	Lymphadenopathy/ Left axillary lymph node enlargement	2	28OCT2020	3/2	1	Yes		NA	R (29OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412110	GENRL	Injection site pain/ Injection site pain	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	26OCT2020	1/2	2	Yes		NA/TC	R (27OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	26OCT2020	1/2	2	Yes		NA/TC	R (27OCT2020)	N/N
16-55/ C4591001 1241 12412111	NERV	Headache/ Headache	1	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
	BLOOD	Lymphadenopathy/ Left armpit linfoadenomegaly#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
		Pyrexia/ Fever#	3	06FEB2021	2/2	1	Yes		NA/TC	R (07FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12412112	GENRL	Fatigue/ Fatigue	1	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		Injection site pain/ Injection site pain	1	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
	GENRL	Pyrexia/ Fever	1	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	1	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
		Pyrexia/ Fever	2	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
	NERV	Headache/ Headache	2	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1241 12412113	GENRL	Injection site pain/ Injection site pain#	3	06FEB2021	2/3	1	Yes		NA/TC	R (08FEB2021)	N/N
	NERV	Headache/ Headache#	3	06FEB2021	2/2	1	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1241 12412117	GENRL	Injection site pain/ Injection site pain	1	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1241 12412118	GENRL	Chills/ Chills	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
		Fatigue/ Fatigue	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
		Pain/ Body pain	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
		Pyrexia/ Fever	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412121	NERV	Headache/ Headache	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1241 12412122	GENRL	Fatigue/ fatigue	2	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
		Pyrexia/ fever	2	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1241 12412123	GENRL	Injection site pain/ Injection site pain#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
	NERV	Headache/ Headache	2	21OCT2020	1/1	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1241 12412128	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	3	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412133	GENRL	Fatigue/ Fatigue	2	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001 1241 12412134	GENRL	Asthenia/ Asthenia#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12412135	GENRL	Pain/ Body pain	1	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
		Pyrexia/ Fever	1	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
		Pyrexia/ Fever	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1241 12412137	GENRL	Injection site pain/ Injection site pain	1	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	27OCT2020	2/1	2	Yes		NA/TC	R (27OCT2020)	N/N
	NERV	Headache/ Headache	2	27OCT2020	2/1	2	Yes		NA/TC	R (27OCT2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	1	07OCT2020	3/1	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12412138		Pyrexia/ Feeling of fever	1	07OCT2020	3/1	1	Yes		NA	R (07OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	26OCT2020	1/5	2	Yes		NA/TC	R (30OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N	
		Pyrexia/ Fever#	3	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N	
		Pyrexia/ Fever#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N	
16-55/ C4591001 1241 12412139	GENRL	Injection site pain/ Injection site pain	1	05OCT2020	1/3	2	Yes		NA	R (07OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	26OCT2020	1/8	2	Yes		NA/TC	R (02NOV2020)	N/N	
16-55/ C4591001 1241 12412140	GENRL	Injection site pain/ Injection site pain	1	06OCT2020	1/1	1	Yes		NA	R (06OCT2020)	N/Y	
16-55/ C4591001 1241 12412141	GENRL	Injection site pain/ Injection site pain	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412142	GENRL	Injection site pain/ Injection site pain	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001 1241 12412143	GENRL	Injection site pain/ Injection site pain	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001 1241 12412149	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/3	2	Yes		NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	26OCT2020	1/5	2	Yes		NA/TC	R (30OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	26OCT2020	1/5	2	Yes		NA/TC	R (30OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	27OCT2020	2/3	2	Yes		NA/TC	R (29OCT2020)	N/N
16-55/ C4591001 1241 12412150	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1241 12412151	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/4	2	Yes		NA	R (10OCT2020)	N/N
	GENRL	Chills/ Chills	2	28OCT2020	1/2	1	Yes		NA/TC	R (29OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412152	GENRL	Fatigue/ Fatigue	2	28OCT2020	1/2	1	Yes		NA/TC	R (29OCT2020)	N/N
		Pyrexia/ Fever	2	28OCT2020	1/2	1	Yes		NA/TC	R (29OCT2020)	N/N
16-55/ C4591001 1241 12412154	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
		Injection site pain/ Injection site pain	2	30OCT2020	2/3	2	Yes		NA	R (01NOV2020)	N/N
16-55/ C4591001 1241 12412154	GENRL	Chills/ Chills#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412155	GENRL	Injection site pain/ Injection site pain	1	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
		Injection site pain/ Injection site pain#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412156	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412157	GENRL	Injection site pain/ Injection site pain	2	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412159	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/3	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1241 12412160	NERV	Headache/ Headache	1	09OCT2020	3/1	1	Yes		NA	R (09OCT2020)	N/N
	NERV	Headache/ Headache	2	31OCT2020	2/1	2	Yes		NA	R (31OCT2020)	N/N
16-55/ C4591001 1241 12412162	SURG	Dental implantation/ Dental implant unit 44	1	28OCT2020	22/1	1	No	O	NA/TC	R (28OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412163	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/4	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1241 12412165	GENRL	Injection site pain/ Injection site pain	1	09OCT2020	1/3	2	Yes		NA	R (11OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
	NERV	Headache/ Headache	2	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12412167		Injection site pain/ Injection site pain	1	13OCT2020	1/1	1	Yes		NA	R (13OCT2020)	N/N	
16-55/ C4591001 1241 12412168	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/2	1	Yes		NA/TCN	R (09FEB2021)	N/N	
	NERV	Headache/ Headache#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
16-55/ C4591001 1241 12412169	GENRL	Injection site pain/ Injection site pain	1	13OCT2020	1/2	1	Yes		NA/TCN	R (14OCT2020)	N/N	
	INFEC	Sinusitis bacterial/ Sinusitis of bacterial etiology	2	13NOV2020	11/12	1	No	O	NA/TC	R (24NOV2020)	N/N	
16-55/ C4591001 1241 12412171	GENRL	Fatigue/ Fatigue#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
		Injection site pain/ Injection site pain#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
16-55/ C4591001 1241 12412172	GENRL	Pyrexia/ Fever	2	06NOV2020	2/2	1	Yes		NA/TC	R (07NOV2020)	N/N	
	NERV	Headache/ Headache	2	06NOV2020	2/2	1	Yes		NA/TC	R (07NOV2020)	N/N	
16-55/ C4591001	GENRL	Pyrexia/ Fever#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412173	GENRL	Injection site swelling/ Injection site swelling	2	11NOV2020	2/3	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1241 12412174	GENRL	Injection site pain/ Injection site pain	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/Y
16-55/ C4591001 1241 12412175	GENRL	Fatigue/ Prostration	1	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
1241 12412176		Injection site pain/ Injection site pain	1	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Chills/ Chills	2	05NOV2020	2/3	2	Yes		NA	R (07NOV2020)	N/N
		Injection site pain/ Injection site pain	2	05NOV2020	2/3	2	Yes		NA	R (07NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	05NOV2020	2/3	2	Yes		NA/TC	R (07NOV2020)	N/N
16-55/ C4591001 1241 12412177	GENRL	Injection site pain/ Injection site pain	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Chills/ Chills#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
		Fatigue/ Fatigue#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12412179	MUSC	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes	NA	NA	R (27JAN2021)	N/N	
		Myalgia/ Myalgia#	3	26JAN2021	1/2	1	Yes	NA	NA	R (27JAN2021)	N/N	
	GENRL	Fatigue/ Prostration#	4	16FEB2021	1/2	1	Yes	NA	NA	R (17FEB2021)	N/N	
	MUSC	Injection site pain/ Injection site pain#	4	16FEB2021	1/2	1	Yes	NA	NA	R (17FEB2021)	N/N	
		Myalgia/ Myalgia#	4	16FEB2021	1/2	1	Yes	NA/TC	NA/TC	R (17FEB2021)	N/N	
	GENRL	Pyrexia/ Fever	1	14OCT2020	1/1	1	Yes	NA/TC	NA/TC	R (14OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	05NOV2020	2/2	1	Yes	NA	NA	R (06NOV2020)	N/N	
	16-55/ C4591001 1241 12412180	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes	NA	NA	R (27JAN2021)	N/N
		GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	2/2	1	Yes	NA	NA	R (18FEB2021)	N/N
	16-55/ C4591001 1241 12412181	GENRL	Pyrexia/ Fever#	4	17FEB2021	2/2	1	Yes	NA	NA	R (18FEB2021)	N/N
Injection site pain/ Injection site pain			1	14OCT2020	1/3	1	Yes	NA	NA	R (16OCT2020)	N/N	
GENRL		Injection site pain/ Injection site pain	2	04NOV2020	1/3	1	Yes	NA	NA	R (06NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412182	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	2/5	1	Yes		NA/TC	R (13FEB2021)	N/N
	NERV	Headache/ Headache#	3	09FEB2021	2/3	1	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1241 12412183	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412186	GENRL	Injection site pain/ Injection site pain	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1241 12412187	GENRL	Pyrexia/ Fever	1	16OCT2020	3/1	1	Yes		NA/TC	R (16OCT2020)	N/N
	NERV	Headache/ Headache	1	16OCT2020	3/1	1	Yes		NA/TC	R (16OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	05NOV2020	2/3	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1241 12412188	GENRL	Pyrexia/ fever	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1241 12412190	BLOOD	Lymphadenopathy/ Left armpit lymph node enlargement	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Investigational Vaccine Dose/ Subject	Action: Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Medical device pain/ Pain in prosthesis in the left hand	1	15OCT2020	2/16	1	Yes	NA	R (30OCT2020)	N/N
	GENRL	Chills/ chills	2	05NOV2020	2/2	1	Yes	NA	R (06NOV2020)	N/N
		Fatigue/ Fatigue	2	05NOV2020	2/2	1	Yes	NA	R (06NOV2020)	N/N
		Medical device pain/ Pain in prosthesis in the left hand	2	05NOV2020	2/3	1	Yes	NA	R (07NOV2020)	N/N
		Pyrexia/ Fever	2	05NOV2020	2/2	1	Yes	NA	R (06NOV2020)	N/N
16-55/ C4591001 1241 12412193	GENRL	Injection site erythema/ Injection site redness	2	06NOV2020	1/2	1	Yes	NA	R (07NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	08FEB2021	1/3	1	Yes	NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412194	GENRL	Chills/ Chills	1	16OCT2020	2/1	1	Yes	NA/TC	R (16OCT2020)	N/N
		Fatigue/ Fatigue	1	16OCT2020	2/1	1	Yes	NA/TC	R (16OCT2020)	N/N
	NERV	Headache/ Headache	1	16OCT2020	2/1	1	Yes	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1241 12412195	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/1	1	Yes	NA	R (26JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	27JAN2021	2/1	1	Yes	NA	R (27JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Prostration#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1241 12412197	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	2/2	1	Yes		NA/TCN	R (28JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	17FEB2021	2/2	2	Yes		NA/TC	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/2	2	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412198	GENRL	Pyrexia/ Fever	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1241 12412201	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
		Pyrexia/ Fever	1	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
		Pyrexia/ Fever	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412202	GASTR	Nausea/ Nausea	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1241 12412203	GENRL	Chills/ Chills#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	17FEB2021	2/1	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1241 12412204	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	04NOV2020	1/2	1	Yes		NA	R (05NOV2020)	N/N
16-55/ C4591001 1241 12412206	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	2/2	2	Yes		NA/TCN	R (17FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/2	2	Yes		NA/TCN	R (17FEB2021)	N/N
16-55/ C4591001 1241 12412207	GENRL	Injection site pain/ Injection site pain	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
	NERV	Headache/ Headache	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1241 12412208	GENRL	Injection site pain/ Injection site pain	2	09NOV2020	5/3	2	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1241 12412209	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	2/3	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	08FEB2021	1/1	1	Yes		NA/TCN	R (08FEB2021)	N/N
16-55/ C4591001 1241 12412211	GENRL	Pyrexia/ Fever	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
	NERV	Headache/ Headache	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1241 12412212	GENRL	Fatigue/ Fatigue#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12412215		Pyrexia/ Fever#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N	
	NERV	Headache/ Headache#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N	
16-55/ C4591001 1241 12412216	GENRL	Fatigue/ Prostration	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N	
		Pyrexia/ Fever	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N	
16-55/ C4591001 1241 12412217	GENRL	Fatigue/ Fatigue#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	
		Injection site pain/ Injection site pain#	3	08FEB2021	1/4	2	Yes		NA/TC	R (11FEB2021)	N/N	
	NERV	Headache/ Headache#	3	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N	
16-55/ C4591001 1241 12412218	INFEC	Conjunctivitis/ Conjunctivitis in the right eye	1	17OCT2020	3/8	1	No	O	NA/TC	R (24OCT2020)	N/N	
	INFEC	Appendicitis/ APPENDICITIS	2	23NOV2020	18/3	3	No	O	NA/TC/TCN	R (25NOV2020)	Y/N	
	GENRL	Chills/ Chills#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N	
		Injection site pain/ Injection site pain#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412221	GENRL	Pyrexia/ Fever#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
		Chills/ Chills#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
		Pyrexia/ Fever#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	MUSC	Myalgia/ Myalgia	1	16OCT2020	2/1	2	Yes		NA	R (16OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	08NOV2020	3/1	2	Yes		NA	R (08NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Pyrexia/ Fever	2	06NOV2020	2/3	1	Yes		NA/TC	R (08NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	06NOV2020	2/3	1	Yes		NA/TC	R (08NOV2020)	N/N
	NERV	Headache/ Headache	2	06NOV2020	2/3	1	Yes		NA/TC	R (08NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
GENRL	Pyrexia/ Fever#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412227	MUSC	Myalgia/ Myalgia#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	2/7	1	Yes		NA/TCN	R (23FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	1/4	2	Yes		NA	R (19OCT2020)	N/N
	GENRL	Chills/ Chills	2	05NOV2020	1/2	2	Yes		NA/TC	R (06NOV2020)	N/N
	GENRL	Pyrexia/ Fever	2	05NOV2020	1/2	2	Yes		NA/TC	R (06NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	05NOV2020	1/2	2	Yes		NA/TC	R (06NOV2020)	N/N
	GENRL	Pyrexia/ Fever#	3	05FEB2021	1/2	1	Yes		NA/TCN	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	3	05FEB2021	1/2	1	Yes		NA/TCN	R (06FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes		NA/TCN	R (07FEB2021)	N/N
16-55/ C4591001 1241 12412232	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
GENRL	Chills/ chills	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12412233	GENRL	Pyrexia/ Fever	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N	
		Injection site pain/ Injection site pain#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N	
16-55/ C4591001 1241 12412235	GENRL	Pyrexia/ Fever#	4	25FEB2021	2/1	1	Yes		NA/TC	R (25FEB2021)	N/N	
		Injection site pain/ Injection site pain	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N	
16-55/ C4591001 1241 12412236	GENRL	Injection site pain/ Injection site pain	1	17OCT2020	2/2	2	Yes		NA/TC	R (18OCT2020)	N/N	
		Injection site pain/ Injection site pain	2	06NOV2020	1/4	2	Yes		NA/TC	R (09NOV2020)	N/N	
16-55/ C4591001 1241 12412237	GENRL	Pyrexia/ Fever	2	06NOV2020	1/2	1	Yes		NA/TC	R (07NOV2020)	N/N	
		Injection site pain/ Injection site pain	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N	
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N	
	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes		NA/TC	R (07FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412239		Injection site pain/ Injection site pain#	3	06FEB2021	2/2	1	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1241 12412244	GENRL	Fatigue/ Fatigue	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1241 12412245	GENRL	Fatigue/ Fatigue	2	06NOV2020	1/1	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Chills/ Chills#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
		Pyrexia/ Fever#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1241 12412247	GENRL	Fatigue/ Fatigue#	3	29JAN2021	1/4	1	Yes		NA/TC	R (01FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	29JAN2021	1/4	1	Yes		NA/TC	R (01FEB2021)	N/N
		Pyrexia/ Fever#	3	29JAN2021	1/4	1	Yes		NA/TC	R (01FEB2021)	N/N
	NERV	Headache/ Headache#	3	29JAN2021	1/4	1	Yes		NA/TC	R (01FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412248	NERV	Pyrexia/ Fever#	4	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N
		Headache/ Headache#	4	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
			Injection site pain/ Injection site pain	1	17OCT2020	2/3	2	Yes		NA/TC	R (19OCT2020)
16-55/ C4591001 1241 12412249	RESP	Oropharyngeal discomfort/ Throat discomfort	2	05NOV2020	1/5	1	Yes		NA/TC	R (09NOV2020)	N/N
16-55/ C4591001 1241 12412252	GENRL	Chills/ Chills	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
		Fatigue/ Fatigue	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	17OCT2020	2/3	1	Yes		NA/TC	R (19OCT2020)	N/N
16-55/ C4591001 1241 12412254	NERV	Tremor/ Leg tremors	1	20OCT2020	5/3	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	1	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412255	EYE	Fatigue/ Prostration	1	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
		Asthenopia/ Weight in the eyes	2	06NOV2020	1/1	1	Yes		NA	R (06NOV2020)	N/N
		Eye irritation/ Eye burning	2	06NOV2020	1/1	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	GENRL	Pyrexia/ Fever	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	2/4	1	Yes		NA	R (12FEB2021)	N/N
	GASTR	Nausea/ Nausea	1	17OCT2020	2/4	2	Yes		NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	06NOV2020	1/4	1	Yes		NA	R (09NOV2020)	N/N
	INV	Body temperature increased/ Subfebrile temperature	2	06NOV2020	1/1	1	Yes		NA	R (06NOV2020)	N/N
	16-55/ C4591001 1241 12412259	GENRL	Chills/ Chills#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)
		Fatigue/ Fatigue#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12412261	NERV	Injection site pain/ Injection site pain#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N	
		Pyrexia/ Fever#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N	
		Headache/ Headache#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/3	1	Yes		NA/TC	R (07FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N	
	GENRL	Pyrexia/ Fever	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N	
	NERV	Headache/ Headache	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	2/1	1	Yes		NA/TC	R (04FEB2021)	N/N	
GENRL	Fatigue/ Fatigue#	4	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N		

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12412271	GENRL	Injection site pain/ Injection site pain#	4	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N	
		Injection site pain/ Injection site pain	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N	
16-55/ C4591001 1241 12412274	GENRL	Injection site pain/ Injection site pain	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
16-55/ C4591001 1241 12412275	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain	1	17OCT2020	2/2	2	Yes		NA	R (18OCT2020)	N/N	
16-55/ C4591001 1241 12412276	GENRL	Fatigue/ Fatigue	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N	
	GENRL	Pyrexia/ Fever	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N	
16-55/ C4591001 1241 12412276	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	17FEB2021	2/1	2	Yes		NA	R (17FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412277	GENRL	Chills/ Chills#	3	26JAN2021	1/1	1	Yes		NA/TC	R (26JAN2021)	N/N
		Pyrexia/ Fever#	3	26JAN2021	1/1	1	Yes		NA/TC	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	2/2	2	Yes		NA/TCN	R (28JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	27JAN2021	2/2	2	Yes		NA	R (28JAN2021)	N/N
	NERV	Headache/ Headache#	3	27JAN2021	2/2	2	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
		Pyrexia/ Fever#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1241 12412278	NERV	Headache/ Headache#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
	GENRL	Injection site erythema/ Injection site redness	1	16OCT2020	1/4	1	Yes		NA	R (19OCT2020)	N/N
		Injection site pain/ Injection site pain	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
		Injection site swelling/ Injection site swelling	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Pyrexia/ Fever	1	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	1	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Diarrhoea/ Diarrhea	1	18OCT2020	3/1	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
		Fatigue/ Prostration	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
		Pyrexia/ Fever	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1241 12412279	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1241 12412280	GENRL	Fatigue/ Fatigue	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
		Fatigue/ Prostration	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
		Injection site pain/ Injection site pain	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1241 12412281	MUSC	Myalgia/ Myalgia	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1241 12412282	GENRL	Chills/ Chills#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001	GENRL	Asthenia/ Asthenia#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12412284	MUSC	Myalgia/ Myalgia#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N	
16-55/ C4591001 1241 12412285	GENRL	Injection site pain/ Injection site pain	2	05NOV2020	1/2	1	Yes		NA/TC	R (06NOV2020)	N/Y	
		Malaise/ Malaise	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/Y	
	MUSC	Myalgia/ Myalgia	2	05NOV2020	1/2	1	Yes		NA/TC	R (06NOV2020)	N/Y	
16-55/ C4591001 1241 12412288	INFEC	Syphilis/ Syphilis	1	23OCT2020	8/C	1	No	O	NA	RG	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N	
	GENRL	Pyrexia/ Fever#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
16-55/ C4591001 1241 12412290	MUSC	Myalgia/ Myalgia	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N	
16-55/ C4591001 1241 12412291	GENRL	Asthenia/ Asthenia#	3	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N	
		Injection site pain/ Injection site pain#	3	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412293	GENRL	Fatigue/ Fatigue	2	06NOV2020	2/2	2	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1241 12412294	GENRL	Fatigue/ Fatigue#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1241 12412295	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	1/4	2	Yes		NA	R (19OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
	NERV	Headache/ Headache	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1241 12412296	GENRL	Fatigue/ Fatigue#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412301	GENRL	Fatigue/ Fatigue#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
		Fatigue/ Fatigue#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ Headache#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	09NOV2020	1/3	1	Yes		NA/TCN	R (11NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/2	2	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C4591001 1241 12412304											
16-55/ C4591001 1241 12412306	NERV	Headache/ Headache#	3	03FEB2021	1/1	1	Yes		NA/TC	R (03FEB2021)	N/N
16-55/ C4591001 1241 12412307	GASTR	Nausea/ Nausea	1	19OCT2020	1/2	1	Yes		NA/TC	R (20OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412312	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/4	2	Yes		NA	R (22OCT2020)	N/N
	NERV	Headache/ Headache	1	19OCT2020	1/2	1	Yes		NA/TC	R (20OCT2020)	N/N
	GENRL	Chills/ Chills	2	09NOV2020	1/1	1	Yes		NA/TC	R (09NOV2020)	N/N
		Injection site pain/ Injection site pain	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N
		Pyrexia/ Fever	2	09NOV2020	1/1	1	Yes		NA/TC	R (09NOV2020)	N/N
	NERV	Headache/ Headache	2	09NOV2020	1/1	1	Yes		NA/TC	R (09NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/2	1	Yes		NA/TCN	R (20OCT2020)	N/N
	EYE	Conjunctivitis allergic/ Allergic conjunctivitis	1	25OCT2020	7/3	1	No	O	NA/TC	R (27OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N
	NERV	Headache/ Headache	2	09NOV2020	1/1	2	Yes		NA/TC	R (09NOV2020)	N/N
16-55/ C4591001 1241 12412314	GENRL	Injection site erythema/ Injection site hyperemia	2	10NOV2020	2/3	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Injection site pain/ Injection site burning	2	09NOV2020	1/7	2	Yes		NA	R (15NOV2020)	N/N
		Injection site pain/ Injection site pain	2	09NOV2020	1/7	2	Yes		NA	R (15NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Injection site pain/ Injection site pain#	4	02MAR2021	2/3	1	Yes		NA	R (04MAR2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	02MAR2021	2/3	1	Yes		NA	R (04MAR2021)	N/N	
	NERV	Headache/ Headache#	4	02MAR2021	2/3	1	Yes		NA	R (04MAR2021)	N/N	
	NERV	Dizziness/ Dizziness#	4	04MAR2021	4/4	2	No	O	NA	R (07MAR2021)	N/N	
	RENAL	Dysuria/ Difficulty urinating#	4	04MAR2021	4/4	2	No	O	NA	R (07MAR2021)	N/N	
16-55/ C4591001 1241 12412315	GENRL	Fatigue/ Prostration#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N	
16-55/ C4591001 1241 12412317	GENRL	Injection site pain/ Injection site pain	2	09NOV2020	1/1	1	Yes		NA	R (09NOV2020)	N/Y	
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	1/2	1	Yes		NA/TC	R (24FEB2021)	N/N	
		Pyrexia/ Fever#	4	23FEB2021	1/2	1	Yes		NA/TC	R (24FEB2021)	N/N	
16-55/ C4591001 1241 12412320	GENRL	Injection site pain/ Injection site pain	1	20OCT2020	2/3	1	Yes		NA/TCN	R (22OCT2020)	N/N	
	GENRL	Pyrexia/ Fever	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412321	MUSC	Myalgia/ Myalgia	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1241 12412322	GENRL	Pyrexia/ Fever	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		Chills/ Chills	2	12NOV2020	2/1	2	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412323	NERV	Headache/ Headache	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/5	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12412324	GENRL	Injection site pain/ Injection site pain#	4	24FEB2021	2/5	1	Yes		NA	R (28FEB2021)	N/N
	GENRL	Chills/ Chills#	3	09FEB2021	2/4	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12412330	MUSC	Myalgia/ Myalgia#	3	09FEB2021	2/4	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412333	MUSC	Arthralgia/ Polyarthralgia	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
		Myalgia/ Myalgia	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	11NOV2020	1/2	2	Yes		NA	R (12NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	11NOV2020	1/2	2	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412334	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	2/4	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12412336	NERV	Headache/ Headache	2	09NOV2020	1/1	1	Yes		NA	R (09NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1241 12412337	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412338	GENRL	Fatigue/ Prostration	1	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N
		Injection site pain/ Injection site pain	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Chills/ Chills	2	10NOV2020	2/2	2	Yes		NA/TC	R (11NOV2020)	N/N	
		Fatigue/ Fatigue	2	10NOV2020	2/2	2	Yes		NA/TC	R (11NOV2020)	N/N	
		Pyrexia/ Fever	2	10NOV2020	2/2	2	Yes		NA/TC	R (11NOV2020)	N/N	
16-55/ C4591001 1241 12412339	GENRL	Chills/ Chills	1	20OCT2020	2/2	1	Yes		NA/TC	R (21OCT2020)	N/N	
		Pyrexia/ Fever	1	20OCT2020	2/2	1	Yes		NA/TC	R (21OCT2020)	N/N	
16-55/ C4591001 1241 12412341	GENRL	Injection site pain/ Injection site pain	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N	
16-55/ C4591001 1241 12412342	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/Y	
	GENRL	Injection site pain/ Injection site pain	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/Y	
16-55/ C4591001 1241 12412343	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
16-55/ C4591001 1241 12412345	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412346	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/4	2	Yes		NA	R (22OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	09NOV2020	1/3	2	Yes		NA/TC	R (11NOV2020)	N/N
	GENRL	Chills/ Chills	2	09NOV2020	1/3	2	Yes		NA/TC	R (11NOV2020)	N/N
		Fatigue/ Fatigue	2	09NOV2020	1/3	2	Yes		NA/TC	R (11NOV2020)	N/N
		Injection site pain/ Injection site pain	2	09NOV2020	1/4	2	Yes		NA/TC	R (12NOV2020)	N/N
		Pyrexia/ Fever	2	09NOV2020	1/3	2	Yes		NA/TC	R (11NOV2020)	N/N
	NERV	Dizziness/ Dizziness	2	09NOV2020	1/3	2	Yes		NA/TC	R (11NOV2020)	N/N
		Headache/ Headache	2	09NOV2020	1/3	2	Yes		NA/TC	R (11NOV2020)	N/N
	16-55/ C4591001 1241 12412347	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)
16-55/ C4591001		Injection site pain/ Injection site pain	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
	GENRL	Injection site swelling/ Injection site swelling	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412348	GENRL	Injection site pain/ Injection site pain	2	16NOV2020	1/3	1	Yes	NA	NA	R (18NOV2020)	N/N
16-55/ C4591001 1241 12412351	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/2	1	Yes	NA/TC	NA/TC	R (09FEB2021)	N/N
16-55/ C4591001 1241 12412352	NERV	Headache/ Headache#	3	08FEB2021	1/2	1	Yes	NA/TC	NA/TC	R (09FEB2021)	N/N
16-55/ C4591001 1241 12412352	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/2	1	Yes	NA	NA	R (20OCT2020)	N/N
16-55/ C4591001 1241 12412353	GENRL	Fatigue/ Prostration	1	20OCT2020	2/1	1	Yes	NA	NA	R (20OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/2	1	Yes	NA	NA	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	12NOV2020	2/2	1	Yes	NA	NA	R (13NOV2020)	N/N
16-55/ C4591001 1241 12412353	GENRL	Chills/ Chills	1	21OCT2020	3/1	1	Yes	NA	NA	R (21OCT2020)	N/N
		Fatigue/ Fatigue	1	21OCT2020	3/1	1	Yes	NA	NA	R (21OCT2020)	N/N
		Pyrexia/ Fever	1	21OCT2020	3/1	1	Yes	NA	NA	R (21OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	11FEB2021	2/2	1	Yes	NA	NA	R (12FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412354	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/4	1	Yes		NA	R (22OCT2020)	N/N
	GASTR	Nausea/ Nausea	1	20OCT2020	2/2	2	Yes		NA	R (21OCT2020)	N/N
	GENRL	Fatigue/ Prostration	1	20OCT2020	2/2	2	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1241 12412355	GENRL	Fatigue/ Fatigue#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
		Pyrexia/ Fever#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	NERV	Headache/ Headache#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1241 12412357	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1241 12412360	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/Y
16-55/ C4591001 1241 12412361	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/4	2	Yes		NA/TC	R (22OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Investigational Vaccine Dose/ Subject	Action: Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills	1	20OCT2020	2/1	1	Yes	NA/TC	R (20OCT2020)	N/N
		Fatigue/ Fatigue	1	20OCT2020	2/1	1	Yes	NA/TC	R (20OCT2020)	N/N
		Pyrexia/ Fever	1	20OCT2020	2/1	1	Yes	NA/TC	R (20OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10NOV2020	2/1	1	Yes	NA/TC	R (10NOV2020)	N/N
		Pyrexia/ Fever	2	10NOV2020	2/1	1	Yes	NA/TC	R (10NOV2020)	N/N
16-55/ C4591001 1241 12412362	GENRL	Injection site erythema/ Injection site redness#	3	27JAN2021	1/1	1	Yes	NA	R (27JAN2021)	N/Y
		Injection site swelling/ Injection site swelling#	3	27JAN2021	1/1	1	Yes	NA	R (27JAN2021)	N/Y
16-55/ C4591001 1241 12412363	NERV	Headache/ Headache	1	19OCT2020	1/2	1	Yes	NA/TC	R (20OCT2020)	N/Y
16-55/ C4591001 1241 12412365	GENRL	Pyrexia/ Fever	1	19OCT2020	1/1	1	Yes	NA/TC	R (19OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	10NOV2020	2/2	1	Yes	NA/TC	R (11NOV2020)	N/N
16-55/ C4591001 1241 12412366	GENRL	Chills/ Chills#	4	20FEB2021	2/1	1	Yes	NA	R (20FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412367	MUSC	Myalgia/ Myalgia#	4	20FEB2021	2/1	1	Yes		NA/TC	R (20FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1241 12412368	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	2/3	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1241 12412369	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy	2	21JAN2021	72/C		No	O	P	UNK	N/N
16-55/ C4591001 1241 12412370	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N
16-55/ C4591001 1241 12412371	INV	Body temperature increased/ Subfebrile temperature	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N
	GENRL	Chills/ Chills	2	10NOV2020	1/2	2	Yes		NA/TC	R (11NOV2020)	N/N
		Fatigue/ Fatigue	2	10NOV2020	1/2	2	Yes		NA/TC	R (11NOV2020)	N/N
		Injection site pain/ Injection site pain	2	10NOV2020	1/4	1	Yes		NA	R (13NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412373	MUSC	Pyrexia/ Fever	2	10NOV2020	1/2	2	Yes		NA/TC	R (11NOV2020)	N/N
		Myalgia/ Myalgia	2	10NOV2020	1/2	2	Yes		NA/TC	R (11NOV2020)	N/N
	NERV	Presyncope/ Lipothymia (Presyncope)	2	09NOV2020	1/1	1	Yes		NA	R (09NOV2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/3	1	Yes		NA/TC	R (24JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12412375	GENRL	Fatigue/ Prostration#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
		Pyrexia/ Fever	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1241 12412377	MUSC	Myalgia/ Myalgia	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
	NERV	Headache/ Headache	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
	NERV	Headache/ Headache	1	20OCT2020	2/1	2	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	09NOV2020	1/2	2	Yes		NA/TCN	R (10NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412378		Injection site pain/ Injection site pain	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N
16-55/ C4591001 1241 12412379	GENRL	Fatigue/ Fatigue#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1241 12412380	GASTR	Nausea/ Nausea	1	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
	NERV	Headache/ Headache	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Chills/ Chills	2	10NOV2020	1/2	1	Yes		NA/TC	R (11NOV2020)	N/N
		Injection site pain/ Injection site pain	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N
		Pyrexia/ Fever	2	10NOV2020	1/2	1	Yes		NA/TC	R (11NOV2020)	N/N
	NERV	Headache/ Headache	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1241 12412381	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	2/2	1	Yes		NA/TCN	R (10FEB2021)	N/N
16-55/ C4591001	SKIN	Pityriasis rosea/ Pityriasis rosea	1	25OCT2020	6/23	2	Yes		NA/TC	R (16NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412382	GENRL	Injection site pain/ Injection site pain	2	15DEC2020	1/2	2	Yes		NA	R (16DEC2020)	N/N
16-55/ C4591001 1241 12412385	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1241 12412387	GENRL	Injection site pain/ Injection site pain#	4	19FEB2021	2/3	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1241 12412387	GENRL	Fatigue/ Fatigue	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1241 12412389	GENRL	Injection site pain/ Injection site pain#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1241 12412389	GENRL	Fatigue/ Fatigue#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1241 12412389	GENRL	Injection site pain/ Injection site pain#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1241 12412390	MUSC	Myalgia/ Myalgia#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1241 12412389	GENRL	Fatigue/ Fatigue#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412390	GENRL	Injection site pain/ Injection site pain	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412391	GENRL	Chills/ Chills	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
		Pyrexia/ Fever	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
	GENRL	Chills/ Chills	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1241 12412392	GASTR	Fatigue/ Fatigue	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
		Diarrhoea/ Diarrhea	2	11NOV2020	2/2	2	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412392	GENRL	Nausea/ Nausea	2	11NOV2020	2/2	2	Yes		NA	R (12NOV2020)	N/N
		Chills/ Chills	2	11NOV2020	2/2	2	Yes		NA	R (12NOV2020)	N/N
		Fatigue/ Fatigue	2	11NOV2020	2/2	2	Yes		NA	R (12NOV2020)	N/N
	MUSC	Injection site pain/ Injection site pain	2	11NOV2020	2/3	1	Yes		NA	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	11NOV2020	2/2	2	Yes		NA	R (12NOV2020)	N/N
		Myalgia/ Myalgia	2	11NOV2020	2/2	2	Yes		NA	R (12NOV2020)	N/N
		NERV	Headache/ Headache	2	11NOV2020	2/2	2	Yes		NA	R (12NOV2020)
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412395	GENRL	Injection site pain/ Injection site pain#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1241 12412397	GASTR	Diarrhoea/ Diarrhea#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1241 12412398	GENRL	Pyrexia/ Fever#	3	26JAN2021	1/3	1	Yes		NA/TC	R (28JAN2021)	N/N
16-55/ C4591001 1241 12412398	GENRL	Injection site pain/ Injection site pain	1	20OCT2020	1/5	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Chills/ Chills	2	11NOV2020	2/3	1	Yes		NA/TC	R (13NOV2020)	N/N
		Injection site pain/ Injection site pain	2	11NOV2020	2/3	1	Yes		NA/TC	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	11NOV2020	2/3	1	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1241 12412399	GENRL	Fatigue/ Prostration	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412400	GENRL	Injection site pain/ Injection site pain#	3	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12412401	NERV	Headache/ Headache#	3	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N	
	SKIN	Urticaria/ Chest region Urticaria	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue#	3	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N	
16-55/ C4591001 1241 12412402	NERV	Headache/ Headache#	3	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N	
	GENRL	Pyrexia/ Fever	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N	
16-55/ C4591001 1241 12412403	GENRL	Fatigue/ Fatigue	2	11NOV2020	2/2	1	Yes		NA/TC	R (12NOV2020)	N/N	
	GENRL	Pain/ Body pain	2	11NOV2020	2/2	1	Yes		NA/TC	R (12NOV2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N	
16-55/ C4591001	GENRL	Chills/ Chills	2	10NOV2020	1/2	1	Yes		NA/TC	R (11NOV2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412404		Injection site pain/ Injection site pain	2	10NOV2020	1/3	2	Yes		NA	R (12NOV2020)	N/N
		Pyrexia/ Fever	2	10NOV2020	1/2	1	Yes		NA/TC	R (11NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	10NOV2020	1/2	1	Yes		NA/TC	R (11NOV2020)	N/N
16-55/ C4591001 1241 12412405	NERV	Headache/ Headache	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1241 12412406	INJ&P	Rib fracture/ Fracture of two ribs on the right#	2	26FEB2021	109/1	2	No	O	NA/TC	R (26FEB2021)	N/N
		Road traffic accident/ Motor vehicle accident#	2	26FEB2021	109/1	2	No	O	NA	R (26FEB2021)	N/N
16-55/ C4591001 1241 12412407	GENRL	Fatigue/ Fatigue	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1241 12412409	GENRL	Pyrexia/ Fever	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
	METAB	Decreased appetite/ Hyporexia	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412410	GASTR	Nausea/ Nausea	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N
	NERV	Headache/ Headache	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 1241 12412411	NEOPL	Fibroadenoma of breast/ Right breast fibroadenoma	2	NOV2020	1/C	1	No	O	NA	RG	N/N
	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
		Pyrexia/ Fever#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ Headache#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy#	3	12FEB2021	5/C		No	O	P	UNK	N/N
16-55/ C4591001 1241 12412413	GASTR	Vomiting/ Vomiting	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Pyrexia/ Fever	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412414	GENRL	Injection site pain/ Injection site pain	1	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/Y

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12412415	GENRL	Chills/ Chills	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N	
		Fatigue/ Fatigue	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N	
		Injection site pain/ Injection site pain	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N	
	GENRL	Chills/ Chills	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N	
16-55/ C4591001 1241 12412416	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/2	2	Yes		NA	R (06FEB2021)	N/N	
	NERV	Headache/ Headache#	3	05FEB2021	1/2	2	Yes		NA	R (06FEB2021)	N/N	
	EYE	Keratitis/ Right eye keratitis#	3	22FEB2021	18/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1241 12412416	GENRL	Fatigue/ Fatigue#	3	11FEB2021	3/1	1	Yes		NA	R (11FEB2021)	N/N	
		Fatigue/ Prostration#	3	11FEB2021	3/1	1	Yes		NA	R (11FEB2021)	N/N	
16-55/ C4591001 1241 12412424	GENRL	Fatigue/ Prostration	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N	
16-55/ C4591001	GENRL	Chills/ Chills	2	11NOV2020	1/2	2	Yes		NA	R (12NOV2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412425	NERV	Headache/ Headache	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1241 12412426	NERV	Headache/ Headache	2	16NOV2020	1/2	2	Yes		NA	R (17NOV2020)	N/N
16-55/ C4591001 1241 12412427	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Fatigue/ Prostration#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412429	GENRL	Pyrexia/ Fever	1	22OCT2020	2/1	1	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	11NOV2020	1/2	2	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412430	GENRL	Fatigue/ Prostration#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/2	1	Yes		NA/TC	R (05FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412432											
16-55/ C4591001 1241 12412438	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1241 12412439	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N
	NERV	Headache/ Headache	1	22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	12NOV2020	2/4	1	Yes		NA/TC	R (15NOV2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	2/4	1	Yes		NA/TC	R (15NOV2020)	N/N
16-55/ C4591001 1241 12412440	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	19FEB2021	2/1	1	Yes		NA/TC	R (19FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	19FEB2021	2/1	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1241 12412441	GENRL	Injection site pain/ Injection site pain#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12412442	GENRL	Injection site pain/ Injection site pain#	4	11FEB2021	2/3	1	Yes		NA/TC	R (13FEB2021)	N/N	
		Pyrexia/ Fever#	4	11FEB2021	2/3	1	Yes		NA/TC	R (13FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/3	1	Yes		NA/TC	R (13FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N	
	GENRL	Chills/ Chills	2	11NOV2020	1/3	2	Yes		NA/TC	R (13NOV2020)	N/N	
	NERV	Headache/ Headache	2	11NOV2020	1/3	2	Yes		NA/TC	R (13NOV2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/2	2	Yes		NA/TC	R (12NOV2020)	N/N	
		Pyrexia/ Fever	2	11NOV2020	1/2	2	Yes		NA/TC	R (12NOV2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
	1241 12412444											
16-55/ C4591001 1241 12412445	EYE	Eye irritation/ Eye burning	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N	
	GASTR	Nausea/ Nausea	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Chills/ Chills	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N	
		Fatigue/ Fatigue	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N	
		Injection site pain/ Injection site pain	1	23OCT2020	2/3	2	Yes		NA/TC	R (25OCT2020)	N/N	
		Pain/ Body pain	1	23OCT2020	2/3	2	Yes		NA/TC	R (25OCT2020)	N/N	
	NERV	Headache/ Headache	1	23OCT2020	2/3	2	Yes		NA/TC	R (25OCT2020)	N/N	
	GENRL	Pyrexia/ Fever	2	12NOV2020	2/2	1	Yes		NA/TC	R (13NOV2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	12NOV2020	2/2	1	Yes		NA/TC	R (13NOV2020)	N/N	
	NERV	Headache/ Headache	2	12NOV2020	2/2	1	Yes		NA/TC	R (13NOV2020)	N/N	
16-55/ C4591001 1241 12412448	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N	
16-55/ C4591001 1241 12412449	GENRL	Injection site pain/ Injection site pain	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N	
	NERV	Headache/ Headache	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N	
16-55/ C4591001	NERV	Headache/ Headache	2	12NOV2020	2/5	1	Yes		NA	R (16NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412450	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/3	1	Yes	NA/TC		R (06FEB2021)	N/N
	NERV	Headache/ Headache#	3	05FEB2021	2/2	2	Yes	NA/TC		R (06FEB2021)	N/N
16-55/ C4591001 1241 12412451	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/3	1	Yes	NA		R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/2	1	Yes	NA		R (12NOV2020)	N/N
16-55/ C4591001 1241 12412452	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	1/2	2	Yes	NA		R (10FEB2021)	N/N
16-55/ C4591001 1241 12412456	NERV	Headache/ Headache	1	23OCT2020	2/1	1	Yes	NA/TC		R (23OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	11NOV2020	1/2	1	Yes	NA		R (12NOV2020)	N/N
16-55/ C4591001 1241 12412457	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/3	1	Yes	NA		R (07FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	05FEB2021	2/3	1	Yes	NA/TC		R (07FEB2021)	N/N
	NERV	Headache/ Headache#	3	05FEB2021	2/3	1	Yes	NA		R (07FEB2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412458	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	2	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1241 12412459	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/3	1	Yes		NA/TCN	R (07FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12412460	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/1	2	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412461	GENRL	Injection site pain/ Injection site pain	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1241 12412462	GENRL	Injection site pain/ Injection site pain#	3	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1241 12412463	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Chills/ Chills	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N
		Fatigue/ Fatigue	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12412464	MUSC	Injection site pain/ Injection site pain	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N	
		Pyrexia/ Fever	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N	
		Myalgia/ Myalgia#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
16-55/ C4591001 1241 12412465	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N	
16-55/ C4591001 1241 12412466	MUSC	Myalgia/ Myalgia	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N	
	NERV	Headache/ Headache#	3	28JAN2021	2/1	2	Yes		NA/TC	R (28JAN2021)	N/N	
16-55/ C4591001 1241 12412468	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/1	1	Yes		NA/TC	R (12NOV2020)	N/N	
16-55/ C4591001 1241 12412470	GENRL	Pyrexia/ Fever	2	12NOV2020	2/1	1	Yes		NA/TC	R (12NOV2020)	N/N	
		Chills/ Chills	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N	
		Fatigue/ Fatigue	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412471	GENRL	Chills/ Chills	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	12NOV2020	2/1	2	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412472		Pyrexia/ Fever	2	12NOV2020	2/1	2	Yes		NA/TC	R (12NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	12NOV2020	2/1	2	Yes		NA/TC	R (12NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
		Pyrexia/ Fever	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
	NERV	Headache/ Headache	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412475	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/1	1	Yes		NA	R (11NOV2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	30JAN2021	2/2	2	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1241 12412477	NERV	Headache/ Headache	2	12NOV2020	2/11	2	Yes		NA	R (22NOV2020)	N/N
16-55/ C4591001 1241 12412478	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	2/5	2	Yes		NA	R (27OCT2020)	N/N
	GENRL	Chills/ Chills	1	24OCT2020	3/1	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	16NOV2020	1/4	1	Yes		NA/TCN	R (19NOV2020)	N/N
16-55/ C4591001 1241 12412479	GENRL	Injection site pain/ Injection site pain	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1241 12412480	GENRL	Asthenia/ Asthenia	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
	NERV	Headache/ Headache	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/1	2	Yes		NA/TC	R (12NOV2020)	N/N
		Pyrexia/ Fever	2	12NOV2020	2/1	2	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412482	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	12NOV2020	1/2	1	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1241 12412485	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412486	NERV	Headache/ Headache	1	23OCT2020	1/1	1	Yes		NA/TC	R (23OCT2020)	N/N
	GASTR	Nausea/ Nausea	1	27OCT2020	5/1	1	Yes		NA	R (27OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412491	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	1/6	1	Yes		NA/TC	R (22FEB2021)	N/N
		Injection site swelling/ Injection site swelling#	4	17FEB2021	1/6	1	Yes		NA	R (22FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412494	GENRL	Injection site erythema/ Injection site hyperemia#	4	18FEB2021	2/5	2	Yes		NA	R (22FEB2021)	N/N
		Injection site pruritus/ Injection site itching#	4	18FEB2021	2/5	2	Yes		NA/TC	R (22FEB2021)	N/N
		Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA/TC	R (24OCT2020)	N/N
		Fatigue/ Fatigue	1	24OCT2020	2/1	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1241 12412495	GENRL	Pyrexia/ Fever	2	12NOV2020	1/2	1	Yes		NA/TC	R (13NOV2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	1/6	1	Yes		NA/TC	R (17NOV2020)	N/N
	INFEC	Nail infection/ Nail infection in the first left toe	2	20NOV2020	9/8	1	No	O	NA/TC	R (27NOV2020)	N/N
		Injection site pain/ Injection site pain#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1241 12412498	GENRL	Chills/ Chills#	4	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
		Pyrexia/ Fever#	4	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Headache/ Headache	1	24OCT2020	2/1	1	Yes		NA/TC	R (24OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412501	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N
		Pyrexia/ Fever	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N
16-55/ C4591001 1241 12412505	NERV	Headache/ Headache	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1241 12412507	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Chills/ Chills#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
		Fatigue/ Prostration#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
	NERV	Headache/ Headache#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412509	GENRL	Chills/ Chills#	3	29JAN2021	1/4	1	Yes		NA	R (01FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	29JAN2021	1/4	1	Yes		NA	R (01FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412510	MUSC	Myalgia/ Myalgia#	3	29JAN2021	1/4	1	Yes		NA	R (01FEB2021)	N/N
	NERV	Headache/ Headache#	3	29JAN2021	1/4	1	Yes		NA	R (01FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	4	18FEB2021	2/6	2	Yes		NA/TC	R (23FEB2021)	N/N
	GENRL	Fatigue/ Prostration#	4	18FEB2021	2/6	2	Yes		NA/TC	R (23FEB2021)	N/N
		Pyrexia/ Fever#	4	18FEB2021	2/6	2	Yes		NA/TC	R (23FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/6	2	Yes		NA/TC	R (23FEB2021)	N/N
	GASTR	Nausea/ Nausea	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
	GASTR	Abdominal pain/ Abdominal pain	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
		Diarrhoea/ diarrhea	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001 1241 12412512	GASTR	Abdominal pain/ Abdominal pain	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
		Diarrhoea/ Diarrhea	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Chills/ Chills#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412515	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Injection site pain	1	24OCT2020	2/1	1	Yes		NA	R (24OCT2020)	N/N
		Chills/ Chills	2	13NOV2020	2/1	2	Yes		NA/TC	R (13NOV2020)	N/N
	MUSC	Injection site pain/ Injection site pain	2	13NOV2020	2/1	2	Yes		NA/TC	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	13NOV2020	2/1	2	Yes		NA/TC	R (13NOV2020)	N/N
		Myalgia/ Myalgia	2	13NOV2020	2/1	2	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1241 12412516	GENRL	Injection site pruritus/ Injection site itching	2	16NOV2020	5/10	2	Yes		NA	R (25NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	13NOV2020	2/1	2	Yes		NA/TCN	R (13NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	13NOV2020	2/3	2	Yes		NA/TCN	R (15NOV2020)	N/N
		Injection site pain/ Injection site pain	1	23OCT2020	1/3	2	Yes		NA/TC	R (25OCT2020)	N/N
16-55/ C4591001 1241 12412517	GENRL	Fatigue/ Fatigue	1	24OCT2020	2/1	2	Yes		NA/TCN	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	12NOV2020	1/3	2	Yes		NA	R (14NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Prostration	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
		Pyrexia/ Fever	2	13NOV2020	2/2	1	Yes		NA/TC	R (14NOV2020)	N/N
16-55/ C4591001 1241 12412518	GENRL	Injection site pain/ Injection site pain#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412525	INJ&P	Ligament injury/ Injury to ligaments in the right ankle	1	06NOV2020	15/63	2	No	O	NA/TC/TCN	R (07JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412527	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Pyrexia/ Fever	2	13NOV2020	2/1	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1241 12412528	GENRL	Chills/ Chills	1	24OCT2020	2/3	3	Yes		NA/TC	R (26OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412529	NERV	Pyrexia/ Fever	1	24OCT2020	2/3	3	Yes		NA/TC	R (26OCT2020)	N/N
		Headache/ Headache	1	24OCT2020	2/6	3	Yes		NA/TC	R (29OCT2020)	N/N
	VASC	Hypotension/ Hypotension	1	24OCT2020	2/6	3	Yes		NA/TC	R (29OCT2020)	N/N
	GENRL	Chills/ Chills	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N
		Injection site pain/ Injection site pain	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
	NERV	Pyrexia/ Fever	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N
		Headache/ Headache	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/4	2	Yes		NA	R (26OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	24OCT2020	2/1	2	Yes		NA/TCN	R (24OCT2020)	N/N
	NERV	Somnolence/ Somnolence	1	24OCT2020	2/1	2	Yes		NA/TCN	R (24OCT2020)	N/N
GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	2/3	1	Yes		NA	R (11FEB2021)	N/N	
16-55/ C4591001 1241 12412530	GENRL	Injection site pain/ Injection site pain	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	04FEB2021	1/2	1	Yes		NA/TC	R (05FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412532		Pyrexia/ Fever#	3	04FEB2021	1/2	1	Yes	NA/TC		R (05FEB2021)	N/N
16-55/ C4591001 1241 12412535	GENRL	Pyrexia/ Fever	2	13NOV2020	2/2	1	Yes	NA/TC		R (14NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	13NOV2020	2/2	1	Yes	NA		R (14NOV2020)	N/N
16-55/ C4591001 1241 12412537	GENRL	Injection site pain/ Injection site pain	1	24OCT2020	2/3	1	Yes	NA		R (26OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	13NOV2020	2/2	2	Yes	NA/TC		R (14NOV2020)	N/N
16-55/ C4591001 1241 12412539	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes	NA/TC		R (27JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	2/2	1	Yes	NA		R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/2	1	Yes	NA/TC		R (18FEB2021)	N/N
16-55/ C4591001 1241 12412540	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/2	1	Yes	NA		R (12NOV2020)	N/N
	GENRL	Chills/ Chills#	3	28JAN2021	2/1	2	Yes	NA/TC		R (28JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12412543	MUSC	Pyrexia/ Fever#	3	28JAN2021	2/1	2	Yes		NA/TC	R (28JAN2021)	N/N	
		Myalgia/ Myalgia#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N	
16-55/ C4591001 1241 12412543	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N	
16-55/ C4591001 1241 12412544	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA/TCN	R (24OCT2020)	N/N	
16-55/ C4591001 1241 12412546	GENRL	Fatigue/ Fatigue	2	13NOV2020	2/5	1	Yes		NA/TC	R (17NOV2020)	N/N	
		Injection site pain/ Injection site pain	2	13NOV2020	2/5	1	Yes		NA/TC	R (17NOV2020)	N/N	
	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy	2	26DEC2020	45/C		No	O	NA	UNK	N/N	
16-55/ C4591001 1241 12412548	GENRL	Fatigue/ Fatigue	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N	
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N	
		Injection site pain/ Injection site pain	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N	
16-55/ C4591001	GENRL	Pyrexia/ Fever#	4	10FEB2021	1/2	2	Yes		NA/TC	R (11FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine Subject	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412549	MUSC	Myalgia/ Myalgia#	4	10FEB2021	1/2	2	Yes	NA/TC		R (11FEB2021)	N/N
16-55/ C4591001 1241 12412552	GENRL	Fatigue/ Fatigue	2	14NOV2020	2/2	1	Yes	NA		R (15NOV2020)	N/N
		Injection site pain/ Injection site pain	2	14NOV2020	2/2	1	Yes	NA		R (15NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	14NOV2020	2/2	1	Yes	NA		R (15NOV2020)	N/N
16-55/ C4591001 1241 12412553	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/3	1	Yes	NA		R (08FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	06FEB2021	2/3	1	Yes	NA		R (08FEB2021)	N/N
		Pyrexia/ Fever#	3	06FEB2021	2/3	1	Yes	NA		R (08FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	06FEB2021	2/3	1	Yes	NA		R (08FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	01MAR2021	1/3	1	Yes	NA		R (03MAR2021)	N/N
		Injection site pain/ Injection site pain#	4	01MAR2021	1/3	1	Yes	NA		R (03MAR2021)	N/N
16-55/ C4591001 1241 12412554	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes	NA		R (24OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INJ&P	Fall/ Skates falling	2	22NOV2020	11/1	1	No	O	NA	R (22NOV2020)	N/N
		Joint injury/ Left knee trauma	2	22NOV2020	11/1	1	No	O	NA	R (22NOV2020)	N/N
16-55/ C4591001 1241 12412556	GENRL	Injection site pain/ Injection site pain	1	24OCT2020	2/3	1	Yes		NA	R (26OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	13NOV2020	2/1	2	Yes		NA/TC	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	13NOV2020	2/1	2	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1241 12412557	GENRL	Fatigue/ Fatigue	1	24OCT2020	2/3	1	Yes		NA	R (26OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/5	2	Yes		NA/TC	R (08FEB2021)	N/N
		Chills/ Chills#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
		Pyrexia/ Fever#	3	28JAN2021	1/2	1	Yes		NA/TC	R (29JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	19FEB2021	2/C	1	Yes		NA	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412560	GENRL	Pyrexia/ Fever#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
		Injection site pain/ Injection site pain	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001 1241 12412561	INFEC	Pulmonary tuberculosis/ Pulmonary Tuberculosis	2	17NOV2020	6/C	1	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1241 12412563	GENRL	Fatigue/ Fatigue#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	27JAN2021	1/1	1	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412564	GENRL	Pyrexia/ Fever#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	24OCT2020	2/1	1	Yes		NA/TC	R (24OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/1	1	Yes		NA	R (11NOV2020)	N/Y



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12412565	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N	
16-55/ C4591001 1241 12412566†	GENRL	Injection site erythema/ Injection site erythema#	3	22JAN2021	1/4	1	Yes		NA	R (25JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N	
		Fatigue/ Prostration#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N	
16-55/ C4591001 1246 12461004	GENRL	Injection site pain/ Painful Left arm IP injection site.#	3	11FEB2021	1/3	2	Yes		NA/TC	R (13FEB2021)	N/N	
16-55/ C4591001 1246 12461008	MUSC	Muscle spasms/ Back Muscle Spasm	2	11NOV2020	27/17	2	No	O	NA/TC	R (27NOV2020)	N/N	
16-55/ C4591001 1246 12461020	MUSC	Pain in extremity/ Painful Left Arm#	3	27FEB2021	1/3	1	Yes		NA/TC	R (01MAR2021)	N/N	
16-55/ C4591001 1246 12461025	SKIN	Urticaria/ urticaria generalized	1	29SEP2020	2/4	3	Yes		NA/TC	R (02OCT2020)	N/N	
	SKIN	Urticaria/ Intermittent urticaria generalised.	1	07OCT2020	10/27	2	Yes		P/TC	R (02NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1246 12461026	INFEC	Sinusitis/ Sinusitis	2	27OCT2020	9/15	2	No	O	NA/TC	R (10NOV2020)	N/N	
16-55/ C4591001 1246 12461028	MUSC	Pain in extremity/ Painful Left arm#	3	24FEB2021	1/3	1	Yes		NA/TC	R (26FEB2021)	N/N	
16-55/ C4591001 1246 12461030	GENRL	Injection site pain/ Painful Left Arm injection site#	3	24FEB2021	1/3	1	Yes		NA/TC	R (26FEB2021)	N/N	
16-55/ C4591001 1246 12461037	GENRL	Injection site pain/ Pain in left arm injection site#	3	10FEB2021	1/5	1	Yes		NA/TC	R (14FEB2021)	N/N	
16-55/ C4591001 1246 12461043	MUSC	Pain in extremity/ Painful Left Arm#	3	01MAR2021	1/3	1	Yes		NA/TC	R (03MAR2021)	N/N	
16-55/ C4591001 1246 12461045	GENRL	Injection site pain/ Painful left arm at injection site#	3	11FEB2021	1/2	1	Yes		NA/TC	R (12FEB2021)	N/N	
16-55/ C4591001 1246 12461050	GENRL	Fatigue/ Fatigue	2	28OCT2020	7/6	1	No	O	NA	R (02NOV2020)	N/N	
16-55/ C4591001 1246 12461052	RESP	Rhinitis allergic/ Worsening of Allergic Rhinitis	2	15NOV2020	25/7	2	No	O	NA/TC	R (21NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1246 12461060	GENRL	Fatigue/ Fatigue#	3	26FEB2021	1/3	1	Yes		NA/TC	R (28FEB2021)	N/N	
		Injection site pain/ Painful Right arm injection site.#	3	26FEB2021	1/3	1	Yes		NA/TC	R (28FEB2021)	N/N	
16-55/ C4591001 1246 12461070	INFEC	Urinary tract infection/ Urine tract Infection-pathogen unknown	2	15NOV2020	23/4	2	No	O	NA/TC	R (18NOV2020)	N/N	
	PSYCH	Depression/ Worsening of depression	2	25DEC2020	63/22	3	No	O	NA/TC/TCN	R (15JAN2021)	Y/N	
16-55/ C4591001 1246 12461072	GENRL	Malaise/ Malaise#	3	20FEB2021	2/4	2	Yes		NA	R (23FEB2021)	N/N	
		Pain/ Body pains (generalized)#	3	20FEB2021	2/4	2	Yes		NA/TC	R (23FEB2021)	N/N	
		Pyrexia/ Low grade fever#	3	20FEB2021	2/4	2	Yes		NA/TC	R (23FEB2021)	N/N	
16-55/ C4591001 1246 12461078	GENRL	Injection site pain/ Painfull Left arm at injection site#	3	11FEB2021	1/5	1	Yes		NA	R (15FEB2021)	N/N	
	GENRL	Pyrexia/ Fever#	4	09MAR2021	6/3	2	Yes		NA/TC/TCN	R (11MAR2021)	N/N	
	GASTR	Stomatitis/ Stomatitis of mouth#	4	12MAR2021	9/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Painful Left Arm injection area#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1246 12461082											
16-55/ C4591001	GENRL	Injection site pain/ Painful left arm injection site.#	3	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N
1246 12461084											
16-55/ C4591001	GENRL	Injection site pain/ Painful left arm injection site#	3	16FEB2021	1/3	1	Yes		NA	R (18FEB2021)	N/N
1246 12461087											
	GENRL	Chills/ Chills#	4	09MAR2021	1/3	2	Yes		NA/TC	R (11MAR2021)	N/N
		Pyrexia/ Fever#	4	09MAR2021	1/3	2	Yes		NA/TC	R (11MAR2021)	N/N
	GASTR	Stomatitis/ Stomatitis mouth#	4	12MAR2021	4/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001	GASTR	Constipation/ Constipation	1	08OCT2020	3/20	2	No	O	NA/TC	R (27OCT2020)	N/N
1246 12461088											
	GENRL	Injection site pain/ Painful left arm at injection side#	3	16FEB2021	1/4	2	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Painful left arm injection site#	3	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N
1246 12461092											
16-55/ C4591001	GENRL	Injection site pain/ Painful left arm at injection side#	3	12FEB2021	1/4	2	Yes		NA/TC	R (15FEB2021)	N/N
1246 12461094											

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1246 12461104	GENRL	Injection site pain/ Painful Left arm at injection site#	3	15FEB2021	1/4	2	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1246 12461114	GENRL	Injection site pain/ Painful left arm at injection site#	3	16FEB2021	1/4	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1246 12461115	GENRL	Injection site pain/ Painful left arm injection site#	3	15FEB2021	1/2	1	Yes		NA/TC	R (16FEB2021)	N/N
	GASTR	Irritable bowel syndrome/ Irritable bowel syndrome#	3	05MAR2021	19/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1246 12461116	GENRL	Injection site pain/ Painful left arm at injection site#	3	16FEB2021	1/4	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1246 12461117	INFEC	Tinea versicolour/ Pityriasis Versicolor on thorax	2	16NOV2020	20/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1246 12461119	GENRL	Injection site pain/ Painful Left Arm injection site.#	3	27FEB2021	1/3	1	Yes		NA/TC	R (01MAR2021)	N/N
16-55/ C4591001 1246 12461131	REPRO	Endometriosis/ Worsening of Endometriosis left ovary	2	06JAN2021	68/15	3	No	O	NA/TC/TCN	R (20JAN2021)	Y/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1246 12461136	MUSC GENRL	Pain in extremity/ Painful Left Arm# Injection site pain/ Painful Left Arm injection side#	3	27FEB2021	1/2	1	Yes		NA/TC	R (28FEB2021)	N/N
16-55/ C4591001 1246 12461139	GENRL	Injection site pain/ Painful left Arm injection side#	3	15FEB2021	1/4	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1246 12461139	GENRL	Injection site pain/ Painful left Arm injection side#	3	15FEB2021	1/8	2	Yes		NA/TC	R (22FEB2021)	N/N
16-55/ C4591001 1247 12471016	INFEC	Vaginal infection/ Vaginitis	1	12OCT2020	19/11	2	No	O	NA	R (22OCT2020)	N/N
16-55/ C4591001 1247 12471019	INFEC	Tinea versicolour/ Tinea Versicolor (upper limbs)	2	28OCT2020	14/C	2	No	O	NA	RG	N/N
16-55/ C4591001 1247 12471040	INFEC	Blister infected/ Infected Fever Blister	2	10NOV2020	27/3	2	No	O	NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1247 12471053	INFEC	Nasopharyngitis/ Common cold	1	08OCT2020	14/3	1	No	O	NA	R (10OCT2020)	N/N
16-55/ C4591001 1247 12471058	INFEC	Otitis media/ Otitis Media Right Ear	2	20JAN2021	98/4	2	No	O	NA/TC	R (23JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1247 12471089	RESP	Allergic sinusitis/ Allergic Sinusitis	1	01OCT2020	3/5	2	No	O	NA/TC	R (05OCT2020)	N/N	
16-55/ C4591001 1247 12471092	INFEC	Escherichia urinary tract infection/ Acute E.coli UTI	1	18OCT2020	20/8	2	No	O	NA/TC	R (25OCT2020)	N/N	
16-55/ C4591001 1247 12471121	INJ&P	Flail chest/ Flail Chest	2	30OCT2020	10/C	3	No	O	NA/TC/TCN	N	Y/N	
		Road traffic accident/ Motorcycle accident	2	30OCT2020	10/1	2	No	O	NA	R (30OCT2020)	N/N	
16-55/ C4591001 1247 12471137	MUSC	Back pain/ Worsening back pain	2	09NOV2020	20/7	2	No	O	NA/TC/TCN	R (15NOV2020)	N/N	
		Intervertebral disc protrusion/ Worsening pain related to L5/S1 and L4/L5 disc protrusion	2	09NOV2020	20/C	3	No	O	NA/TC/TCN	N	Y/N	
16-55/ C4591001 1247 12471142	INFEC	Escherichia urinary tract infection/ Uncomplicated E.coli urinary tract infection	1	12OCT2020	12/15	1	No	O	NA/TC	R (26OCT2020)	N/N	
16-55/ C4591001 1247 12471147	VASC	Hypertension/ Exacerbation of hypertension	1	13OCT2020	13/10	1	No	O	NA/TC	R (22OCT2020)	N/N	
16-55/ C4591001	GENRL	Chest pain/ Chest pain	2	12NOV2020	18/2	1	No	O	NA	R (13NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1247 12471168	BLOOD	Lymphadenopathy/ Left axilla Lymphadenopathy	2	27OCT2020	2/9	1	Yes		NA	R (04NOV2020)	N/N	
16-55/ C4591001 1247 12471172	GENRL	Injection site pain/ Local injection site pain#	3	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N	
1247 12471181	GENRL	Malaise/ Malaise#	4	26FEB2021	2/1	1	Yes		NA	R (26FEB2021)	N/N	
16-55/ C4591001 1247 12471183	GENRL	Injection site pain/ Injection site pain	1	06OCT2020	1/3	2	Yes		NA	R (08OCT2020)	N/N	
	GENRL	Injection site swelling/ Injection site swelling	1	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	27OCT2020	1/2	2	Yes		NA	R (28OCT2020)	N/N	
	GENRL	Chills/ Chills	2	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N	
		Fatigue/ Fatigue	2	28OCT2020	2/1	2	Yes		NA	R (28OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	29OCT2020	3/2	1	Yes		NA	R (30OCT2020)	N/N	
		Injection site pain/ Injection site pain	2	29OCT2020	3/2	1	Yes		NA	R (30OCT2020)	N/N	
	NERV	Headache/ Headache	2	29OCT2020	3/2	2	Yes		NA	R (30OCT2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1247 12471184	GENRL	Fatigue/ Fatigue	1	06OCT2020	1/9	2	Yes		NA	R (14OCT2020)	N/N
		Injection site pain/ Local injection site pain	1	06OCT2020	1/3	2	Yes		NA	R (08OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain-general	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	27OCT2020	1/3	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1247 12471185	GENRL	Fatigue/ Fatigue	1	06OCT2020	1/9	1	Yes		NA	R (14OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ Headache	1	06OCT2020	1/5	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Chills/ Chills	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
		Injection site pain/ Injection site pain	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
	MUSC	Myalgia/ Muscle Pain	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Injection pain	1	08OCT2020	3/2	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	27OCT2020	1/3	2	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1247 12471186	NERV	Headache/ Headache	1	06OCT2020	1/4	1	Yes		NA	R (09OCT2020)	N/N	
	GASTR	Diarrhoea/ Diarrhea	1	09OCT2020	4/2	2	Yes		NA	R (10OCT2020)	N/N	
16-55/ C4591001 1247 12471193	NERV	Headache/ Headache	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N	
	GASTR	Diarrhoea/ Diarrhea	1	07OCT2020	2/4	1	Yes		NA	R (10OCT2020)	N/N	
	GENRL	Chills/ Chills	1	10OCT2020	5/2	1	Yes		NA	R (11OCT2020)	N/N	
	MUSC	Arthralgia/ Joint pain	1	10OCT2020	5/2	1	Yes		NA	R (11OCT2020)	N/N	
16-55/ C4591001 1247 12471196	GENRL	Injection site pain/ Local injection pain	1	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N	
	GASTR	Nausea/ Nausea	1	08OCT2020	3/5	1	Yes		NA	R (12OCT2020)	N/N	
	NERV	Headache/ Headache	1	08OCT2020	3/5	1	Yes		NA	R (12OCT2020)	N/N	
	MUSC	Arthralgia/ Joint pain	1	10OCT2020	5/5	2	Yes		NA	R (14OCT2020)	N/N	
	MUSC	Myalgia/ Muscle pain Generalised	1	11OCT2020	6/4	1	Yes		NA	R (14OCT2020)	N/N	
	GASTR	Nausea/ Nausea	2	28OCT2020	2/3	1	Yes		NA	R (30OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1247 12471197	GENRL	Fatigue/ Fatigue	1	07OCT2020	2/7	2	Yes		NA	R (13OCT2020)	N/N	
	NERV	Headache/ Headache	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N	
16-55/ C4591001 1247 12471199	GENRL	Fatigue/ Fatigue	1	06OCT2020	1/1	2	Yes		NA	R (06OCT2020)	N/N	
		Injection site erythema/ Injection site redness	1	06OCT2020	1/2	3	Yes		NA	R (07OCT2020)	N/N	
		Injection site pain/ Injection site pain	1	06OCT2020	1/2	2	Yes		NA	R (07OCT2020)	N/N	
		Injection site swelling/ Injection site swelling	1	06OCT2020	1/1	3	Yes		NA	R (06OCT2020)	N/N	
16-55/ C4591001 1247 12471201	NERV	Headache/ Headache	1	10OCT2020	4/2	1	Yes		NA	R (11OCT2020)	N/N	
16-55/ C4591001 1247 12471203	NERV	Headache/ Headache	1	12OCT2020	6/3	1	Yes		NA	R (14OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	13OCT2020	7/2	1	Yes		NA	R (14OCT2020)	N/N	
	NERV	Headache/ Headache	2	28OCT2020	1/2	2	Yes		NA/TC	R (29OCT2020)	N/N	
	VASC	Hypertension/ newly diagnosed hypertension (permanent)	2	24NOV2020	28/C	1	No	O	NA/TC/TCN	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1247 12471205	GASTR	Diarrhoea/ Diarrhea	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
		Injection site pain/ Local injection site pain	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
	INJ&P	Stab wound/ Left arm stab	1	17OCT2020	11/16	1	No	O	NA/TC	R (01NOV2020)	N/N
16-55/ C4591001 1247 12471209	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	28OCT2020	1/4	2	Yes		NA/TC	R (31OCT2020)	N/N
	NERV	Headache/ Headache	2	28OCT2020	1/11	2	Yes		NA/TC	R (07NOV2020)	N/N
16-55/ C4591001 1247 12471215	INFEC	Nasopharyngitis/ Common Cold*		07OCT2020	-5/3	1	No	O	NA	R (09OCT2020)	N/N
16-55/ C4591001 1247 12471220	GASTR	Diarrhoea/ Diarrhea	1	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	13OCT2020	6/2	1	Yes		NA	R (14OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1247 12471222	BLOOD	Injection site pain/ Injection Pain	1	13OCT2020	6/2	1	Yes	NA	NA	R (14OCT2020)	N/N
		Lymphadenopathy/ Left axillary lymphadenopathy	2	29OCT2020	2/5	1	Yes	NA	NA	R (02NOV2020)	N/N
		Arthralgia/ Generalized Joint pain	2	29OCT2020	2/1	2	Yes	NA	NA	R (29OCT2020)	N/N
		Headache/ Headaches	2	29OCT2020	2/1	2	Yes	NA/TC	NA/TC	R (29OCT2020)	N/N
		Arthralgia/ Generalized Joint pain	2	30OCT2020	3/C	2	Yes	NA/TC	NA/TC	RG	N/N
	GENRL	Chills/ Chills	1	08OCT2020	1/2	1	Yes	NA	NA	R (09OCT2020)	N/N
	MUSC	Injection site pain/ Injection site pain	1	08OCT2020	1/4	1	Yes	NA	NA	R (11OCT2020)	N/N
		Myalgia/ New muscle pain (general)	1	08OCT2020	1/2	1	Yes	NA	NA	R (09OCT2020)	N/N
		Chills/ Chills	2	30OCT2020	1/3	2	Yes	NA	NA	R (01NOV2020)	N/N
		Myalgia/ Muscle pains generalized	2	30OCT2020	1/3	2	Yes	NA	NA	R (01NOV2020)	N/N
Headache/ Headache		2	30OCT2020	1/4	2	Yes	NA/TC	NA/TC	R (02NOV2020)	N/N	
16-55/ C4591001 1247 12471223	GENRL	Injection site pain/ Local injection site pain	2	30OCT2020	1/3	1	Yes	NA	NA	R (01NOV2020)	N/N
	NERV	Headache/ Headache	2	30OCT2020	1/3	1	Yes	NA	NA	R (01NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	PSYCH	Irritability/ Irritable mood	2	30OCT2020	1/1	1	No	O	NA	R (30OCT2020)	N/N	
	GENRL	Oedema peripheral/ Bilateral ankle edema	2	04NOV2020	6/23	2	No	O	NA	R (26NOV2020)	N/N	
	SKIN	Urticaria/ Urticarial rash (upper body and bilateral arms)#	4	03MAR2021	3/C	2	Yes		NA/TC	N	N/N	
16-55/ C4591001 1247 12471226	PSYCH	Depression/ Severe depressive episode	2	04FEB2021	98/5	2	No	O	NA	R (08FEB2021)	Y/N	
16-55/ C4591001 1247 12471232	NERV	Headache/ Headache	1	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N	
	GENRL	Pyrexia/ Fever	2	30OCT2020	2/4	1	Yes		NA	R (02NOV2020)	N/N	
	NERV	Headache/ Headache	2	30OCT2020	2/4	1	Yes		NA/TC	R (02NOV2020)	N/N	
16-55/ C4591001 1247 12471236	NERV	Headache/ Headache	1	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N	
16-55/ C4591001 1247 12471240	GENRL	Injection site pain/ Injection Pain	1	09OCT2020	2/3	1	Yes		NA	R (11OCT2020)	N/N	
16-55/ C4591001 1247 12471244	NERV	Facial paralysis/ Recurrence of Left Bells Palsy Left facial hemipareses#	3	11FEB2021	9/C	2	Yes		NA/TC	RG	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1247 12471245	GENRL	Injection site pain/ Local Injection site pain	2	30OCT2020	1/3	1	Yes		NA	R (01NOV2020)	N/N
16-55/ C4591001 1247 12471258	GENRL	Injection site pain/ Local injection site pain	2	30OCT2020	1/4	1	Yes		NA	R (02NOV2020)	N/N
	MUSC	Myalgia/ Muscle pains (generalised)	2	30OCT2020	1/4	2	Yes		NA	R (02NOV2020)	N/N
16-55/ C4591001 1248 12481001	GENRL	Chills/ Chills	2	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N
		Pyrexia/ Fever	2	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1248 12481004	GENRL	Fatigue/ fatigue#	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
		Pain/ body aches#	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
		Pyrexia/ mild fever#	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1248 12481005	EYE	Photophobia/ Light Sensitivity (Eyes)	1	29AUG2020	4/5	1	Yes		NA	R (02SEP2020)	N/N
	INFEC	Ear infection/ Right Ear Infection	1	29AUG2020	4/1	2	No	O	NA/TC	R (29AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1248 12481012	EAR	Vertigo/ Vertigo	1	30AUG2020	5/4	1	No	O	NA	R (02SEP2020)	N/N	
	INJ&P	Foot fracture/ Right Foot Fracture	2	28SEP2020	12/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1248 12481017	GENRL	Injection site pain/ Local Soreness at Injection Site Left Arm	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N	
16-55/ C4591001 1248 12481019	GENRL	Chills/ Chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	
16-55/ C4591001 1248 12481023		Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	
	GASTR	Diarrhoea/ Diarrhea	1	30AUG2020	3/1	1	No	O	NA	R (30AUG2020)	N/N	
16-55/ C4591001 1248 12481024	RESP	Cough/ Cough	1	01SEP2020	5/4	1	Yes		NA/TC	R (04SEP2020)	N/N	
	SKIN	Hyperhidrosis/ Sweats	1	01SEP2020	5/4	1	Yes		NA	R (04SEP2020)	N/N	
16-55/ C4591001 1248 12481024	RESP	Sputum discoloured/ Green Phlegm	2	06JAN2021	111/34	1	No	O	NA	R (08FEB2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Left Arm Pain Injection Site	1	30AUG2020	1/4	1	Yes		NA	R (02SEP2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1248 12481038 16-55/ C4591001 1248 12481054	GENRL	Injection site pain/ Injection Site Reaction Pain*		31AUG2020	1/4	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C4591001 1248 12481056	GENRL	Chest pain/ Chest Pain	1	12SEP2020	12/2	1	No	O	NA	R (13SEP2020)	N/N
16-55/ C4591001 1248 12481061	NERV	Dizziness/ Light-headedness	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/Y
16-55/ C4591001 1248 12481065	GASTR	Abdominal pain upper/ Stomachache	1	07SEP2020	4/3	1	No	O	NA	R (09SEP2020)	N/N
		Diarrhoea/ Diarrhea	1	07SEP2020	4/3	1	No	O	NA	R (09SEP2020)	N/N
	INFEC	Tooth abscess/ Abscess (tooth)	2	07OCT2020	14/7	2	No	O	NA/TC/TCN	R (13OCT2020)	N/N
16-55/ C4591001 1248 12481068	GENRL	Fatigue/ Tiredness	1	05SEP2020	1/3	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1248 12481075	GENRL	Fatigue/ Mild Fatigue	1	05SEP2020	1/1	1	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Generalized Mild Muscle Aches	1	05SEP2020	1/1	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1248 12481076	GENRL	Influenza like illness/ Flu Like Symptoms	1	06SEP2020	2/2	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1248 12481077	GENRL	Injection site pain/ Pain Injection Site	1	05SEP2020	1/2	2	Yes		NA	R (06SEP2020)	N/N
	GENRL	Pyrexia/ Fever	1	06SEP2020	2/2	2	Yes		NA	R (07SEP2020)	N/N
	MUSC	Myalgia/ Muscle Ache	1	06SEP2020	2/1	2	Yes		NA	R (06SEP2020)	N/N
	NERV	Headache/ Headache Mild	1	06SEP2020	2/1	2	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1248 12481081	GENRL	Injection site pain/ Injection site Reaction (Pain)	1	06SEP2020	2/2	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1248 12481086	MUSC	Myalgia/ Muscle soreness#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1248 12481098	NERV	Headache/ Headache	1	20SEP2020	13/5	1	No	O	NA	R (24SEP2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1248 12481099 16-55/ C4591001 1248 12481103	GENRL	Pyrexia/ Fever Temperature (Unknown Temperature)	1	08SEP2020	1/3	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1248 12481123	INJ&P	Procedural pain/ Tooth Ache (after root canal procedure)	1	01OCT2020	20/7	1	No	O	NA	R (07OCT2020)	N/N
16-55/ C4591001 1248 12481131	GENRL	Chills/ Chills	1	12SEP2020	1/1	1	Yes		NA	R (12SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	17SEP2020	6/1	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1248 12481145	GENRL	Injection site pain/ Injection site Reaction (mild pain right upper arm)	1	13SEP2020	1/3	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1248 12481146	GENRL	Injection site pain/ Injection Site Pain	1	14SEP2020	2/3	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1248 12481158	GENRL	Injection site pain/ Injection Site Reaction Pain	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1248 12481159	NERV	Lethargy/ Lethargy	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Chills/ Chills	1	16SEP2020	3/15	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1248 12481170	GENRL	Fatigue/ Fatigue	1	16SEP2020	3/21	2	Yes		NA	R (06OCT2020)	N/N
		Pain/ Body Aches#	4	06FEB2021	2/1	2	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1248 12481176	GENRL	Pain/ Body Aches	1	19SEP2020	5/2	2	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1248 12481187	NERV	Headache/ Headache	1	19SEP2020	5/2	3	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Reaction Pain	1	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1248 12481188	NERV	Headache/ Headache	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	2/1	2	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Reaction Pain	1	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1248 12481193	GENRL	Influenza like illness/ Flu-Like Symptoms	1	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1248 12481194	MUSC	Myalgia/ Muscle Aches	1	17SEP2020	1/17	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1248 12481195	GENRL	Exercise tolerance decreased/ Mild Decrease in Exercise Tolerance	1	17SEP2020	1/21	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1248 12481200	NERV	Dizziness/ dizziness	1	07OCT2020	21/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1248 12481204	GENRL	Chills/ chills#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
		Fatigue/ fatigue#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
		Pain/ body aches#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ headache#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1248 12481205	GENRL	Fatigue/ Tiredness	1	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1248 12481210	MUSC	Pain in extremity/ Left Arm Pain	1	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N
	GENRL	Fatigue/ fatigue#	4	01FEB2021	1/4	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Injection site soreness#	4	01FEB2021	1/4	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1248 12481212	MUSC	Myalgia/ muscle aches#	4	01FEB2021	1/4	1	Yes		NA	R (04FEB2021)	N/N
	GASTR	Nausea/ Nausea	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1248 12481213	GENRL	Chills/ Chills	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N
	PSYCH	Disorientation/ disoriented	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
	SKIN	Rash/ Skin Rash on Face and Abdomen	1	20SEP2020	3/5	1	No	O	NA	R (24SEP2020)	N/N
16-55/ C4591001 1248 12481215	GENRL	Chills/ chills#	4	09FEB2021	1/1	1	Yes		NA	R (09FEB2021)	N/N
		Pain/ body aches#	4	09FEB2021	1/1	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001	GASTR	Vomiting/ Vomiting*		20SEP2020	/2	1	No	O	NA/TCN	R (21SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1248 12481218	NERV	Syncope/ vasovagal syncope*		20SEP2020	/1	2	No	O	NA/W	R (20SEP2020)	N/N	
16-55/ C4591001 1251 12511003	GASTR	Diarrhoea/ Diarrhea#	3	21JAN2021	2/1	1	Yes		NA	R (21JAN2021)	N/N	
16-55/ C4591001 1251 12511013	GENRL	Pain/ Body Aches	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N	
	NERV	Headache/ Headache	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N	
16-55/ C4591001 1251 12511031	METAB	Diabetes mellitus inadequate control/ worsening diabetes type 11#	4	25FEB2021	14/C	4	No	O	NA/TC/TCN	N	Y/N	
16-55/ C4591001 1251 12511033	NERV	Idiopathic intracranial hypertension/ Pseudotumor Cerebri	2	JAN2021	114/C	3	No	O	NA/TC	N	Y/N	
16-55/ C4591001 1251 12511046	GENRL	Injection site pain/ upper left arm pain at injection site	1	14SEP2020	22/18	1	Yes		NA/TC	R (01OCT2020)	N/N	
16-55/ C4591001 1251 12511058	INFEC	Otitis externa/ swimmers ear Left	1	08SEP2020	14/5	1	No	O	NA/TC	R (12SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1251 12511060	RESP	Nasal congestion/ Nasal Congestion	1	02SEP2020	8/3	1	Yes		NA	R (04SEP2020)	N/N	
	INJ&P	Exposure during pregnancy/ exposure during pregnancy subjects wife is pregnant	2	JAN2021	108/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1251 12511068	GASTR	Vomiting/ Vomiting	2	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N	
	GENRL	Chills/ Chills	2	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N	
	INJ&P	Foot fracture/ Jones Fracture#	2	11FEB2021	149/29	3	No	O	NA/TC/TCN	R (11MAR2021)	N/N	
16-55/ C4591001 1251 12511081	RESP	Sinus congestion/ sinus congestion	1	30SEP2020	31/44	1	No	O	NA/TC	R (12NOV2020)	N/N	
		Wheezing/ Wheezing	1	30SEP2020	31/44	1	No	O	NA/TC	R (12NOV2020)	N/N	
16-55/ C4591001 1251 12511082	GENRL	Chills/ chills	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N	
	INJ&P	Contusion/ head contusion	2	09DEC2020	80/C	1	No	O	NA	RG	N/N	
		Muscle strain/ cervical strain	2	09DEC2020	80/C	1	No	O	NA	RG	N/N	
16-55/ C4591001	GASTR	Diarrhoea/ Diarrhea	1	05SEP2020	5/1	1	Yes		NA	R (05SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1251 12511093	NERV	Headache/ headache intermittent	2	12OCT2020	18/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001												
1251 12511124	MUSC	Plantar fasciitis/ Plantar Fasciitis	2	09OCT2020	11/C	1	No	O	NA	N	N/N	
16-55/ C4591001												
1251 12511127	REPRO	Ovarian cyst/ ovarian cyst	1	10SEP2020	3/C	2	No	O	NA	N	N/N	
16-55/ C4591001												
1251 12511131	GENRL	Chills/ Chills	2	30SEP2020	1/1	1	Yes		NA/TC	R (30SEP2020)	N/N	
16-55/ C4591001												
1251 12511141	GENRL	Injection site pain/ Right deltoid pain at injection site#	4	13MAR2021	2/C	1	Yes		NA	N	N/N	
16-55/ C4591001												
1251 12511147	GENRL	Injection site pain/ Pain at Injection Site Left Deltoid	2	30SEP2020	1/11	1	Yes		NA	R (10OCT2020)	N/N	
16-55/ C4591001												
1251 12511155	GENRL	Chills/ Chills	2	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/N	
16-55/ C4591001												
1251 12511161												

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1251 12511171	MUSC	Pyrexia/ Fever	2	07OCT2020	1/3	1	Yes		NA/TC	R (09OCT2020)	N/N	
		Myalgia/ Muscle Aches (Body)	2	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N	
16-55/ C4591001 1251 12511191	GENRL	Pain/ body aches	2	14OCT2020	1/2	1	Yes		NA/TC	R (15OCT2020)	N/N	
16-55/ C4591001 1251 12511218	GENRL	Pyrexia/ fever of 101.4	2	14OCT2020	1/2	2	Yes		NA/TC	R (15OCT2020)	N/N	
		Pyrexia/ Fever greater than 100.4 (101.8)	2	15OCT2020	2/1	2	Yes		NA/TC	R (15OCT2020)	N/N	
16-55/ C4591001 1251 12511221	GENRL	Injection site pain/ Muscle Pain at Injection Site	1	30SEP2020	2/4	1	Yes		NA	R (03OCT2020)	N/N	
16-55/ C4591001 1251 12511223	MUSC	Myalgia/ Intermittent Muscle Pain Left Deltoid	2	19OCT2020	1/38	1	Yes		NA	R (25NOV2020)	N/N	
	MUSC	Muscle discomfort/ Intermittent Muscle Discomfort Right Upper Arm	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/Y	
16-55/ C4591001 1251 12511232	GENRL	Pain/ Body Aches	2	28OCT2020	1/1	1	Yes		NA	R (28OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1251 12511233	GENRL	Fatigue/ fatigue	1	10OCT2020	4/5	1	Yes		NA	R (14OCT2020)	N/N
	RESP	Nasal congestion/ nasal congestion	1	10OCT2020	4/5	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1251 12511239	CARD	Myocardial ischaemia/ Myocardial ischemia	2	13NOV2020	12/4	4	No	O	NA/TC	R (16NOV2020)	Y/N
16-55/ C4591001 1251 12511245	GENRL	Injection site pain/ pain at injection site left arm	1	15OCT2020	1/4	1	Yes		NA/TC	R (18OCT2020)	N/N
	GENRL	Pain/ Bodyaches	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N
		Pyrexia/ Fever	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N
	NERV	Headache/ Headaches	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N
	SKIN	Hidradenitis/ Hidradenitis Suppurative	2	01DEC2020	29/C	3	No	O	NA/TC	N	N/N
16-55/ C4591001 1251 12511259	SKIN	Pruritus/ itching-left arm	2	16DEC2020	29/7	1	No	O	NA	RS (22DEC2020)	N/N
	SKIN	Urticaria/ welts-left arm#	2	17DEC2020	30/6	1	No	O	NA	R (22DEC2020)	N/N
16-55/ C4591001	NERV	Seizure/ seizure	2	15DEC2020	29/1	3	No	O	NA/TC	R (15DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1251 12511262	NERV	Dizziness/ moderate dizziness	2	18DEC2020	32/1	1	No	O	NA/TCN	R (18DEC2020)	N/N
16-55/ C4591001 1254 12541003	GENRL	Injection site pain/ Soreness at injection site#	4	21FEB2021	2/2	1	Yes		NA	R (22FEB2021)	N/N
16-55/ C4591001 1254 12541005	GENRL	Injection site pain/ Soreness at the injection site	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001 1254 12541008	MUSC	Myalgia/ generalized Muscle Aches	1	27AUG2020	2/2	2	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001 1254 12541020	GENRL	Injection site pain/ Injection Site Soreness#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1254 12541027	MUSC	Myalgia/ Muscle aches#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1254 12541030	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	29AUG2020	1/2	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C4591001 1254 12541030	GENRL	Injection site pain/ INJECTION SITE PAIN	1	29AUG2020	1/2	1	Yes		NA	R (30AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541031	GASTR	Diarrhoea/ DIARRHEA	2	19SEP2020	1/2	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	19SEP2020	1/2	1	Yes		NA	R (20SEP2020)	N/N
		Fatigue/ FATIGUE	2	19SEP2020	1/3	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Pain/ BODYACHE	2	20SEP2020	2/2	1	Yes		NA/TC	R (21SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	20SEP2020	2/2	1	Yes		NA/TC	R (21SEP2020)	N/N
	GENRL	Chills/ chills#	3	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
		Injection site pain/ soreness at injection site#	3	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
		Pain/ body aches#	3	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1254 12541032		Pain/ Body ache#	4	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Injection site pain/ Injection site soreness#	3	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Soreness at injection site#	4	25FEB2021	2/3	1	Yes		NA	R (27FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541033	NERV	Headache/ headache	1	30AUG2020	2/2	2	Yes		NA	R (31AUG2020)	N/N
	GENRL	Chills/ CHILLS	2	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
		Pyrexia/ FEVER TEMPERATURE AT 101.5F	2	20SEP2020	2/1	1	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1254 12541034	GENRL	Chills/ Chills#	4	21JAN2021	2/1	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
		Injection site pain/ Soreness at Injection#	4	21JAN2021	2/3	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1254 12541035	GENRL	Pyrexia/ FEVER OF 100.9F	1	30AUG2020	2/1	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1254 12541036	GENRL	Injection site pain/ Soreness at the Injection Site#	3	30JAN2021	1/3	2	Yes		NA	R (01FEB2021)	N/N
	GENRL	Injection site pain/ Injection site soreness#	4	20FEB2021	1/3	1	Yes		NA	R (22FEB2021)	N/N
	MUSC	Myalgia/ Muscle aches#	4	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541038	GENRL	Fatigue/ Fatigue#	4	21FEB2021	2/2	1	Yes		NA	R (22FEB2021)	N/N
	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	30AUG2020	2/2	1	Yes		NA	R (31AUG2020)	N/N
	GENRL	Chills/ CHILLS	2	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1254 12541039		Injection site pain/ pain at injection site	2	20SEP2020	2/3	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	03SEP2020	6/3	2	No	O	NA	R (05SEP2020)	N/N
	RESP	Pulmonary pain/ lungs burning sensation	1	12SEP2020	15/1	1	No	O	NA	R (12SEP2020)	N/N
	INV	Body temperature increased/ Elevated temperature of 99.8F	2	21SEP2020	3/2	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
	INV	Body temperature increased/ Elevated temperature of 99.9F#	4	20FEB2021	2/1	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1254 12541040	MUSC	Myalgia/ generalized muscle soreness	1	30AUG2020	2/2	1	Yes		NA	R (31AUG2020)	N/N
16-55/ C4591001 1254 12541041	GENRL	Injection site pain/ Injection Site Soreness#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541042	GENRL	Injection site pain/ Injection Site Soreness#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Injection site pain/ Soreness at Injection Site#	3	20DEC2020	2/2	1	Yes		NA	R (21DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	07JAN2021	1/2	2	Yes		NA	R (08JAN2021)	N/N
	GENRL	Injection site pain/ Soreness at Injection Site#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1254 12541049	MUSC	Myalgia/ Myalgia#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	23JAN2021	1/4	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	13FEB2021	1/3	1	Yes		NA	R (15FEB2021)	N/N
	GENRL	Chills/ Chills#	4	14FEB2021	2/1	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1254 12541050	GENRL	Pyrexia/ Fever of 100.5F#	4	14FEB2021	2/1	1	Yes		NA	R (14FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ Soreness at Injection Site#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	02FEB2021	1/31	2	Yes		NA	R (04MAR2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541051	GENRL	Injection site pain/ Injection Site Soreness#	4	02FEB2021	1/3	2	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ Fever of 100.5F#	4	02FEB2021	1/3	2	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ fever of 100.5F	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1254 12541052	GENRL	Injection site pain/ Injection site soreness#	3	03FEB2021	1/4	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1254 12541053	GENRL	Fatigue/ fatigue	1	31AUG2020	1/3	2	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Left arm injection site soreness	1	31AUG2020	1/4	1	Yes		NA	R (03SEP2020)	N/N
		Injection site pain/ pain at injection site	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Fatigue/ fatigue	2	24SEP2020	2/4	2	Yes		NA	R (27SEP2020)	N/N
		Pain/ bodyache	2	24SEP2020	2/3	2	Yes		NA/TC	R (26SEP2020)	N/N
	METAB	Decreased appetite/ loss of appetite	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1254 12541054	GENRL	Fatigue/ Fatigue#	3	10FEB2021	1/4	2	Yes		NA	R (13FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541056	GENRL	Injection site pain/ Injection Site Soreness#	3	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
		Pyrexia/ Fever of 101.9F#	3	11FEB2021	2/3	2	Yes		NA/TC	R (13FEB2021)	N/N
		Injection site pain/ soreness at injection site	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
		Nausea/ nausea	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ soreness at injection site	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N
		Dizziness/ lightheadedness	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N
		Headache/ headache	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N
		Pyrexia/ fever of 102F	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
		Pyrexia/ fever of 104.9	2	22SEP2020	2/1	3	Yes		NA/TC	R (22SEP2020)	N/N
	16-55/ C4591001 1254 12541057	RESP	Cough/ Cough	1	10SEP2020	11/1	1	No	O	NA	R (10SEP2020)
16-55/ C4591001 1254 12541058	GENRL	Injection site pain/ Site Injection Soreness#	3	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Soreness at injection site#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541061	GENRL	Injection site pain/ Injection Site Soreness#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1254 12541062	MUSC	Musculoskeletal chest pain/ Rib cage pain	1	06SEP2020	6/9	2	Yes		NA	R (14SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1254 12541063	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	01SEP2020	1/3	1	Yes		NA/TC	R (03SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	22SEP2020	1/4	1	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Pain/ bodyache	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1254 12541064	GENRL	Injection site pain/ Soreness of Injection Site#	3	20DEC2020	2/1	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Injection site pain/ Soreness at Injection Site#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Chills/ Intermittent Chills#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N
		Fatigue/ Fatigue#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541066	NERV	Pain/ Body ache#	4	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N
		Headache/ Headache#	4	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N
	NERV	Somnolence/ drowsiness	1	09SEP2020	8/10	2	No	O	NA	R (18SEP2020)	N/N
	VASC	Hot flush/ worsening hot flashes	1	09SEP2020	8/C	1	No	O	NA	RG	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1254 12541067	GENRL	Injection site pain/ Injection Site Soreness#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
		Injection site pain/ injection site pain	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
	GASTR	Nausea/ nausea	1	03SEP2020	2/1	1	No	O	NA	R (03SEP2020)	N/N
16-55/ C4591001 1254 12541068	GENRL	Injection site pain/ Injection Site Soreness	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ muscle pain at injection site	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Arm Soreness#	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541071	GENRL	Chills/ Chills#	4	03MAR2021	1/2	2	Yes		NA	R (04MAR2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	03MAR2021	1/3	2	Yes		NA	R (05MAR2021)	N/N
	INV	Body temperature increased/ Elevated Body Temperature#	4	04MAR2021	2/1	2	Yes		NA	R (04MAR2021)	N/N
	NERV	Headache/ Moderate Headache#	4	04MAR2021	2/2	2	Yes		NA	R (05MAR2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	31JAN2021	2/2	1	Yes		NA	R (01FEB2021)	N/N
		Injection site pain/ Soreness at injection site#	3	31JAN2021	2/3	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	20FEB2021	1/5	1	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ Soreness at injection site#	4	20FEB2021	1/5	1	Yes		NA	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	4	20FEB2021	1/5	1	Yes		NA	R (24FEB2021)	N/N
	16-55/ C4591001 1254 12541072	GENRL	Injection site pain/ INJECTION SITE PAIN	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)
	GENRL	Injection site pain/ soreness at injection site	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1254 12541073	MUSC	Pain in extremity/ RIGHT ARM SORENESS	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541075	METAB	Type 2 diabetes mellitus/ worsening of diabetes mellitus type 2	1	11SEP2020	10/68	2	No	O	NA/TC	R (17NOV2020)	N/N
	GENRL	Injection site pain/ soreness pf injection site	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ fever of 100.4F	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
	MUSC	Back pain/ low back pain	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
	GENRL	Injection site pain/ Site Injection Soreness#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Injection site pain/ Site Injection Soreness#	4	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Pain/ body aches generalized	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Chills/ chills	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		Fatigue/ fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
NERV	Headache/ headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1254 12541079	GENRL	Injection site pain/ Soreness at Injection Site#	3	29DEC2020	1/1	1	Yes		NA	R (29DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue#	4	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	20JAN2021	1/3	2	Yes		NA/TC	R (22JAN2021)	N/N
16-55/ C4591001 1254 12541080	GENRL	Injection site pain/ injection site pain	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	25SEP2020	2/7	1	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ fever 100.4F	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	2	28SEP2020	5/2	1	Yes		NA	R (29SEP2020)	N/N
		Injection site pruritus/ ITCHY AT INJECTION SITE	2	28SEP2020	5/2	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1254 12541081	GENRL	Injection site pain/ injection site pain	1	03SEP2020	1/3	2	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1254 12541082	GENRL	Injection site pain/ Soreness at injection site#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Injection site pain/ Soreness at Injection Site#	4	09FEB2021	1/30	1	Yes		NA	R (10MAR2021)	N/N
	NERV	Headache/ Mild Headache#	4	10FEB2021	2/1	2	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1254 12541083	INV	Body temperature increased/ ELEVATED BODY TEMPERATURE 99.6F/36.6C	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N	
16-55/ C4591001 1254 12541086	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	2/4	1	Yes		NA	R (07SEP2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1254 12541087	GENRL	Injection site pain/ LEFT ARM SORENESS AT INJECTION SITE	1	03SEP2020	1/5	1	Yes		NA	R (07SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 1254 12541089	GENRL	Injection site pain/ Injection site soreness#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N	
16-55/ C4591001 1254 12541090	GASTR	Diarrhoea/ diarrhea	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N	
	GENRL	Injection site pain/ Injection Site Soreness#	3	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	20FEB2021	2/1	2	Yes		NA	R (20FEB2021)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541091	INV	Fatigue/ Fatigue#	4	20FEB2021	2/1	1	Yes		NA	R (20FEB2021)	N/N
		Body temperature increased/ Elevated body temperature of 99.9F#	4	20FEB2021	2/1	1	Yes		NA	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	3	29JAN2021	1/1	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1254 12541094	GENRL	Fatigue/ Fatigue#	4	20FEB2021	1/3	1	Yes		NA	R (22FEB2021)	N/N
	EYE	Eye irritation/ mild burning sensation in both eyes	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ Injection site tenderness	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001	NERV	Pain/ Body ache	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
		Headache/ headache	1	04SEP2020	1/3	1	Yes		NA/TC	R (06SEP2020)	N/N
	GENRL	Chills/ chills	2	27SEP2020	2/1	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001	NERV	Pain/ bodyache	2	27SEP2020	2/2	2	Yes		NA/TC	R (28SEP2020)	N/N
		Pyrexia/ Fever at 100.4F	2	27SEP2020	2/1	2	Yes		NA/TC	R (27SEP2020)	N/N
	NERV	Headache/ headache	2	27SEP2020	2/2	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ left arm injection site soreness	1	04SEP2020	1/4	1	Yes		NA	R (07SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1254 12541099	GENRL	Fatigue/ FATIGUE	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N	
	INV	Weight increased/ WEIGHT GAIN	1	10SEP2020	7/	1	No	O	NA/TC	R	N/N	
	GENRL	Injection site pain/ soreness at injection site	2	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/N	
	GENRL	Chills/ chills	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N	
		Fatigue/ fatigue	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N	
		Pain/ bodyache	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N	
16-55/ C4591001 1254 12541100	GENRL	Injection site pain/ Injection Site Soreness#	2	27JAN2021	125/2	1	Yes		NA	R (28JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	2	28JAN2021	126/2	1	Yes		NA	R (29JAN2021)	N/N	
16-55/ C4591001 1254 12541101	GENRL	Fatigue/ Fatigue#	3	28JAN2021	2/3	2	Yes		NA	R (30JAN2021)	N/N	
		Injection site pain/ Injection site soreness#	3	28JAN2021	2/4	2	Yes		NA/TC	R (31JAN2021)	N/N	
	GENRL	Injection site pain/ Soreness at injection site#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N	
16-55/ C4591001	PSYCH	Insomnia/ Insomnia	1	14SEP2020	10/2	2	No	O	NA	R (15SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1254 12541102	GENRL	Chills/ Chills#	4	09JAN2021	1/1	1	Yes		NA	R (09JAN2021)	N/N	
16-55/ C4591001 1254 12541104	GENRL	Injection site pain/ Soreness at Injection Site#	4	09JAN2021	1/3	2	Yes		NA	R (11JAN2021)	N/N	
		Pyrexia/ Fever of 101F#	4	09JAN2021	1/2	1	Yes		NA	R (10JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	10JAN2021	2/3	2	Yes		NA	R (12JAN2021)	N/N	
		Pain/ Body Ache#	4	10JAN2021	2/2	2	Yes		NA	R (11JAN2021)	N/N	
16-55/ C4591001 1254 12541105	GENRL	Chills/ CHILLS	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N	
		Pain/ bodyache	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N	
16-55/ C4591001 1254 12541107	GENRL	Injection site pain/ Soreness at injection site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N	
	PSYCH	Depression/ worsening of depression	2	OCT2020	3/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1254 12541109	GENRL	Injection site pain/ Soreness at injection site#	3	31JAN2021	2/2	1	Yes		NA	R (01FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541110	BLOOD	Lymphadenopathy/ Bilateral swollen lymph nodes#	4	21FEB2021	2/2	2	Yes		NA/TC	R (22FEB2021)	N/N
	GENRL	Injection site bruising/ Injection Site Bruising#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1254 12541111	GENRL	Fatigue/ Fatigue#	4	20FEB2021	2/1	1	Yes		NA	R (20FEB2021)	N/N
	INV	Body temperature increased/ Elevated body temperature of 99.7F#	4	20FEB2021	2/1	2	Yes		NA/TC	R (20FEB2021)	N/N
	GENRL	Chills/ chills	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1254 12541114	INJ&P	Pain/ generalized body ache	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
	INJ&P	Limb injury/ Finger Puncture Injury	1	17SEP2020	10/1	1	No	O	NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1254 12541114	GENRL	Injection site pain/ Soreness of Injection Site#	3	21DEC2020	1/4	1	Yes		NA	R (24DEC2020)	N/N
	GENRL	Injection site pain/ Soreness at Injection Site#	4	13JAN2021	1/1	2	Yes		NA/TC	R (13JAN2021)	N/N
	NERV	Headache/ Headache#	4	13JAN2021	1/2	2	Yes		NA/TC	R (14JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	14JAN2021	2/2	2	Yes		NA	R (15JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	14JAN2021	2/2	2	Yes		NA	R (15JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541115	GENRL	Injection site pain/ pain at injection site	2	30SEP2020	1/17	2	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1254 12541117	RESP	Productive cough/ INCREASED PHELM	1	14SEP2020	5/45	1	Yes		NA	R (28OCT2020)	N/N
	INFEC	Chlamydial infection/ Chlamydia infection	2	21DEC2020	83/8	2	No	O	NA/TC	R (28DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	3	25JAN2021	3/6	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/4	2	Yes		NA	R (21FEB2021)	N/N
		Pain/ Body ache#	4	18FEB2021	2/4	2	Yes		NA	R (21FEB2021)	N/N
	INFEC	Chlamydial infection/ Chlamydia Infection#	4	13MAR2021	25/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1254 12541119	GASTR	Abdominal distension/ abdominal bloating	1	10SEP2020	1/4	1	Yes		NA	R (13SEP2020)	N/N
		Diarrhoea/ diarrhea	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	GASTR	Nausea/ nausea	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ headache	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541120	GENRL	Injection site pain/ LEFT ARM INJECTION SITE SORENESS	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1254 12541121	GENRL	Injection site pain/ INJECTION SITE SORENESS	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/Y
	GENRL	Fatigue/ MILD FATIGUE	1	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1254 12541123	GENRL	Fatigue/ Fatigue#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ Soreness at the Injection Site#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
		Pain/ Body ache#	3	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	16FEB2021	1/3	2	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
		Pain/ Generalized Body Ache#	4	17FEB2021	2/1	2	Yes		NA/TC	R (17FEB2021)	N/N
	INV	Body temperature increased/ Elevated Body Temperature of 100.0F#	4	17FEB2021	2/2	2	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1254 12541124	GENRL	Injection site pain/ Injection site pain	1	19SEP2020	1/2	2	Yes		NA/TC	R (20SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue	1	20SEP2020	2/1	2	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ muscle bodyaches	1	20SEP2020	2/1	2	Yes		NA/TC	R (20SEP2020)	N/N
	NERV	Headache/ Headache	1	20SEP2020	2/1	2	Yes		NA/TC	R (20SEP2020)	N/N
	MUSC	Pain in extremity/ pain right index finger	1	27SEP2020	9/2	1	No	O	NA	R (28SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	10OCT2020	1/3	2	Yes		NA/TC	R (12OCT2020)	N/N
	GENRL	Chills/ chills	2	11OCT2020	2/1	1	Yes		NA	R (11OCT2020)	N/N
		Pain/ body aches	2	11OCT2020	2/1	2	Yes		NA/TC	R (11OCT2020)	N/N
	INV	Heart rate increased/ elevated heart rate	2	11OCT2020	2/8	2	Yes		NA	R (18OCT2020)	N/N
	NERV	Headache/ headache	2	11OCT2020	2/2	2	Yes		NA/TC	R (12OCT2020)	N/N
16-55/ C4591001 1254 12541126	GENRL	Injection site pain/ injection site pain	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ tenderness at injection site	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
	NERV	Somnolence/ drowsiness	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1254 12541131	GENRL	Injection site pain/ Injection Site Soreness#	3	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541133	GENRL	Injection site pain/ Injection Site Pain#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1254 12541134	GENRL	Chills/ chills	1	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
	SKIN	Hyperhidrosis/ SWEATING	1	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
	GASTR	Nausea/ NAUSEA	1	14SEP2020	4/2	1	Yes		NA	R (15SEP2020)	N/N
	SKIN	Hyperhidrosis/ sweating	2	02OCT2020	1/15	2	Yes		NA	R (16OCT2020)	N/N
	GASTR	Nausea/ nausea	2	03OCT2020	2/3	2	Yes		NA	R (05OCT2020)	N/N
	GENRL	Chills/ chills	2	04OCT2020	3/13	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Injection site pain/ Injection site soreness#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	NERV	Headache/ Headache#	4	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1254 12541135	NERV	Headache/ Headache	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GASTR	Nausea/ nausea	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Lethargy/ Lethargy	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Abdominal pain upper/ stomach pain	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
		Nausea/ nausea	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Soreness at Injection Site#	3	29JAN2021	1/6	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
		Pain/ Body ache#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Chills/ Chills#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Pain/ Body aches#	4	20FEB2021	2/3	2	Yes		NA	R (22FEB2021)	N/N
	NERV	Headache/ Headaches#	4	20FEB2021	2/2	2	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1254 12541140	GENRL	Injection site pain/ injection site pain	1	12SEP2020	1/15	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Injection site erythema/ erythema at injection site	1	13SEP2020	2/14	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	03OCT2020	1/5	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1254 12541142	EYE	Eye irritation/ left eye irritation	1	12SEP2020	1/3	1	No	O	NA	R (14SEP2020)	N/N
		Ocular hyperaemia/ left eye redness	1	12SEP2020	1/3	1	No	O	NA	R (14SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ intermittent chills	1	12SEP2020	1/14	1	Yes		NA	R (25SEP2020)	N/N
	INJ&P	Maternal exposure during pregnancy/ Maternal Exposure During Pregnancy	1	12SEP2020	1/C		No	O	P	UNK	N/N
	INV	Body temperature increased/ elevated body temperature at 100.0F	1	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Pyrexia/ fever at 102.0F	1	14SEP2020	3/1	2	Yes		NA/TC	R (14SEP2020)	N/N
	INV	Body temperature increased/ elevated body temperature at 100.0F	1	14SEP2020	3/2	2	Yes		NA/TC	R (15SEP2020)	N/N
	GASTR	Abdominal pain upper/ stomach pain	1	15SEP2020	4/1	2	No	O	NA/TC	R (15SEP2020)	N/N
	NERV	Headache/ headache intermittent	1	15SEP2020	4/11	2	Yes		NA/TC	R (25SEP2020)	N/N
	GASTR	Nausea/ Nausea	1	26SEP2020	15/C	1	No	O	NA	RG	N/N
	INV	Weight decreased/ weight loss	1	OCT2020	20/C	1	No	O	NA	N	N/N
	SKIN	Alopecia/ hair loss	1	OCT2020	20/C	1	No	O	NA	N	N/N
16-55/ C4591001 1254 12541144	GASTR	Nausea/ worsening of Nausea	1	12SEP2020	1/3	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	12SEP2020	1/6	1	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Injection Site Tenderness	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	03OCT2020	1/5	1	Yes		NA	R (07OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541145	GENRL	Injection site pain/ Soreness at injection site	2	03OCT2020	1/3	1	Yes		NA	R (05OCT2020)	N/N
		Pyrexia/ fever 100.6F	2	04OCT2020	2/3	1	Yes		NA/TC	R (06OCT2020)	N/N
		Diarrhoea/ diarrhea	2	06OCT2020	4/1	3	Yes		NA/TC	R (06OCT2020)	N/N
		Vomiting/ vomiting	2	06OCT2020	4/1	2	Yes		NA/TC	R (06OCT2020)	N/N
	RESP	Pharyngeal swelling/ Throat Swollen Internal	2	22JAN2021	112/1	2	No	O	NA/TC	R (22JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)	N/N
	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	22SEP2020	11/C		No	O	NA	UNK	N/N
	16-55/ C4591001 1254 12541147	GENRL	Injection site pain/ injection site pain	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)
16-55/ C4591001 1254 12541148	GENRL	Injection site pain/ Injection Site Soreness#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Injection site soreness#	4	21FEB2021	2/1	1	Yes		NA	R (21FEB2021)	N/N
	GENRL	Fatigue/ fatigue	1	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N
	REPRO	Premenstrual syndrome/ worsening of premenstrual syndrome symptoms	1	14SEP2020	3/4	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1254 12541150	PSYCH	Insomnia/ Worsening of Insomnia	2	15DEC2020	74/C	2	No	O	NA/TC	RG	N/N	
	GENRL	Injection site pain/ Injection Site Soreness#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N	
	INFEC	Chlamydial infection/ Chlamydia infection	2	05JAN2021	92/9	2	No	O	NA/TC	R (13JAN2021)	N/N	
			Gonorrhoea/ Gonorrhea	2	05JAN2021	92/9	2	No	O	NA/TC	R (13JAN2021)	N/N
	NERV	Headache/ headache	1	14SEP2020	1/1	1	Yes		NA	R (14SEP2020)	N/N	
	GENRL	Injection site pain/ injection site pain	1	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N	
			Pain/ body ache	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Pain/ body aches	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N	
	GENRL	Fatigue/ FATIGUE	1	16SEP2020	3/25	2	Yes		NA	R (10OCT2020)	N/N	
16-55/ C4591001 1254 12541153	PSYCH	Irritability/ IRRITABILITY	1	16SEP2020	3/42	2	No	O	NA	R (27OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541155	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/Y
	GENRL	Injection site pain/ Injection Site Soreness#	3	16JAN2021	1/2	1	Yes		NA	R (17JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1254 12541157	GENRL	Injection site pain/ Injection Site Soreness#	3	13FEB2021	1/3	1	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1254 12541158	GENRL	Injection site pain/ Injection site Soreness#	3	30DEC2020	2/2	1	Yes		NA	R (31DEC2020)	N/N
	GENRL	Chills/ Chills#	4	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1254 12541159	GENRL	Injection site pain/ soreness at the injection site	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
		Pain/ bodyache	1	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ soreness at injection site	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
	INV	Body temperature increased/ elevated body temperature of 99.9F	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1254 12541162	SKIN	Pruritus/ generalized itching	1	20SEP2020	3/53	1	No	O	NA	R (11NOV2020)	N/N
16-55/ C4591001 1254 12541163	GENRL	Fatigue/ fatigue	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Injection site pain/ injection site soreness	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1254 12541164	GENRL	Injection site pain/ Pain at the Injection Site#	3	20DEC2020	2/2	1	Yes		NA	R (21DEC2020)	N/N
	GENRL	Injection site pain/ Pain at the Injection Site#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1254 12541165	GENRL	Injection site pain/ injection site pain	1	19SEP2020	1/4	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	10OCT2020	1/4	1	Yes		NA	R (13OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	11OCT2020	2/2	1	Yes		NA	R (12OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541166	NERV	Headache/ headache	2	11OCT2020	2/1	1	Yes		NA/TC	R (11OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	19SEP2020	1/3	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	10OCT2020	1/4	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1254 12541168†	INFEC	Abscess limb/ abscess left thigh	2	28OCT2020	14/10	2	No	O	NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1254 12541169	MUSC	Back pain/ back pain	1	25SEP2020	2/5	2	Yes		NA/TC	R (29SEP2020)	N/N
	NERV	Headache/ headache	1	25SEP2020	2/5	2	Yes		NA/TC	R (29SEP2020)	N/N
	SKIN	Alopecia/ Hair Loss	1	01OCT2020	8/125	1	No	O	NA	R (02FEB2021)	N/N
	GENRL	Chills/ chills	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
		Fatigue/ fatigue	2	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
		Injection site pain/ soreness at injection site	2	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
		Injection site swelling/ swelling at injection site	2	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
	RESP	Rhinorrhoea/ runny nose	2	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site swelling/ Left Arm Swelling at Injection Site.#	3	28JAN2021	2/4	2	Yes		NA/TC	R (31JAN2021)	N/N
		Pain/ Body aches#	3	28JAN2021	2/3	2	Yes		NA	R (30JAN2021)	N/N
	GENRL	Chills/ Chills#	3	29JAN2021	3/2	2	Yes		NA	R (30JAN2021)	N/N
	GASTR	Gastritis/ Gastritis#	4	20FEB2021	2/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1254 12541170	GENRL	Injection site pain/ left injection site pain	1	23SEP2020	1/4	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
		Injection site pain/ SORENESS AT INJECTION SITE	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1254 12541172	GENRL	Injection site pain/ Site Injection Soreness#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1254 12541173	GENRL	Injection site pain/ injection site soreness	1	23SEP2020	1/5	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Chills/ chills	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
		Pyrexia/ fever at 100.6F	2	17OCT2020	2/2	2	Yes		NA/TC	R (18OCT2020)	N/N
	MUSC	Myalgia/ generalized muscle ache	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541174	GENRL	Injection site pain/ Injection Site Pain#	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Pyrexia/ Fever of 101.0F#	3	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1254 12541175	GENRL	Injection site pain/ Injection Site Soreness#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1254 12541176	GENRL	Injection site pain/ INJECTION SITE SORENESS LEFT ARM	1	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	24SEP2020	2/4	1	Yes		NA/TC	R (27SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	15OCT2020	1/4	2	Yes		NA/TC	R (18OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	16OCT2020	2/2	2	Yes		NA	R (17OCT2020)	N/N
	NERV	Headache/ headache	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 1254 12541177	GENRL	Fatigue/ FATIGUE	1	23SEP2020	1/4	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Chills/ CHILLS	1	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1254 12541179		Injection site pain/ Injection Site Pain#	3	08JAN2021	2/3	1	Yes		NA	R (10JAN2021)	N/N	
	GENRL	Injection site pain/ Soreness at Injection Site#	4	30JAN2021	1/2	1	Yes		NA	R (31JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	31JAN2021	2/1	1	Yes		NA	R (31JAN2021)	N/N	
		Fatigue/ Fatigue#	4	31JAN2021	2/1	1	Yes		NA	R (31JAN2021)	N/N	
16-55/ C4591001 1254 12541180	GENRL	Injection site pain/ pain at injection site	1	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N	
		Pain/ bodyache	1	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	2	17OCT2020	2/3	2	Yes		NA	R (19OCT2020)	N/N	
	MUSC	Myalgia/ generalized muscle pain	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N	
	NERV	Headache/ headache	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N	
	GASTR	Aphthous ulcer/ canker sore	2	18OCT2020	3/13	2	Yes		NA	R (30OCT2020)	N/N	
16-55/ C4591001 1254 12541181	GENRL	Injection site pain/ Injection site soreness	1	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N	
	GENRL	Injection site pain/ Soreness at injection Site#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541182 16-55/ C4591001 1254 12541184 16-55/ C4591001 1254 12541185 16-55/ C4591001 1254 12541187 16-55/ C4591001	GENRL	Injection site pain/ Soreness at Injection Site#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
	INV	Body temperature increased/ Elevated Body Temperature of 100F#	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
	GENRL	Injection site pain/ INJECTION SITE SORENESS	1	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Injection site pain/ Injection site soreness#	3	28FEB2021	2/1	1	Yes		NA	R (28FEB2021)	N/N
	EYE	Vitreous floaters/ vision changes eye floaters right eye	1	17OCT2020	4/20	1	No	O	NA	R (05NOV2020)	N/N
	NERV	Headache/ headache	1	18OCT2020	5/17	2	No	O	NA	R (03NOV2020)	N/N
	GASTR	Abdominal pain lower/ right lower quadrant pain	1	02NOV2020	20/5	1	No	O	NA	R (06NOV2020)	N/N
	GENRL	Injection site pain/ Left Arm Sore at Injection Site#	3	22JAN2021	2/6	2	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ fatigue	1	17OCT2020	3/2	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
NERV	Headache/ intermittent headaches	2	05NOV2020	1/4	1	Yes		NA	R (08NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1254 12541188	GENRL	Fatigue/ fatigue	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C4591001 1254 12541189	GENRL	Injection site pain/ Soreness at the Injection Site#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	NERV	Headache/ Headache#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ soreness at injection site#	4	18FEB2021	2/7	2	Yes		NA/TC	R (24FEB2021)	N/N
		Pain/ bodyaches#	4	18FEB2021	2/3	2	Yes		NA/TC	R (20FEB2021)	N/N
		Pyrexia/ fever of 100.7F#	4	18FEB2021	2/2	2	Yes		NA	R (19FEB2021)	N/N
	MUSC	Arthralgia/ generalized joint pain#	4	18FEB2021	2/7	2	Yes		NA/TC	R (24FEB2021)	N/N
	NERV	Headache/ headache#	4	18FEB2021	2/2	2	Yes		NA/TC/W	R (19FEB2021)	N/N
16-55/ C4591001 1254 12541193	GENRL	Injection site pain/ soreness of injection site	2	07NOV2020	1/2	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C4591001 1254 12541194	NERV	Headache/ mild headache	1	17OCT2020	1/3	1	Yes		NA	R (19OCT2020)	N/N
	GENRL	Fatigue/ fatigue	1	18OCT2020	2/2	1	Yes		NA	R (19OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541199	PSYCH	Anxiety/ worsening of anxiety	1	18OCT2020	2/2	1	Yes		NA	R (19OCT2020)	N/N
	SKIN	Pruritus/ body itch	1	18OCT2020	2/2	1	No	O	NA/TCN	R (19OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	2	28JAN2021	84/2	1	Yes		NA	R (29JAN2021)	N/N
		Injection site pain/ Soreness at injection site#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Injection site soreness#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site	1	21OCT2020	1/18	1	Yes		NA	R (07NOV2020)	N/N
	NERV	Headache/ headache	1	21OCT2020	1/18	1	Yes		NA/TC	R (07NOV2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	1	23OCT2020	3/16	1	Yes		NA	R (07NOV2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	02DEC2020	2/2	1	Yes		NA	R (03DEC2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1254 12541201	GENRL	Injection site pain/ Soreness of injection site	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Injection site pain/ injection site soreness	1	24OCT2020	1/3	1	Yes		NA	R (26OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	METAB	Hyperlipidaemia/ worsening hyperlipidemia	1	26OCT2020	3/C	2	No	O	NA/TC	N	N/N	
	GENRL	Injection site pain/ Soreness of Injection Site	2	14NOV2020	1/2	1	Yes		NA	R (15NOV2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	15NOV2020	2/1	1	Yes		NA	R (15NOV2020)	N/N	
		Pain/ Body Aches	2	15NOV2020	2/1	1	Yes		NA/TC	R (15NOV2020)	N/N	
		Pyrexia/ Fever of 100.5 F	2	15NOV2020	2/1	1	Yes		NA	R (15NOV2020)	N/N	
16-55/ C4591001 1254 12541204	GENRL	Injection site erythema/ redness at injection site	2	14NOV2020	1/1	1	Yes		NA	R (14NOV2020)	N/N	
		Injection site pain/ pain at injection site	2	14NOV2020	1/1	1	Yes		NA	R (14NOV2020)	N/N	
	MUSC	Myalgia/ bilateral sore neck muscles	2	14NOV2020	1/2	1	No	O	NA	R (15NOV2020)	N/N	
	NERV	Headache/ headache	2	14NOV2020	1/1	1	Yes		NA	R (14NOV2020)	N/N	
	GENRL	Injection site pain/ Injection Site Soreness#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N	
		Pyrexia/ Fever 100.4F#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N	
	GENRL	Injection site pain/ Soreness at injection site#	4	24FEB2021	2/4	2	Yes		NA/TC	R (27FEB2021)	N/N	
16-55/ C4591001	GENRL	Pain/ Body Aches#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1254 12541208 16-55/ C4591001	GENRL	Injection site pain/ Injection site soreness#	3	30JAN2021	1/3	1	Yes		NA	R (01FEB2021)	N/N
1254 12541211	GENRL	Fatigue/ Fatigue#	3	31JAN2021	2/2	1	Yes		NA	R (01FEB2021)	N/N
	GASTR	Nausea/ Nausea#	4	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N
	GENRL	Chills/ Chills#	4	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N
	MUSC	Myalgia/ Muscle aches#	4	20FEB2021	1/2	2	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001	GASTR	Nausea/ nausea#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
1258 12581004	GENRL	Chills/ chills#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
		Pyrexia/ Fever#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue	2	03OCT2020	10/6	1	No	O	NA	R (08OCT2020)	N/N
1258 12581016		Malaise/ Malaise	2	03OCT2020	10/6	1	No	O	NA	R (08OCT2020)	N/N
16-55/ C4591001	INFEC	Otitis media/ right otitis media	1	30SEP2020	7/7	1	No	O	NA/TC	R (06OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1258 12581044	INFEC	Otitis media/ right otitis media	1	08OCT2020	11/5	1	No	O	NA/TC	R (12OCT2020)	N/N
16-55/ C4591001 1258 12581046	RESP	Cough/ cough	1	08OCT2020	11/3	1	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1260 12601002	GASTR	Vomiting/ vomiting	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ fatigue	1	27AUG2020	2/5	1	Yes		NA	R (31AUG2020)	N/N
		Injection site pain/ soreness at the injection site	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	NERV	Migraine without aura/ increased intensity of migraine without aura	1	27AUG2020	2/1	2	Yes		NA/TC	R (27AUG2020)	N/N
	GENRL	Fatigue/ fatigue	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ soreness at injection site	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
		Pain/ generalized body aches	2	16SEP2020	2/3	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1260 12601004	GENRL	Fatigue/ fatigue	1	26AUG2020	1/7	2	Yes		NA	R (01SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601005	MUSC	Myalgia/ muscle pain	1	31AUG2020	6/2	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	05OCT2020	19/2	1	No	O	NA	R (06OCT2020)	N/N
		Malaise/ MALAISE	2	05OCT2020	19/2	1	No	O	NA	R (06OCT2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Myalgia/ general muscle aches#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Chills/ chills	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
		Pain/ generalized body aches	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
	16-55/ C4591001 1260 12601006	GENRL	Injection site pain/ Soreness at injection site	1	27AUG2020	2/2	1	Yes		NA/TC	R (28AUG2020)
	MUSC	Arthralgia/ Left hand joint pain	1	27AUG2020	2/2	1	Yes		NA/TC	R (28AUG2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	16SEP2020	1/6	1	Yes		NA/TC	R (21SEP2020)	N/N
	MUSC	Arthralgia/ joint pain left wrist/hand	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1260 12601007	NERV	Headache/ headache	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N	
	GASTR	Constipation/ constipation	2	15OCT2020	31/8	1	No	O	NA/TC/TCN	R (22OCT2020)	N/N	
	GENRL	Injection site pain/ soreness at the injection site#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N	
	GENRL	Fatigue/ fatigue#	4	19JAN2021	1/2	1	Yes		NA/TC	R (20JAN2021)	N/N	
		Injection site pain/ soreness at the injection site#	4	19JAN2021	1/2	1	Yes		NA/TC	R (20JAN2021)	N/N	
	NERV	Headache/ headache#	4	19JAN2021	1/2	1	Yes		NA/TC	R (20JAN2021)	N/N	
16-55/ C4591001 1260 12601009	GASTR	Diarrhoea/ diarrhea	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N	
	GENRL	Injection site pain/ Soreness at Injection site	1	27AUG2020	1/4	1	Yes		NA	R (30AUG2020)	N/N	
	GENRL	Injection site swelling/ swelling at injection site	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N	
	GENRL	Injection site pain/ pain at injection site	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	
	MUSC	Myalgia/ generalized myalgias	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ soreness at injection site#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1260 12601010	GENRL	Chills/ chills#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
		Fatigue/ fatigue#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
		Injection site pain/ soreness at the injection site#	4	13FEB2021	2/5	1	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ headache#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1260 12601011	GENRL	Injection site pain/ injection site pain	1	29AUG2020	3/2	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	24DEC2020	2/3	1	Yes		NA/TC	R (26DEC2020)	N/N
	MUSC	Pain in extremity/ bilateral arm soreness#	4	14JAN2021	2/3	1	Yes		NA/TC	R (16JAN2021)	N/N
16-55/ C4591001 1260 12601012	GENRL	Injection site pain/ soreness at injection site	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ fatigue	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
	NERV	Headache/ Headache	2	07OCT2020	20/2	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	16JAN2021	2/2	2	Yes		NA/TC	R (17JAN2021)	N/N
		Pyrexia/ low grade temp 100.0#	3	16JAN2021	2/2	1	Yes		NA/TC	R (17JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601013	NERV	Headache/ headache#	3	16JAN2021	2/2	2	Yes		NA/TC	R (17JAN2021)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	4	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
	GASTR	Nausea/ severe nausea#	4	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Fatigue/ fatigue	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
		Injection site pain/ injection site pain	1	29AUG2020	2/3	2	Yes		NA	R (31AUG2020)	N/N
	NERV	Headache/ intermittent episodes of headaches	1	29AUG2020	2/2	2	Yes		NA/TC	R (30AUG2020)	N/N
	GENRL	Fatigue/ fatigue	1	03SEP2020	7/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Malaise/ Malaise	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	Pyrexia/ Low Grade Fever (100.2 max)	2	18SEP2020	2/32	1	Yes		NA	R (19OCT2020)	N/N	
	NERV	Headache/ Headache	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1260 12601014	GENRL	Injection site pain/ soreness at injection site	1	28AUG2020	1/4	1	Yes		NA/TC	R (31AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601016	NERV	Headache/ headache	1	31AUG2020	4/2	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Injection site pain/ Arm soreness at injection site	2	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Chills/ chills	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
		Injection site pain/ soreness at injection site	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N
		Pain/ body aches	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N
		Pyrexia/ fever (99.3)	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Chills/ Chills	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
		Fatigue/ Fatigue	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1260 12601017		Injection site pain/ Arm soreness at injection site	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
		Pain/ Generalized body aches	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
	GASTR	Diarrhoea/ diarrhea	1	29AUG2020	2/3	1	Yes		NA	R (31AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601018	GENRL	Injection site pain/ soreness at injection site	1	29AUG2020	2/5	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Injection site Soreness	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	NERV	Presyncope/ Vasovagal reaction to blood draw	2	16OCT2020	29/1	1	No	O	NA/TCN	R (16OCT2020)	N/N
	GENRL	Fatigue/ fatigue	1	28AUG2020	1/2	2	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	01JAN2021	2/1	1	Yes		NA/TC	R (01JAN2021)	N/N
	NERV	Headache/ headache#	3	01JAN2021	2/1	1	Yes		NA/TC	R (01JAN2021)	N/N
	BLOOD	Lymphadenopathy/ lymph node swelling in left armpit#	4	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	23JAN2021	2/1	1	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Malaise/ malaise#	4	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
	16-55/ C4591001 1260 12601022	GENRL	Injection site pain/ muscle pain at injection site	2	01OCT2020	16/3	1	No	O	NA	R (03OCT2020)
GENRL	Injection site pain/ soreness at the injection site#	3	22DEC2020	1/4	1	Yes		NA/TC	R (25DEC2020)	N/N	
GENRL	Injection site pain/ soreness at the injection site#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ soreness at the injection site#	3	18DEC2020	1/2	1	Yes		NA/TC	R (19DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1260 12601023	GENRL	Injection site pain/ soreness at the injection site#	4	08JAN2021	1/33	1	Yes		NA/TC	R (09FEB2021)	N/N
16-55/ C4591001 1260 12601024	MUSC	Myalgia/ generalized muscle aches	1	31AUG2020	1/5	1	Yes		NA/TC	R (04SEP2020)	N/N
	GENRL	Chills/ chills	1	01SEP2020	2/4	1	Yes		NA/TC	R (04SEP2020)	N/N
		Pyrexia/ fever 101.5 F	1	01SEP2020	2/4	2	Yes		NA/TC	R (04SEP2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	21DEC2020	1/2	1	Yes		NA/TC	R (22DEC2020)	N/N
	NERV	Headache/ headache#	3	21DEC2020	1/3	1	Yes		NA/TC	R (23DEC2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N
16-55/ C4591001 1260 12601029	GENRL	Fatigue/ fatigue	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
		Injection site pain/ soreness at the site of injection	1	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1260 12601034	GENRL	Injection site erythema/ redness at injection site#	3	22DEC2020	2/4	1	Yes		NA	R (25DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601036	GENRL	Injection site pain/ arm soreness to touch at injection site#	3	22DEC2020	2/4	1	Yes		NA/TC	R (25DEC2020)	N/N
		Injection site swelling/ swelling at the injection site#	3	22DEC2020	2/4	1	Yes		NA	R (25DEC2020)	N/N
		Injection site pain/ achy arm at site of injection	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		Injection site pain/ soreness at injection site	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		Pain/ generalized body aches	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1260 12601038	GENRL	Chills/ chills#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1260 12601042	GENRL	Injection site pain/ Soreness at injection site	1	01SEP2020	1/3	2	Yes		NA/TC	R (03SEP2020)	N/N
16-55/ C4591001 1260 12601044	GENRL	Injection site pain/ Soreness at injection site	2	23SEP2020	2/6	1	Yes		NA	R (28SEP2020)	N/N
	GASTR	Diarrhoea/ diarrhea	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1260 12601045	GENRL	Injection site pain/ local arm pain/soreness at the injection site#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N	
	GENRL	Chills/ chills	1	01SEP2020	1/3	1	Yes		NA/TC	R (03SEP2020)	N/N	
			Injection site pain/ soreness at injection site	1	01SEP2020	1/3	1	Yes		NA/TC	R (03SEP2020)	N/N
	MUSC	Joint range of motion decreased/ unable to rotate right arm	1	01SEP2020	1/3	2	Yes		NA/TC	R (03SEP2020)	N/N	
	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/Y	
	GENRL	Injection site pain/ soreness at injection site	1	02SEP2020	2/3	1	Yes		NA	R (04SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/5	1	Yes		NA	R (28SEP2020)	N/N	
			Injection site pain/ Soreness at injection site	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
			Pyrexia/ Fever (T-max 100.1)	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1260 12601048	GENRL	Injection site pain/ soreness at the injection site#	3	27JAN2021	1/6	1	Yes		NA	R (01FEB2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ soreness at injection site	1	02SEP2020	1/2	1	Yes		NA/TC	R (03SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1260 12601050	GENRL	Fatigue/ Fatigue	1	17SEP2020	16/8	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	2/1	2	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1260 12601055	GENRL	Injection site pain/ soreness at the injection site#	3	18DEC2020	1/2	1	Yes		NA/TC	R (19DEC2020)	N/N
	GENRL	Chills/ chills#	4	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
		Pyrexia/ febrile 101.9#	4	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	4	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
16-55/ C4591001 1260 12601058	GASTR	Diarrhoea/ intermittent episodes of diarrhea	1	06SEP2020	3/4	2	Yes		NA	R (09SEP2020)	N/N
	GENRL	Chills/ chills#	3	26DEC2020	5/3	1	Yes		NA	R (28DEC2020)	N/N
		Malaise/ malaise#	3	26DEC2020	5/3	1	Yes		NA	R (28DEC2020)	N/N
	GENRL	Chills/ chills#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
		Fatigue/ fatigue#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1260 12601061	GENRL	Fatigue/ Fatigue	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N	
	SKIN	Dermatitis contact/ Contact dermatitis	2	16OCT2020	22/3	1	No	O	NA/TC	R (18OCT2020)	N/N	
16-55/ C4591001 1260 12601063	GENRL	Injection site pain/ soreness at the injection site	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N	
	NERV	Headache/ headache	1	08SEP2020	5/4	2	Yes		NA/TC	R (11SEP2020)	N/N	
16-55/ C4591001 1260 12601065	GENRL	Injection site pain/ soreness at injection site	2	25SEP2020	1/4	2	Yes		NA/TC	R (28SEP2020)	N/N	
	GENRL	Injection site pain/ soreness at the injection site#	3	27JAN2021	1/3	1	Yes		NA/TC	R (29JAN2021)	N/N	
	REPRO	Metrorrhagia/ spotting between periods, on lupron#	3	29JAN2021	3/2	1	Yes		NA	R (30JAN2021)	N/N	
16-55/ C4591001 1260 12601067	GENRL	Injection site pain/ soreness at injection site	1	05SEP2020	2/4	1	Yes		NA	R (08SEP2020)	N/N	
16-55/ C4591001 1260 12601068	GENRL	Injection site pain/ soreness at injection site	1	04SEP2020	1/7	2	Yes		NA	R (10SEP2020)	N/N	
	GENRL	Chills/ chills	1	05SEP2020	2/6	2	Yes		NA	R (10SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1260 12601074		Pyrexia/ fever	1	05SEP2020	2/6	2	Yes		NA	R (10SEP2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain - Left arm	1	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/Y	
	MUSC	Myalgia/ Generalized Myalgia	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
	NERV	Headache/ Headache	1	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N	
	GENRL	Pain/ Body Aches (Generalized)	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N	
16-55/ C4591001 1260 12601075	GENRL	Pyrexia/ Fever (101.2 Max)	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N	
	NERV	Migraine with aura/ Migraine with aura	2	03OCT2020	4/3	1	Yes		NA	R (05OCT2020)	N/N	
	GENRL	Injection site pain/ soreness at injection site	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N	
	MUSC	Tendon disorder/ worsening of tendopathy (hands)	2	18OCT2020	17/15	2	No	O	NA/TC/TCN	R (01NOV2020)	N/N	
	INFEC	Appendicitis/ acute appendicitis	2	04DEC2020	64/5	2	No	O	NA/TC	R (08DEC2020)	Y/N	
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1260 12601076		Injection site pain/ Soreness at injection site	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
	GENRL	Injection site pain/ soreness at the injection site#	3	31DEC2020	1/2	1	Yes		NA	R (01JAN2021)	N/N	
	NERV	Headache/ headaches#	3	31DEC2020	1/2	1	Yes		NA	R (01JAN2021)	N/N	
16-55/ C4591001 1260 12601077	GENRL	Injection site pain/ soreness at injection site	1	08SEP2020	1/4	2	Yes		NA	R (11SEP2020)	N/N	
16-55/ C4591001 1260 12601082	GENRL	Injection site pain/ Soreness at injection site#	3	08JAN2021	22/34	1	Yes		NA	R (10FEB2021)	N/N	
		Pyrexia/ Fever#	3	08JAN2021	22/3	1	Yes		NA/TC	R (10JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	09JAN2021	2/33	1	Yes		NA/TC	R (10FEB2021)	N/N	
		Fatigue/ Fatigue#	4	09JAN2021	2/34	1	Yes		NA	R (11FEB2021)	N/N	
16-55/ C4591001 1260 12601084	GENRL	Chills/ chills	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	
		Pyrexia/ fever	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	
	MUSC	Myalgia/ generalized myalgia	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pain/ Body Aches	2	29SEP2020	2/1	2	Yes		NA	R (29SEP2020)	N/N
	GENRL	Fatigue/ fatigue#	3	23DEC2020	1/3	1	Yes		NA/TC	R (25DEC2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	24DEC2020	2/1	1	Yes		NA/TC	R (24DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	4	15JAN2021	1/3	1	Yes		NA/TC	R (17JAN2021)	N/N
		Injection site pain/ soreness at the injection site#	4	15JAN2021	1/3	1	Yes		NA/TC	R (17JAN2021)	N/N
	NERV	Headache/ headache#	4	15JAN2021	1/3	1	Yes		NA/TC	R (17JAN2021)	N/N
	GENRL	Pain/ body aches#	4	16JAN2021	2/2	1	Yes		NA/TC	R (17JAN2021)	N/N
16-55/ C4591001 1260 12601085	GENRL	Fatigue/ Fatigue	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ Injection site pain - Left arm	1	08SEP2020	1/3	2	Yes		NA/TC	R (10SEP2020)	N/Y
	MUSC	Myalgia/ generalized Myalgia	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	29SEP2020	1/4	1	Yes		NA	R (02OCT2020)	N/N
		Pain/ generalized body aches	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ fever	2	30SEP2020	2/2	2	Yes		NA/TC	R (01OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601091	GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1260 12601092	GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ Intermittent headaches	1	10SEP2020	2/4	2	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	03OCT2020	2/4	1	Yes		NA	R (06OCT2020)	N/N
	NERV	Headache/ mild headaches	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1260 12601094	GENRL	Fatigue/ Fatigue	1	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
		Pyrexia/ fever 100.8#	3	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
	NERV	Headache/ headache#	3	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
16-55/ C4591001 1260 12601098	GENRL	Injection site pain/ pain at injection site	2	01OCT2020	2/38	2	Yes		NA/TC	R (07NOV2020)	N/N
	NERV	Headache/ headache#	4	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601099	GASTR	Nausea/ Nausea	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Feeling hot/ feeling of warmth	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ Soreness at injection site	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ Soreness at injection site	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1260 12601100	NERV	Headache/ Headache	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1260 12601104	GENRL	Chills/ chills	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601106	GENRL	Injection site pain/ Soreness at injection site	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Somnolence/ Drowsiness	1	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1260 12601107	GENRL	Injection site pain/ soreness at the injection site#	3	22DEC2020	1/2	1	Yes		NA/TC	R (23DEC2020)	N/N
	GASTR	Nausea/ nausea#	3	12JAN2021	22/2	1	Yes		NA/TC	R (13JAN2021)	N/N
	NERV	Dizziness/ dizziness#	3	12JAN2021	22/2	1	Yes		NA/TC	R (13JAN2021)	N/N
	GENRL	Pyrexia/ fever of 101#	3	14JAN2021	24/2	1	Yes		NA/TC	R (15JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site	1	10SEP2020	1/4	2	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1260 12601108	NERV	Headache/ headache	1	10SEP2020	1/4	2	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	01OCT2020	1/3	2	Yes		NA/TC	R (03OCT2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	INFEC	Urinary tract infection/ Urinary Tract Infection#	4	09MAR2021	37/4	2	Yes		NA/TC	R (12MAR2021)	N/N
	INJ&P	Ankle fracture/ Closed trimalleolar fracture of right ankle#	4	09MAR2021	37/C	3	No	O	NA/TC	N	Y/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Fall/ fall#	4	09MAR2021	37/C	3	No	O	NA/TC	N	N/N
	NERV	Encephalopathy/ acute encephalopathy#	4	09MAR2021	37/2	2	No	O	NA/TC	R (10MAR2021)	N/N
	PSYCH	Mental status changes/ Altered Mental Status#	4	09MAR2021	37/2	2	No	O	NA/TC	R (10MAR2021)	N/N
	VASC	Hypotension/ hypotension#	4	10MAR2021	38/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1260 12601110	GASTR	Diarrhoea/ diarrhea	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
	MUSC	Myalgia/ generalized myalgias#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1260 12601111	NERV	Headache/ headache	1	01OCT2020	22/1	1	No	O	NA	R (01OCT2020)	N/N
	NERV	Headache/ headache	2	02OCT2020	2/1	1	No	O	NA/TC	R (02OCT2020)	N/N
	NERV	Presyncope/ vasovagal pre syncopal lightheadness	2	02NOV2020	33/1	1	No	O	NA/TCN	R (02NOV2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	MUSC	Myalgia/ General Muscle aches#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601112	GENRL	Chills/ chills#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		Injection site pain/ injection site pain#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		Pain/ achy body#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		Injection site pain/ Injection Site Pain - Left arm	1	15SEP2020	6/1	1	Yes		NA	R (15SEP2020)	N/N
	MUSC	Myalgia/ generalized Myalgia	1	17SEP2020	8/3	2	Yes		NA/TC	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1260 12601114		Fatigue/ Fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Pain/ Generalized body aches	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	1/2	2	Yes		NA/TC	R (11SEP2020)	N/N
	NERV	Headache/ headache	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Chills/ chills	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	Fatigue/ fatigue	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601115	NERV	Injection site pain/ soreness at injection site	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
		Pain/ generalized body aches	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
		Dizziness/ dizziness	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	1/3	1	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	12SEP2020	3/2	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ headache	1	12SEP2020	3/2	1	Yes		NA/TC	R (13SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Aches	2	01OCT2020	1/5	1	Yes		NA/TC	R (05OCT2020)	N/N
16-55/ C4591001 1260 12601117	NERV	Headache/ Headache (No aura)	2	01OCT2020	1/5	2	Yes		NA/TC	R (05OCT2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	02OCT2020	2/4	2	Yes		NA/TC	R (05OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	03OCT2020	3/3	1	Yes		NA	R (05OCT2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	29DEC2020	1/3	1	Yes		NA	R (31DEC2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	4	20JAN2021	2/2	1	Yes		NA/TC	R (21JAN2021)	N/N
		Pain/ body aches#	4	20JAN2021	2/2	1	Yes		NA/TC	R (21JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1260 12601118	GENRL	Pyrexia/ fever 100.7#	4	20JAN2021	2/2	1	Yes		NA/TC	R (21JAN2021)	N/N	
		Injection site pain/ soreness at injection site	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N	
16-55/ C4591001 1260 12601119	NERV	Dizziness/ Dizziness	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
	GENRL	Injection site pain/ soreness at injection site	1	11SEP2020	1/5	1	Yes		NA	R (15SEP2020)	N/N	
16-55/ C4591001 1260 12601120	GENRL	Fatigue/ fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	
	METAB	Injection site erythema/ redness at injection site	1	12SEP2020	2/4	1	Yes		NA	R (15SEP2020)	N/N	
		Decreased appetite/ lack of appetite	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	2	04OCT2020	3/1	1	Yes		NA	R (04OCT2020)	N/N	
	GENRL	Injection site pain/ soreness at injection site	2	04OCT2020	3/3	1	Yes		NA	R (06OCT2020)	N/N	
		Fatigue/ Fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	
MUSC	Injection site pain/ Soreness at injection site	1	12SEP2020	2/4	1	Yes		NA	R (15SEP2020)	N/N		
	MUSC	Myalgia/ Generalized muscle aches	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1260 12601123	NERV	Headache/ Headache	1	12SEP2020	2/2	2	Yes		NA/TC	R (13SEP2020)	N/N	
	GASTR	Diarrhoea/ Diarrhea	1	18SEP2020	8/2	1	Yes		NA	R (19SEP2020)	N/N	
	GENRL	Injection site pain/ pain at injection site	2	01OCT2020	2/6	2	Yes		NA/TC	R (06OCT2020)	N/N	
	GENRL	Pain/ generalized body aches	2	01OCT2020	2/1	2	Yes		NA/TC	R (01OCT2020)	N/N	
	NERV	Headache/ headache (no aura)	1	02OCT2020	18/2	1	No	O	NA	R (03OCT2020)	N/N	
	GENRL	Injection site pain/ soreness at the injection site#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N	
	METAB	Hyperglycaemia/ hyperglycemia (blood sugars 30 points higher than normal)#	3	21JAN2021	1/6	1	Yes		NA	R (26JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	12FEB2021	2/3	1	Yes		NA	R (14FEB2021)	N/N	
	GENRL	Injection site pain/ soreness at the injection site#	4	12FEB2021	2/3	1	Yes		NA	R (14FEB2021)	N/N	
	GENRL	Chills/ Chills	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N	
16-55/ C4591001 1260 12601126		Fatigue/ Fatigue	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N	
		Pain/ Aches all over	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601127	MUSC	Pain in extremity/ Left Arm Pain	1	17SEP2020	1/10	1	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ Headache	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Fatigue/ fatigue reactogenicity from the vaccine because it was within 24 hours of vaccination	2	16NOV2020	1/3	1	Yes		NA/TC	R (18NOV2020)	N/N
		Injection site pain/ soreness at injection site	2	16NOV2020	1/8	1	Yes		NA/TC	R (23NOV2020)	N/N
		Pain/ body aches - reactogenicity from the vaccine, not a covid illness happened within 24 hrs	2	16NOV2020	1/3	1	Yes		NA/TC	R (18NOV2020)	N/N
	NERV	Headache/ headache was part of the reactogenicity of the medication because it happened in 24 hrs	2	16NOV2020	1/3	1	Yes		NA/TC	R (18NOV2020)	N/N
	GENRL	Feeling hot/ feeling of warmth all over body	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ soreness at injection site	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	NERV	Lethargy/ lethargy	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	06OCT2020	1/5	1	Yes		NA	R (10OCT2020)	N/N
GENRL	Fatigue/ fatigue	2	07OCT2020	2/6	1	Yes		NA	R (12OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601128	NERV	Pyrexia/ fever	2	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
		Headache/ headache	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
		Taste disorder/ change in taste	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Pain/ achiness - generalized	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Fatigue/ fatigue#	3	21DEC2020	1/4	1	Yes		NA	R (24DEC2020)	N/N
	BLOOD	Injection site erythema/ redness at injection site#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
		Injection site pain/ pain at the injection site#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
		Malaise/ malaise#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
		Lymphadenopathy/ bilateral enlarged lymph nodes in neck#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Pain/ body aches generalized#	4	12JAN2021	1/3	1	Yes		NA/TC/TCN	R (14JAN2021)	N/N
NERV	Headache/ headache#	4	12JAN2021	1/3	1	Yes		NA/TC	R (14JAN2021)	N/N	
16-55/ C4591001 1260 12601129	GENRL	Injection site pain/ soreness at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001	CARD	Palpitations/ Intermittent Palpitations	1	24SEP2020	7/9	1	No	O	NA	R (02OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1260 12601130	SKIN	Rash/ small rash on bilateral wrists and bilateral top of the feet	2	23OCT2020	15/12	1	No	O	NA/TC	R (03NOV2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N
		Pain/ generalized body aches#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N
		Pyrexia/ fever 102 degrees#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N
16-55/ C4591001 1260 12601132	GENRL	Injection site pain/ Arm soreness at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	GASTR	Nausea/ Nausea	1	20SEP2020	3/1	1	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ Headache	1	20SEP2020	3/1	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Injection site swelling/ swelling at injection site	2	28OCT2020	20/7	1	No	O	NA	R (03NOV2020)	N/N
	GENRL	Injection site erythema/ redness at injection site#	3	21DEC2020	1/6	1	Yes		NA	R (26DEC2020)	N/N
		Injection site pain/ soreness at injection site#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1261 12611001	GENRL	Injection site swelling/ swelling at injection site#	3	21DEC2020	1/8	1	Yes		NA	R (28DEC2020)	N/N	
		Injection site pain/ Injection site pain	2	16SEP2020	1/8	1	Yes		NA/TC	R (23SEP2020)	N/N	
	NERV	Headache/ Headache	2	17SEP2020	2/7	1	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 1261 12611002	GENRL	Chills/ Chills#	3	15JAN2021	1/2	1	Yes		NA/TC	R (16JAN2021)	N/N	
	MUSC	Injection site pain/ Injection Site pain#	3	15JAN2021	1/2	1	Yes		NA/TC	R (16JAN2021)	N/N	
		Pyrexia/ Fever#	3	15JAN2021	1/2	1	Yes		NA/TC	R (16JAN2021)	N/N	
		Myalgia/ Diffuse myalgia#	3	15JAN2021	1/2	1	Yes		NA/TC	R (16JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N	
	MUSC	Injection site pain/ Injection site arm pain#	4	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N	
		Pyrexia/ Fever#	4	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N	
Myalgia/ Diffuse myalgia#		4	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N		
16-55/ C4591001 1261 12611005	SKIN	Urticaria/ Urticarial abdominal rash	1	29AUG2020	3/1	1	Yes		NA	R (29AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1261 12611006	GENRL	Chills/ CHILLS - ADVERSE REACTION TO VACCINATION 1	1	28AUG2020	2/3	1	Yes		NA/TC	R (30AUG2020)	N/N	
	MUSC	Myalgia/ DIFFUSE MYALGIA - ADVERSE REACTION TO VACCINATION 1	1	28AUG2020	2/3	1	Yes		NA/TC	R (30AUG2020)	N/N	
	NERV	Headache/ HEADACHE - ADVERSE REACTION TO VACCINATION 1	1	28AUG2020	2/3	1	Yes		NA/TC	R (30AUG2020)	N/N	
	INFEC		Abscess/ Lip Abscess	2	23SEP2020	7/9	3	No	O	NA/TC/TCN	R (01OCT2020)	Y/N
			Cellulitis/ Lip cellulitis	2	23SEP2020	7/9	3	No	O	NA/TC	R (01OCT2020)	Y/N
IMMUN		Drug hypersensitivity/ Hypersensitivity to antibiotics	2	26SEP2020	10/2	3	No	CD	NA/TC	R (27SEP2020)	Y/N	
16-55/ C4591001 1261 12611007	GENRL	Chills/ Chills#	3	30DEC2020	1/2	1	Yes		NA/TC	R (31DEC2020)	N/N	
		Fatigue/ Fatigue#	3	30DEC2020	1/2	1	Yes		NA/TC	R (31DEC2020)	N/N	
		Injection site pain/ Injection site pain#	3	30DEC2020	1/2	1	Yes		NA/TC	R (31DEC2020)	N/N	
16-55/ C4591001 1261 12611009	GENRL	Injection site bruising/ Local bruising at injection site	1	29AUG2020	2/5	2	Yes		NA/TC/TCN	R (02SEP2020)	N/N	
		Injection site pain/ Local myalgia/tenderness at injection site	1	29AUG2020	2/5	2	Yes		NA/TC/TCN	R (02SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1261 12611010	GENRL	Chills/ Chills#	4	28JAN2021	1/2	1	Yes		NA/TC	R (29JAN2021)	N/N	
	MUSC	Arthralgia/ Diffuse Arthralgia#	4	28JAN2021	1/2	1	Yes		NA/TC	R (29JAN2021)	N/N	
	NERV	Headache/ Headache#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N	
	MUSC	Arthralgia/ Arthralgia- generalized (not injection site arthralgia)	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue#	4	28JAN2021	2/3	1	Yes		NA/TC	R (30JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site arm pain#	4	28JAN2021	2/4	1	Yes		NA/TC	R (31JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	29JAN2021	3/2	1	Yes		NA/TC	R (30JAN2021)	N/N	
	MUSC	Myalgia/ Diffuse myalgia#	4	29JAN2021	3/2	1	Yes		NA/TC	R (30JAN2021)	N/N	
	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N	
16-55/ C4591001 1261 12611013		Malaise/ Malaise	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N	
	MUSC	Myalgia/ Diffuse Myalgia	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1261 12611016	GENRL	Fatigue/ Fatigue#	4	12JAN2021	2/2	1	Yes		NA/TC	R (13JAN2021)	N/N	
		Injection site pain/ Injection site pain#	4	12JAN2021	2/4	1	Yes		NA/TC	R (15JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	27JAN2021	2/3	1	Yes		NA/TC	R (29JAN2021)	N/N	
		Injection site pain/ Injection site pain#	4	27JAN2021	2/3	1	Yes		NA/TC	R (29JAN2021)	N/N	
		Pyrexia/ Fever#	4	27JAN2021	2/3	1	Yes		NA/TC	R (29JAN2021)	N/N	
	MUSC	Myalgia/ Diffuse myalgia#	4	27JAN2021	2/3	1	Yes		NA/TC	R (29JAN2021)	N/N	
	NERV	Headache/ Headache#	4	27JAN2021	2/3	1	Yes		NA/TC	R (29JAN2021)	N/N	
	16-55/ C4591001 1261 12611017	GENRL	Injection site pain/ Localized myalgia at injection site	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N	
16-55/ C4591001 1261 12611020	MUSC	Arthralgia/ Left shoulder pain	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N	
	MUSC	Arthralgia/ Left shoulder pain	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N	
	GENRL	Chills/ Chills	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1261 12611022	INFEC	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Conjunctivitis/ Conjunctivitis	2	21SEP2020	1/8	2	No	O	NA	R (28SEP2020)	N/N
16-55/ C4591001 1261 12611023	GENRL	Injection site pain/ Injection site pain#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
		Fatigue/ Fatigue#	4	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
		Tongue disorder/ Tongue lesion#	4	27JAN2021	9/C	1	No	O	NA	N	N/N
16-55/ C4591001 1261 12611024	GENRL	Chills/ Chills#	4	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
		Pyrexia/ Fever#	4	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
		Myalgia/ Diffuse Myalgia#	4	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1261 12611025	GENRL	Adverse drug reaction/ Systemic injection reaction	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1261 12611027	MUSC	Fatigue/ Fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Myalgia/ Diffuse Myalgia	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001 1261 12611029	GENRL	Fatigue/ Fatigue#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Pyrexia/ Fever	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1261 12611030	NERV	Headache/ Headache	2	25SEP2020	2/2	2	Yes		NA/TC	R (26SEP2020)	N/N
	NERV	Syncope/ Vasovagal syncope	1	03SEP2020	2/1	2	Yes		NA	R (03SEP2020)	N/N
16-55/ C4591001 1261 12611031	GENRL	Fatigue/ Fatigue	2	28SEP2020	6/2	1	Yes		NA	R (29SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	2/5	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	4	28JAN2021	4/2	1	Yes		NA/TC	R (29JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1261 12611032		Pyrexia/ Fever#	4	28JAN2021	4/2	1	Yes		NA/TC	R (29JAN2021)	N/N
16-55/ C4591001 1261 12611033	GENRL	Pyrexia/ Fever#	4	19JAN2021	1/2	1	Yes		NA/TC	R (20JAN2021)	N/N
16-55/ C4591001 1261 12611034	INFEC	Urinary tract infection/ Urinary Tract Infection	2	21NOV2020	59/10	2	No	O	NA/TC	R (30NOV2020)	N/N
16-55/ C4591001 1261 12611036	GENRL	Injection site pain/ Injection site arm pain#	2	22DEC2020	90/4	1	Yes		NA	R (25DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	14JAN2021	1/2	1	Yes		NA/TC	R (15JAN2021)	N/N
		Injection site pain/ Injection site arm pain#	4	14JAN2021	1/2	1	Yes		NA/TC	R (15JAN2021)	N/N
		Pyrexia/ Fever#	4	14JAN2021	1/2	1	Yes		NA/TC	R (15JAN2021)	N/N
	MUSC	Myalgia/ Diffuse myalgia#	4	14JAN2021	1/2	1	Yes		NA/TC	R (15JAN2021)	N/N
16-55/ C4591001 1261 12611038	GENRL	Adverse drug reaction/ Systemic injection reaction	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		Chills/ Chills	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1261 12611039	MUSC	Pyrexia/ Fever	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		Myalgia/ Diffuse Myalgia	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		Headache/ Headache	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1261 12611042	GENRL	Injection site erythema/ Injection site redness	2	27SEP2020	4/3	1	Yes		NA	R (29SEP2020)	N/N
	GENRL	Chills/ Chills	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	INJ&P	Vaccination complication/ Vaccine Reaction	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1261 12611043	MUSC	Myalgia/ Diffuse Myalgia	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ Headache	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ Headache	2	27SEP2020	3/2	1	Yes		NA/TC	R (28SEP2020)	N/N
	GENRL	Injection site pain/ Injection site arm pain#	3	18DEC2020	2/2	1	Yes		NA/TC	R (19DEC2020)	N/N
16-55/ C4591001 1261 12611043	GENRL	Injection site erythema/ Injection site redness#	4	07JAN2021	1/8	1	Yes		NA/TC	R (14JAN2021)	N/N
	GENRL	Injection site pain/ Injection site arm pain#	4	07JAN2021	1/8	1	Yes		NA/TC	R (14JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1261 12611046	GENRL	Fatigue/ Fatigue#	3	23DEC2020	1/5	1	Yes		NA	R (27DEC2020)	N/N
		Injection site pain/ Injection site arm pain#	3	23DEC2020	1/5	1	Yes		NA	R (27DEC2020)	N/N
	MUSC	Myalgia/ Diffuse Myalgia#	3	23DEC2020	1/5	1	Yes		NA	R (27DEC2020)	N/N
16-55/ C4591001 1261 12611047	GENRL	Malaise/ Malaise	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
		Pyrexia/ Fever	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	MUSC	Myalgia/ Diffuse Myalgia	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Chills/ Chills	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
		Fatigue/ Fatigue	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
	INJ&P	Vaccination complication/ Systemic vaccine reaction	2	26SEP2020	2/3	2	Yes		NA	R (28SEP2020)	N/N
	MUSC	Myalgia/ Diffuse Myalgia	2	26SEP2020	2/3	2	Yes		NA	R (28SEP2020)	N/N
16-55/ C4591001 1261 12611050	GENRL	Injection site pain/ Injection site arm pain#	3	22DEC2020	1/2	1	Yes		NA/TC	R (23DEC2020)	N/N
	GENRL	Chills/ Chills#	4	12JAN2021	1/3	1	Yes		NA/TC	R (14JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1261 12611051	NERV	Fatigue/ Fatigue#	4	12JAN2021	1/3	1	Yes		NA/TC	R (14JAN2021)	N/N
		Injection site pain/ Injection site arm pain#	4	12JAN2021	1/3	1	Yes		NA/TC	R (14JAN2021)	N/N
		Pyrexia/ Fever#	4	12JAN2021	1/3	1	Yes		NA/TC	R (14JAN2021)	N/N
		Headache/ Headache#	4	12JAN2021	1/3	1	Yes		NA/TC	R (14JAN2021)	N/N
	GENRL	Injection site bruising/ Injection site bruising	2	30SEP2020	2/10	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Injection site erythema/ Injection site redness (7cm in diameter using caliper)	2	30SEP2020	2/10	2	Yes		NA	R (09OCT2020)	N/N
		Injection site swelling/ Injection site swelling (7 cm diameter using caliper)	2	30SEP2020	2/10	2	Yes		NA	R (09OCT2020)	N/N
	GENRL	Chills/ Chills#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
	MUSC	Fatigue/ Fatigue#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
		Injection site pain/ Injection site arm pain#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
Myalgia/ Diffused myalgia#		4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N	
NERV	Headache/ Headache#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1261 12611053	RESP	Asthma/ Increased asthma symptoms#	4	14JAN2021	2/2	1	No	O	NA/TC	R (15JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Chills/ Chills#	4	06FEB2021	2/1	1	Yes		NA/TC	R (06FEB2021)	N/N
		Pyrexia/ Fever#	4	06FEB2021	2/1	1	Yes		NA/TC	R (06FEB2021)	N/N
	MUSC	Myalgia/ Diffuse myalgias#	4	06FEB2021	2/1	1	Yes		NA/TC	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	4	06FEB2021	2/1	1	Yes		NA/TC	R (06FEB2021)	N/N
	GENRL	Pyrexia/ Fever	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1261 12611054	INJ&P	Muscle strain/ Left lower back strain secondary to exercise	1	13SEP2020	6/19	2	No	O	NA/TC	R (01OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
		Injection site pain/ Pain at injection site	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
		Pyrexia/ Fever	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Injection site erythema/ Injection site redness#	4	13JAN2021	1/7	1	Yes		NA/TC	R (19JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1261 12611057	MUSC	Injection site pain/ Injection site pain#	4	13JAN2021	1/7	1	Yes		NA/TC	R (19JAN2021)	N/N	
		Pyrexia/ Fever#	4	13JAN2021	1/3	1	Yes		NA/TC	R (15JAN2021)	N/N	
		Myalgia/ Diffuse myalgia#	4	13JAN2021	1/3	2	Yes		NA/TC	R (15JAN2021)	N/N	
		Chills/ Chills#	4	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N	
	MUSC	Fatigue/ Fatigue#	4	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N	
		Arthralgia/ Generalized Arthralgia#	4	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
	GENRL	Injection site erythema/ Erythema at Injection site	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/N	
GENRL	Injection site pain/ Injection site pain	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/N		
	Injection site warmth/ Warmth over injection site	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/N		
	Fatigue/ Fatigue	2	01OCT2020	2/5	1	Yes		NA	R (05OCT2020)	N/N		
GASTR	Diarrhoea/ Diarrhea	1	14SEP2020	6/1	1	No	O	NA	R (14SEP2020)	N/N		

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1261 12611060	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/2	1	Yes	NA/TC		R (02OCT2020)	N/N
		Injection site pain/ Injection site pain	2	01OCT2020	2/2	1	Yes	NA/TC		R (02OCT2020)	N/N
16-55/ C4591001 1261 12611062	GENRL	Chills/ Chills#	4	11JAN2021	1/3	1	Yes	NA/TC		R (13JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	12JAN2021	2/2	1	Yes	NA/TC		R (13JAN2021)	N/N
	MUSC	Myalgia/ Diffuse myalgia#	4	12JAN2021	2/2	1	Yes	NA/TC		R (13JAN2021)	N/N
	NERV	Headache/ Headache#	4	12JAN2021	2/2	1	Yes	NA/TC		R (13JAN2021)	N/N
16-55/ C4591001 1261 12611063	GENRL	Adverse drug reaction/ Systemic injection reaction	2	01OCT2020	1/2	1	Yes	NA		R (02OCT2020)	N/N
		Chills/ Chills	2	01OCT2020	1/2	1	Yes	NA		R (02OCT2020)	N/N
	MUSC	Myalgia/ DIFFUSE MYALGIA - ADVERSE REACTION TO VACCINATION 2	2	01OCT2020	1/2	1	Yes	NA		R (02OCT2020)	N/N
	NERV	Headache/ HEADACHE - ADVERSE REACTION TO VACCINATION 2	2	01OCT2020	1/2	1	Yes	NA		R (02OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	19FEB2021	1/6	2	Yes	NA		R (24FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1261 12611064		Injection site pain/ Injection site pain#	4	19FEB2021	1/6	1	Yes		NA	R (24FEB2021)	N/N	
	BLOOD	Lymph node pain/ Tender bilateral, neck lymph nodes#	4	20FEB2021	2/5	1	Yes		NA	R (24FEB2021)	N/N	
	GENRL	Pyrexia/ Fever#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N	
	MUSC	Arthralgia/ Generalized Arthralgia#	4	20FEB2021	2/5	2	Yes		NA	R (24FEB2021)	N/N	
		Myalgia/ Myalgia#	4	20FEB2021	2/5	2	Yes		NA	R (24FEB2021)	N/N	
	NERV	Headache/ Headache#	4	20FEB2021	2/5	2	Yes		NA	R (24FEB2021)	N/N	
16-55/ C4591001 1261 12611065	GENRL	Injection site pain/ Injection site arm soreness	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N	
	MUSC	Myalgia/ Diffuse myalgia	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N	
16-55/ C4591001 1261 12611067	GENRL	Chills/ Chills#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N	
		Injection site pain/ Injection site arm pain#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N	
		Pyrexia/ Fever#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	4	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
		Fatigue/ Fatigue#	4	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1261 12611070	GASTR	Aphthous ulcer/ Worsening frequency of canker sores	1	16SEP2020	7/25	1	No	O	NA	R (10OCT2020)	N/N
	SKIN	Dermatitis/ Facial dermatitis	2	25OCT2020	25/7	1	No	O	NA	R (31OCT2020)	N/N
16-55/ C4591001 1261 12611071	GENRL	Malaise/ Malaise	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	MUSC	Myalgia/ Diffuse myalgias	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1261 12611074	GENRL	Chills/ CHILLS - ADVERSE REACTION TO VACCINATION 1	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
		Pyrexia/ FEVER SECONDARY TO VACCINATION 1	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	INJ&P	Vaccination complication/ Systemic Vaccine Reaction	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	MUSC	Myalgia/ DIFFUSE MYALGIA - ADVERSE REACTION TO VACCINATION 1	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ HEADACHE - ADVERSE REACTION TO VACCINATION 1	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1261 12611077	INJ&P	Corneal abrasion/ Corneal Abrasion	1	18SEP2020	8/27	2	No	O	NA/TC	R (14OCT2020)	N/N	
	GENRL	Chills/ CHILLS - ADVERSE REACTION TO VACCINATION 2	2	02OCT2020	1/2	3	Yes		NA/TC	R (03OCT2020)	N/N	
		Pyrexia/ FEVER SECONDARY TO VACCINATION 2	2	02OCT2020	1/2	3	Yes		NA/TC	R (03OCT2020)	N/N	
	MUSC	Arthralgia/ DIFFUSE GENERALIZED ARTHRALGIA AS REACTION RELATED TO 2ND VACCINATION	2	02OCT2020	1/2	3	Yes		NA/TC	R (03OCT2020)	N/N	
		Myalgia/ MYALGIA - ADVERSE REACTION TO VACCINATION 2	2	02OCT2020	1/2	3	Yes		NA/TC	R (03OCT2020)	N/N	
	SKIN	Urticaria/ Hives around neck	1	30SEP2020	20/2	1	No	O	NA/TC	R (01OCT2020)	N/N	
	INJ&P	Vaccination complication/ Systemic vaccine reaction	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N	
	MUSC	Arthralgia/ Arthralgias secondary to vaccine reaction - diffuse generalized	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N	
		Myalgia/ Diffuse Myalgia secondary to vaccine reaction	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N	
	NERV	Headache/ Headache secondary to vaccine	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N	
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	05JAN2021	2/2	1	Yes		NA/TC	R (06JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1261 12611078		Injection site bruising/ Injection site bruising#	4	05JAN2021	2/4	1	Yes		NA	R (08JAN2021)	N/N	
		Injection site pain/ Injection site arm pain#	4	05JAN2021	2/4	1	Yes		NA/TC	R (08JAN2021)	N/N	
		Pyrexia/ Fever#	4	05JAN2021	2/2	1	Yes		NA/TC	R (06JAN2021)	N/N	
	MUSC	Myalgia/ Diffuse Myalgia#	4	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N	
	NERV	Headache/ Headache#	4	05JAN2021	2/2	1	Yes		NA/TC	R (06JAN2021)	N/N	
16-55/ C4591001 1264 12641013	GASTR	Dyspepsia/ Heartburn	2	30SEP2020	19/1	1	No	O	NA/TC	R (30SEP2020)	N/N	
16-55/ C4591001 1264 12641014	MUSC	Myalgia/ myalgia	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N	
	GASTR	Diarrhoea/ diarrhea	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N	
16-55/ C4591001 1264 12641017	SKIN	Pain of skin/ Scalp pain	1	07SEP2020	17/10	2	No	O	NA/TC/TCN	R (16SEP2020)	N/N	
	MUSC	Back pain/ Back pain	2	01OCT2020	20/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001	CARD	Sinus tachycardia/ Sinus tachycardia	2	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1264 12641021	GASTR	Nausea/ Nausea	2	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N	
	GENRL	Chills/ Chills	2	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N	
		Fatigue/ Fatigue	2	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N	
		Injection site pain/ Injection site pain	2	13SEP2020	2/2	2	Yes		NA/TC	R (14SEP2020)	N/N	
		Pyrexia/ Fever	2	13SEP2020	2/2	2	Yes		NA/TC	R (14SEP2020)	N/N	
	NERV	Disturbance in attention/ Concentration impairment	2	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	14SEP2020	3/2	1	Yes		NA	R (15SEP2020)	N/N	
	RESP	Rhinorrhoea/ Rhinorrhoea	2	15SEP2020	4/1	1	Yes		NA	R (15SEP2020)	N/N	
16-55/ C4591001 1264 12641025	GENRL	Chills/ Chills	2	12SEP2020	1/2	2	Yes		NA/TC	R (13SEP2020)	N/N	
		Fatigue/ Fatigue	2	12SEP2020	1/2	2	No	O	NA/TC	R (13SEP2020)	N/N	
	REPRO	Menorrhagia/ Heavy menstruation	2	10OCT2020	29/7	2	Yes		NA	R (16OCT2020)	N/N	
		Menstruation irregular/ Irregular menstruation	2	10OCT2020	29/7	2	Yes		NA	R (16OCT2020)	N/N	
16-55/ C4591001	GENRL	Chills/ Chills	2	13SEP2020	1/2	1	Yes		NA	R (14SEP2020)	N/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1264 12641028	MUSC	Arthralgia/ Arthralgia	2	13SEP2020	1/2	1	Yes		NA	R (14SEP2020)	N/N	
16-55/ C4591001 1264 12641032	METAB	Decreased appetite/ loss of appetite	1	24AUG2020	2/3	1	Yes		NA	R (26AUG2020)	N/N	
16-55/ C4591001 1264 12641034	NERV	Presyncope/ presyncope	1	27AUG2020	5/1	1	Yes		NA	R (27AUG2020)	N/N	
16-55/ C4591001 1264 12641034	REPRO	Scrotal pain/ Scrotal pain	1	25AUG2020	2/2	2	Yes		NA	R (26AUG2020)	N/N	
16-55/ C4591001 1264 12641037	INFEC	Tinea infection/ ring worm	1	31AUG2020	8/34	1	No	O	NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001 1264 12641049	EAR	Vertigo/ Vertigo	1	07SEP2020	14/3	1	Yes		NA	R (09SEP2020)	N/N	
16-55/ C4591001 1264 12641060	EAR	Vertigo/ Vertigo	2	15SEP2020	2/11	1	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1264 12641060	MUSC	Arthralgia/ Arthralgia (left hand)	2	30SEP2020	14/6	2	No	O	NA	R (05OCT2020)	N/N	
16-55/ C4591001	GENRL	Chills/ Chills	2	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1264 12641065		Fatigue/ Fatigue	2	17SEP2020	1/3	2	Yes		NA/TC	R (19SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	17SEP2020	1/3	2	Yes		NA/TC	R (19SEP2020)	N/N	
16-55/ C4591001 1264 12641069	GENRL	Influenza like illness/ Flu-like symptoms	2	19SEP2020	2/7	1	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1264 12641070	GENRL	Fatigue/ Fatigue	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001 1264 12641072	MUSC	Myalgia/ Myalgia (persistent soreness in left deltoid)	2	19SEP2020	2/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1264 12641073	GENRL	Swelling face/ Swelling in lower jaw	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N	
16-55/ C4591001 1264 12641082	CARD	Tachycardia/ Tachycardia	2	21SEP2020	1/4	2	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Pyrexia/ Fever	2	21SEP2020	1/4	1	Yes		NA	R (24SEP2020)	N/N	
	MUSC	Arthralgia/ Arthralgia	2	21SEP2020	1/4	2	Yes		NA	R (24SEP2020)	N/N	

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16-55/ C4591001 1264 12641083	NERV	Myalgia/ Myalgia	2	21SEP2020	1/4	2	Yes		NA	R (24SEP2020)	N/N	
		Headache/ Headache	2	21SEP2020	1/4	2	Yes		NA/TC	R (24SEP2020)	N/N	
	MUSC	Back pain/ Back pain	1	02SEP2020	3/7	2	No	O	NA/TC	R (08SEP2020)	N/N	
16-55/ C4591001 1264 12641088	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N	
16-55/ C4591001 1264 12641090	MUSC	Injection site pain/ Pain at injection site	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N	
		Pyrexia/ Fever	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N	
	GENRL	Myalgia/ Myalgia	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N	
16-55/ C4591001 1264 12641091	GENRL	Fatigue/ Fatigue	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N	
		Fatigue/ Fatigue	1	21SEP2020	21/3	1	No	O	NA	R (23SEP2020)	N/N	
16-55/ C4591001 1264 12641091	GENRL	Fatigue/ Fatigue	2	23SEP2020	3/3	1	Yes		NA	R (25SEP2020)	N/N	
		Pyrexia/ Fever	2	23SEP2020	3/3	1	Yes		NA/TC	R (25SEP2020)	N/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1264 12641092	GENRL	Influenza like illness/ Flu-like symptoms	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1264 12641093	INFEC	Wound infection/ Wound infection	2	14OCT2020	24/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1264 12641101	MUSC	Muscle spasms/ Muscle cramps in backs of thighs	1	16SEP2020	15/1	1	No	O	NA	R (16SEP2020)	N/N
16-55/ C4591001 1264 12641105	NERV	Peripheral sensory neuropathy/ Peripheral sensory neuropathy	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1264 12641113	GENRL	Fatigue/ Fatigue	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1264 12641116	GENRL	Chills/ Chills	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		Pyrexia/ Fever	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1264 12641120	MUSC	Myalgia/ Myalgia	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
	GASTR	Constipation/ Constipation	1	08SEP2020	1/C	1	No	O	NA/TCN	RG	N/N
16-55/ C4591001 1264 12641123	EAR	Ear pain/ Ear pain	1	22SEP2020	15/2	1	No	O	NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1264 12641135	MUSC	Myalgia/ Myalgia	2	28SEP2020	1/1	2	Yes		NA/TC	R (28SEP2020)	N/N
	MUSC	Back pain/ Back pain	1	23SEP2020	15/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1264 12641141	INFEC	Herpes zoster/ Shingles flare	1	26SEP2020	18/33	2	No	O	NA/TC	R (28OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	GASTR	Vomiting/ Vomiting	2	13OCT2020	15/6	1	No	O	NA	R (18OCT2020)	N/N
16-55/ C4591001	GASTR	Umbilical hernia/ Umbilical hernia	1	13SEP2020	4/C	2	No	O	NA/TC/TCN	RG	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1264 12641145	METAB	Decreased appetite/ Loss of appetite	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	30SEP2020	2/3	2	Yes		NA	R (02OCT2020)	N/N	
		Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N	
16-55/ C4591001 1264 12641157	GENRL	Influenza like illness/ Flu-like symptoms	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N	
16-55/ C4591001 1264 12641158	GENRL	Influenza like illness/ Flu-like symptoms	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N	
16-55/ C4591001 1264 12641162	GENRL	Injection site pain/ Pain at injection site	2	06OCT2020	1/8	2	Yes		NA	R (13OCT2020)	N/N	
	VASC	Flushing/ Facial flushing	2	02NOV2020	28/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1264 12641168	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N	
16-55/ C4591001 1264 12641171	GENRL	Fatigue/ Fatigue	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1264 12641172	METAB	Influenza like illness/ Flu-like symptoms	2	06OCT2020	1/3	1	Yes		NA/TC	R (08OCT2020)	N/N	
		Decreased appetite/ Anorexia	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N	
	NERV	Headache/ Headache	2	06OCT2020	1/C	1	No	O	NA/TC	RG	N/N	
		Headache/ Headache	1	03OCT2020	17/3	2	No	O	NA/TC	R (05OCT2020)	N/N	
	GASTR	Nausea/ Nausea	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N	
		GENRL	Malaise/ Malaise	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
			NERV	Headache/ Headache	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)
	RESP	Nasal congestion/ Nasal congestion	1	19SEP2020	3/7	1	No	O	NA	R (25SEP2020)	N/N	
	16-55/ C4591001 1264 12641177	MUSC	Pain in extremity/ Arm Soreness	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
		RESP	Oropharyngeal pain/ Sore throat	2	10OCT2020	2/2	1	No	O	NA	R (11OCT2020)	N/N
16-55/ C4591001	BLOOD	Lymph node pain/ Lymph node pain	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1264 12641181	GENRL	Chills/ Chills	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
1264 12641185	GENRL	Influenza like illness/ Flu-like symptoms	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
1264 12641187	NERV	Injection site pain/ Injection site pain	2	12OCT2020	1/4	1	Yes		NA	R (15OCT2020)	N/N
1264 12641187	NERV	Headache/ Headache	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
1264 12641190	GENRL	Injection site pain/ Injection site pain	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
1264 12641190	NERV	Headache/ Headache	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
1264 12641197	GENRL	Chills/ Chills	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
1264 12641197	GASTR	Fatigue/ Fatigue	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
1264 12641197	GASTR	Abdominal pain upper/ Stomach pain	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
1264 12641197	MUSC	Arthralgia/ Arthralgia (generalized)	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1264 12641200	GENRL	Chills/ Chills	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
		Pyrexia/ Fever	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1264 12641206	GASTR	Nausea/ Nausea	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
	MUSC	Arthralgia/ Arthralgia (generalized)	2	12OCT2020	1/C	2	Yes		NA/TC	RG	N/N
	NERV	Hyperaesthesia/ Increased skin sensitivity	2	12OCT2020	1/C	1	Yes		NA	RG	N/N
	GENRL	Injection site pain/ Injection site pain	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1264 12641208	GENRL	Fatigue/ Fatigue	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Chills/ Chills	2	15OCT2020	1/2	2	Yes		NA	R (16OCT2020)	N/N
		Fatigue/ Fatigue	2	15OCT2020	1/2	2	Yes		NA	R (16OCT2020)	N/N
	MUSC	Myalgia/ Myalgia (generalized)	2	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	NERV	Headache/ Headache	2	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001 1264 12641209	NERV	Dizziness/ Dizziness	1	21OCT2020	1/1	1	Yes		NA	R (21OCT2020)	N/N	
16-55/ C4591001 1264 12641210	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N	
16-55/ C4591001 1264 12641212	GENRL	Injection site pain/ Injection site pain	2	13NOV2020	1/4	1	Yes		NA	R (16NOV2020)	N/N	
16-55/ C4591001 1264 12641213	GENRL	Injection site reaction/ Injection site reaction	2	09NOV2020	1/1	1	Yes		NA	R (09NOV2020)	N/N	
16-55/ C4591001 1264 12641215	GENRL	Injection site pain/ Pain at injection site	1	22OCT2020	2/4	1	Yes		NA	R (25OCT2020)	N/N	
16-55/ C4591001 1264 12641221	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/4	1	Yes		NA	R (26OCT2020)	N/N	
	MUSC	Neck pain/ Neck pain	1	23OCT2020	1/4	1	Yes		NA	R (26OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1264 12641225	GENRL	Fatigue/ Fatigue	2	13NOV2020	1/5	1	Yes		NA	R (17NOV2020)	N/N
	MUSC	Myalgia/ Myalgia (left side)	2	13NOV2020	1/5	1	Yes		NA	R (17NOV2020)	N/N
	NERV	Headache/ Headache	2	13NOV2020	1/5	1	Yes		NA	R (17NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	13NOV2020	1/1	1	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1264 12641226		Pyrexia/ Fever	2	13NOV2020	1/1	1	Yes		NA/TC	R (13NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1264 12641227		Injection site pain/ Injection site pain	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ Headache	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
GENRL	Chills/ Chills	2	16NOV2020	1/2	1	Yes		NA	R (17NOV2020)	N/N	
GENRL	Pyrexia/ Fever	2	17NOV2020	2/2	1	Yes		NA	R (18NOV2020)	N/N	
NERV	Headache/ Headache	2	17NOV2020	2/2	2	Yes		NA	R (18NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1264 12641228	GENRL	Chills/ Chills	2	16NOV2020	1/3	2	Yes		NA	R (18NOV2020)	N/N
		Fatigue/ Fatigue	2	16NOV2020	1/3	2	Yes		NA	R (18NOV2020)	N/N
		Pyrexia/ Fever	2	16NOV2020	1/2	2	Yes		NA/TC	R (17NOV2020)	N/N
	MUSC	Myalgia/ Myalgia (generalized)	2	16NOV2020	1/3	2	Yes		NA/TC	R (18NOV2020)	N/N
16-55/ C4591001 1265 12651004	GENRL	Injection site pain/ Pain at injection site (left deltoid)	2	31OCT2020	48/4	1	No	O	NA	R (03NOV2020)	N/N
16-55/ C4591001 1265 12651007	GENRL	Chills/ Chills#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
	MUSC	Arthralgia/ Sore shoulders#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1265 12651010	GENRL	Fatigue/ Fatigue	1	28AUG2020	2/1	2	No	O	NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	29AUG2020	3/1	2	No	O	NA	R (29AUG2020)	N/N
	GENRL	Chills/ Chills#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N
		Pyrexia/ Fever#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1265 12651013	MUSC	Myalgia/ Myalgias#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site (Left deltoid)#	4	12JAN2021	2/2	1	Yes		NA/TC	R (13JAN2021)	N/N
	GENRL	Fatigue/ Mild fatigue	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
		Injection site pain/ Soreness at injection site	2	02OCT2020	2/2	1	No	O	NA	R (03OCT2020)	N/N
	MUSC	Myalgia/ New or increased muscle pain	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	MUSC	Myalgia/ New or increased muscle pain	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Chills/ Chill#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
		Fatigue/ Fatigue#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
		Pain/ Body aches#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
		Pyrexia/ Fever#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1265 12651025	GENRL	Influenza like illness/ Mild flu-like sensation	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1265 12651029	SKIN	Injection site discomfort/ Discomfort at injection site	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
		Hyperhidrosis/ Mild sweats	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
		Chills/ Chills	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001 1265 12651035	MUSC	Malaise/ General malaise	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
		Myalgia/ Increased muscle pain#	3	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N
		Insomnia/ insomnia#	3	11FEB2021	1/4	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1265 12651037	GENRL	Chills/ Chills#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
		Chills/ Chills#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
		MUSC	Myalgia/ New or increased muscle pain#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)
16-55/ C4591001 1265 12651040	INFEC	Herpes simplex/ Herpes simplex outbreak	2	10OCT2020	17/11	1	No	O	NA	R (20OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1265 12651041	GENRL	Pyrexia/ Fever	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1265 12651043	RESP	Rhinitis allergic/ Allergic rhinitis	2	28OCT2020	36/2	1	No	O	NA	R (29OCT2020)	N/N
16-55/ C4591001 1265 12651044	GENRL	Pain/ Diffuse body ache	1	21SEP2020	20/3	3	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ Fever	1	21SEP2020	20/3	3	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1265 12651047	GENRL	Pyrexia/ Fever#	4	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N
	MUSC	Myalgia/ Muscle aches#	4	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ Headache#	4	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1265 12651058	GENRL	Injection site pain/ Injection site soreness (left deltoid)#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Arthralgia/ Left shoulder pain#	4	24FEB2021	3/8	1	No	O	NA	R (03MAR2021)	N/N
		Pain in extremity/ Left hand pain#	4	24FEB2021	3/8	1	No	O	NA	R (03MAR2021)	N/N
16-55/ C4591001 1265 12651059	EAR	Vertigo positional/ Benign positional vertigo	1	12SEP2020	9/1	1	No	O	NA/TCN	R (12SEP2020)	N/N
16-55/ C4591001 1265 12651061	GENRL	Fatigue/ Fatigue	2	26SEP2020	2/1	2	Yes		NA	R (26SEP2020)	N/N
	MUSC	Injection site pain/ Pain at the injection site	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		DECREASED APPETITE/ ANOREXIA	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
		MYALGIA/ New or increased muscle ache, bilateral lower legs	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1265 12651062	GENRL	Fatigue/ Fatigue	2	26SEP2020	2/2	2	Yes		NA/TC	R (27SEP2020)	N/N
	MUSC	Arthralgia/ Arthralgias	2	26SEP2020	2/2	2	Yes		NA/TC	R (27SEP2020)	N/N
		MYALGIA/ MYALGIAS	2	26SEP2020	2/2	2	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1265 12651065	MUSC	Pain in extremity/ Sore arm	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1265 12651072	GENRL	Chills/ Chills#	4	03MAR2021	2/1	1	Yes		NA	R (03MAR2021)	N/N	
		Pyrexia/ Fever#	4	03MAR2021	2/1	1	Yes		NA	R (03MAR2021)	N/N	
	MUSC	Myalgia/ New or increased muscle pain#	4	03MAR2021	2/1	1	Yes		NA	R (03MAR2021)	N/N	
16-55/ C4591001 1265 12651079	GENRL	Pyrexia/ Fever	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N	
	NERV	Headache/ Headache	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N	
16-55/ C4591001 1265 12651081	RESP	Upper-airway cough syndrome/ Post nasal drip	2	30SEP2020	2/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1265 12651082	BLOOD	Lymph node pain/ Irritation of lymph nodes under armpit#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N	
	GENRL	Chills/ Chills#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N	
		Injection site pain/ Muscle ache at injection site#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N	
16-55/ C4591001 1265 12651090	GASTR	Constipation/ Constipation with left lower quadrant pain	1	14SEP2020	5/1	2	No	O	NA/TC	R (14SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1265 12651097	MUSC	Tenosynovitis stenosaurs/ De Quervain's tenosynovitis	2	09OCT2020	9/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1265 12651098	GASTR	Vomiting/ Vomiting	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
	GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
	MUSC	Myalgia/ Muscle pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
16-55/ C4591001 1265 12651099	GASTR	Dyspepsia/ Dyspepsia	1	25SEP2020	15/C	1	No	CD	NA/TC	RG	N/N	
16-55/ C4591001 1265 12651101	METAB	Hypoglycaemia/ Hypoglycemia	1	12SEP2020	2/2	3	No	CD	NA/TC	R (13SEP2020)	Y/N	
	GASTR	Abdominal pain/ Abdominal pain	1	25SEP2020	15/14	2	No	O	NA/TC	R (08OCT2020)	N/N	
	PSYCH	Confusional state/ Confusion/altered mental status	1	28SEP2020	18/2	2	No	CD	NA	R (29SEP2020)	N/N	
	IMMUN	Hypersensitivity/ Allergic reaction	2	30OCT2020	31/3	1	No	O	NA/TC	R (01NOV2020)	N/N	
16-55/ C4591001 1265 12651108	GENRL	Chills/ chills#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1265 12651110	MUSC	Injection site pain/ pain at injection site, left deltoid#	4	15FEB2021	1/4	1	Yes		NA	R (18FEB2021)	N/N
		Pyrexia/ fever#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
		Myalgia/ Muscle pain	1	15SEP2020	2/6	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	17SEP2020	4/3	1	Yes		NA	R (19SEP2020)	N/N
	SKIN	Night sweats/ Night sweats	1	17SEP2020	4/3	1	Yes		NA	R (19SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	08OCT2020	2/4	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1265 12651124	SKIN	Night sweats/ Night sweats	2	08OCT2020	2/4	1	Yes		NA	R (11OCT2020)	N/N
	GENRL	Chills/ Chills#	4	18JAN2021	1/2	1	Yes		NA/TC	R (19JAN2021)	N/N
16-55/ C4591001 1265 12651126	GENRL	Pain/ Body aches#	4	18JAN2021	1/2	1	Yes		NA/TC	R (19JAN2021)	N/N
		Chills/ Chills#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
	MUSC	Pyrexia/ Fever#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
		Myalgia/ Muscle aches#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1265 12651136	NERV	Headache/ Headache#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N	
	MUSC	Back pain/ Lower back pain	2	26OCT2020	19/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1265 12651138	GENRL	Fatigue/ Mild fatigue	2	13OCT2020	6/4	1	Yes		NA	R (16OCT2020)	N/N	
16-55/ C4591001 1265 12651143†	MUSC	Myalgia/ Muscle pain#	4	09MAR2021	2/2	1	Yes		NA	R (10MAR2021)	N/N	
	NERV	Headache/ Headache#	4	09MAR2021	2/2	1	Yes		NA	R (10MAR2021)	N/N	
	GASTR	Diarrhoea/ Diarrhea	2	20OCT2020	14/3	1	No	O	NA	R (22OCT2020)	N/N	
16-55/ C4591001 1265 12651145	EYE	Meibomianitis/ Right eye meibomitis	2	24OCT2020	18/C	1	No	O	NA/TC	N	N/N	
	INFEC	Conjunctivitis/ Right eye conjunctivitis	2	24OCT2020	18/C	1	No	O	NA/TC	N	N/N	
	GASTR	Toothache/ TOOTH PAIN	1	06OCT2020	19/3	1	No	O	NA/TC	R (08OCT2020)	N/N	
16-55/ C4591001 1265 12651149	BLOOD	Lymphadenopathy/ Sore and swollen underarm lymph node (both arms)	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1265 12651151	GASTR	Rectal haemorrhage/ Rectal bleeding	2	28OCT2020	15/6	1	No	O	NA	R (02NOV2020)	N/N	
16-55/ C4591001 1265 12651153	RESP	Asthma/ Asthma exacerbation	1	28SEP2020	8/1	1	No	O	NA/TC	R (28SEP2020)	N/N	
	EYE	Amaurosis fugax/ Right eye blindness, diagnosed with Right Amaurosis Fugax	2	01NOV2020	20/1	2	No	O	NA	R (01NOV2020)	N/N	
16-55/ C4591001 1265 12651155	GENRL	Fatigue/ Slight fatigue	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
		Injection site discomfort/ Discomfort at injection site	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 1265 12651159†	GENRL	Chills/ Chills	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
	MUSC	Myalgia/ Muscle pain	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 1265 12651161	INFEC	Gastroenteritis/ Gastroenteritis	1	11OCT2020	20/2	1	No	O	NA	R (12OCT2020)	N/N	
16-55/ C4591001 1265 12651168	MUSC	Back pain/ Lower back pain	1	25SEP2020	3/3	1	No	O	NA	R (27SEP2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	RENAL	Pollakiuria/ Frequent Urination	1	25SEP2020	3/3	1	No	O	NA	R (27SEP2020)	N/N
	RENAL	Costovertebral angle tenderness/ Costovertebral angle tenderness	1	28SEP2020	6/4	1	No	O	NA	R (01OCT2020)	N/N
		Pollakiuria/ Urinary frequency	1	28SEP2020	6/4	1	No	O	NA	R (01OCT2020)	N/N
	MUSC	Back pain/ Lower back pain	2	17OCT2020	4/3	1	No	O	NA	R (19OCT2020)	N/N
	RENAL	Pollakiuria/ Frequent urination	2	17OCT2020	4/3	1	No	O	NA	R (19OCT2020)	N/N
16-55/ C4591001 1265 12651170	GENRL	Chills/ Chills	1	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		Fatigue/ Fatigue	1	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1265 12651174	GENRL	Sensation of foreign body/ Globus Sensation	1	14OCT2020	21/7	1	No	O	NA/TC	R (20OCT2020)	N/N
16-55/ C4591001 1265 12651177	GENRL	Pyrexia/ fever#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
	NERV	Headache/ headache#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001	REPRO	Ovarian cyst/ New diagnosis of left ovarian complex cyst	1	08OCT2020	14/C	1	No	O	NA	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1265 12651180 16-55/ C4591001	NERV	Hypoaesthesia/ Left arm numbness	2	17OCT2020	2/13	1	No	O	NA	R (29OCT2020)	N/N
1265 12651186† 16-55/ C4591001	GENRL	Chills/ chills	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
1269 12691016		Pyrexia/ fever	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	RESP	Oropharyngeal pain/ sore throat	2	23SEP2020	14/5	1	No	O	NA	R (27SEP2020)	N/N
16-55/ C4591001 1269 12691022	NERV	Headache/ headache	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	13SEP2020	3/3	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Chills/ chills	2	13SEP2020	3/1	1	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1269 12691029	NERV	Headache/ headache	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
		Somnolence/ drowsiness	2	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1269 12691042	GENRL	Chills/ chills	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		Fatigue/ fatigue	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
	MUSC	Pain in extremity/ arm soreness	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1269 12691050	RESP	Dyspnoea/ Shortness of breath	1	28AUG2020	4/1	1	No	O	NA/TC	R (28AUG2020)	N/N
		Nasal congestion/ Nasal congestion	1	28AUG2020	4/1	1	No	O	NA/TC	R (28AUG2020)	N/N
	RESP	Dyspnoea/ Shortness of breath	2	15SEP2020	1/1	1	No	O	NA	R (15SEP2020)	N/N
16-55/ C4591001 1269 12691056	GENRL	Chills/ chills	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
		Pyrexia/ fever	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N
	NERV	Headache/ headache	2	16SEP2020	2/2	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1269 12691058	GENRL	Chills/ chills	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
		Pyrexia/ fever	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1269 12691063	MUSC	Myalgia/ body muscle aches	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Chills/ chills	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1269 12691064	NERV	Headache/ headache	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Injection site pain/ soreness at injection site	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1269 12691065	NERV	Headache/ headache	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Chills/ chills	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Chills/ chills	1	29AUG2020	3/1	1	Yes		NA	R (29AUG2020)	N/N
		Pyrexia/ Fever	1	29AUG2020	3/1	2	Yes		NA/TC	R (29AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1269 12691076	RESP	Nasal congestion/ nasal congestion	1	29AUG2020	3/1	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Fatigue/ fatigue	1	03SEP2020	8/1	1	No	O	NA	R (03SEP2020)	N/N
	RESP	Cough/ cough	1	03SEP2020	8/1	1	No	O	NA/TC	R (03SEP2020)	N/N
		Dyspnoea/ shortness of breath	1	03SEP2020	8/1	1	No	O	NA/TC	R (03SEP2020)	N/N
	GASTR	Diarrhoea/ diarrhea	1	07SEP2020	11/6	1	No	O	NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1269 12691078		Nausea/ nausea	1	07SEP2020	11/6	1	No	O	NA/TC	R (12SEP2020)	N/N
		Vomiting/ vomiting	1	07SEP2020	11/1	1	No	O	NA/TC	R (07SEP2020)	N/N
	GENRL	Chills/ chills	2	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N
		Fatigue/ fatigue	2	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1269 12691087	METAB	Decreased appetite/ loss of appetite	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Mucosal disorder/ increased mucus production	2	04OCT2020	14/3	1	No	O	NA	R (06OCT2020)	N/N
	RESP	Throat irritation/ scratchy throat	2	04OCT2020	14/3	1	No	O	NA	R (06OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1269 12691088	GASTR	Abdominal pain lower/ lower abdominal pain	2	22SEP2020	2/7	1	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C4591001 1269 12691091	GENRL	Injection site pain/ soreness at injection site	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Chills/ chills	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1269 12691094	GENRL	Chills/ chills	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		Pyrexia/ fever	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1269 12691097	CARD	Palpitations/ palpitation	1	09SEP2020	9/1	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Chills/ chills	1	09SEP2020	9/1	1	Yes		NA/TC	R (09SEP2020)	N/N
		Pyrexia/ fever	1	09SEP2020	9/1	1	Yes		NA/TC	R (09SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	1	09SEP2020	9/1	1	Yes		NA/TC	R (09SEP2020)	N/N
	INJ&P	Facial bones fracture/ fractured nose	1	17SEP2020	17/5	2	No	O	NA/TC	R (21SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1269 12691105	GENRL	Pyrexia/ fever	1	02SEP2020	1/2	1	Yes		NA/TC	R (03SEP2020)	N/N
	NERV	Headache/ headache	1	02SEP2020	1/3	1	Yes		NA/TC	R (04SEP2020)	N/N
16-55/ C4591001 1269 12691116	GENRL	Pyrexia/ fever	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
	SKIN	Intertrigo/ intertrigo	2	14NOV2020	52/C	2	No	O	NA/TC	N	N/N
	SKIN	Transient acantholytic dermatosis/ grover's disease	2	28NOV2020	66/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1269 12691125	GENRL	Chills/ chills	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
		Injection site pain/ soreness at injection site	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
		Pyrexia/ fever	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
	MUSC	Myalgia/ myalgias	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1269 12691126	GASTR	Paraesthesia oral/ tingling in mouth,lips and tongue	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1269 12691127	GENRL	Chest discomfort/ chest pressure	1	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N	
	MUSC	Arthralgia/ achy joints	1	10SEP2020	2/3	1	Yes		NA/TC	R (12SEP2020)	N/N	
	NERV		Hypogeusia/ diminished sense of taste	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
			Hyposmia/ Diminished sense of smell	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	RESP		Dyspnoea/ shortness of breath	1	10SEP2020	2/1	1	No	O	NA	R (10SEP2020)	N/N
			Oropharyngeal discomfort/ throat discomfort	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
	GENRL		Chills/ chills	1	12SEP2020	4/2	1	Yes		NA/TC	R (13SEP2020)	N/N
	RESP		Cough/ dry cough	1	16SEP2020	8/2	1	No	O	NA	R (17SEP2020)	N/N
			Dyspnoea/ shortness of breath	1	16SEP2020	8/2	1	No	O	NA	R (17SEP2020)	N/N
			Oropharyngeal pain/ sore throat	1	16SEP2020	8/2	1	No	O	NA/TC	R (17SEP2020)	N/N
		GENRL	Injection site pain/ tenderness at injection site	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Pyrexia/ fever	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
	MUSC	Myalgia/ muscle aches	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1269 12691129	GENRL	Fatigue/ fatigue	2	03OCT2020	4/2	1	No	O	NA	R (04OCT2020)	N/N	
		Injection site pain/ muscle pain at the injection site	2	03OCT2020	4/2	1	Yes		NA	R (04OCT2020)	N/N	
	PSYCH	Insomnia/ insomnia	2	03OCT2020	4/2	1	No	O	NA	R (04OCT2020)	N/N	
16-55/ C4591001 1269 12691136	GENRL	Chills/ chills	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N	
		Malaise/ malaise	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N	
	MUSC	Pyrexia/ fever	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N	
		Myalgia/ muscle soreness	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N	
16-55/ C4591001 1270 12701003	GASTR	Nausea/ Nausea	1	25AUG2020	1/1	1	Yes		NA/TC	R (25AUG2020)	N/N	
16-55/ C4591001 1270 12701004	INJ&P	Craniocerebral injury/ Closed Head Injury	2	28OCT2020	43/9	2	No	O	NA/TC	R (05NOV2020)	N/N	
	MUSC	Road traffic accident/ Driver in Motor Vehicle Accident	2	28OCT2020	43/1	2	No	O	NA	R (28OCT2020)	N/N	
		Arthralgia/ Right Hip Joint Pain	2	28OCT2020	43/C	2	No	O	NA/TC/TCN	RG	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Back pain/ Low Back Pain	2	28OCT2020	43/C	2	No	O	NA/TC/TCN	RG	N/N	
		Neck pain/ Neck Pain	2	28OCT2020	43/72	2	No	O	NA/TC/TCN	R (07JAN2021)	N/N	
		Temporomandibular joint syndrome/ Left Temporomandibular Pain	2	28OCT2020	43/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1270 12701011	GENRL	Injection site pain/ Pain at injection site	1	26AUG2020	1/4	1	Yes		NA	R (29AUG2020)	N/N	
	NERV	Headache/ Headache	1	26AUG2020	1/3	1	Yes		NA/TC	R (28AUG2020)	N/N	
	PSYCH	Attention deficit hyperactivity disorder/ Attention Defecit Hyperactivity Disorder	2	14OCT2020	30/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1270 12701015	SKIN	Skin irritation/ Worsening skin irritation in arm pits	2	21OCT2020	35/142	1	No	O	NA/TC	R (11MAR2021)	N/N	
16-55/ C4591001 1270 12701018	GENRL	Pyrexia/ Fever	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
16-55/ C4591001 1270 12701020	GENRL	Fatigue/ Fatigue	1	30AUG2020	4/3	1	Yes		NA	R (01SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	19SEP2020	3/3	2	Yes		NA	R (21SEP2020)	N/N	
		Pain/ Body Aches	2	19SEP2020	3/3	2	Yes		NA	R (21SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1270 12701022	INJ&P	Corneal abrasion/ Right corneal abrasion	2	08NOV2020	53/9	1	No	O	NA/TC	R (16NOV2020)	N/N
	NERV	Lumbar radiculopathy/ Lumbar Radiculopathy#	2	20DEC2020	95/C	1	No	O	NA	RG	N/N
	MUSC	Flank pain/ Flank Pain	2	01OCT2020	14/23	1	No	O	NA	R (23OCT2020)	N/N
	MUSC	Muscle spasms/ Muscle Spasm of Back	2	01OCT2020	14/23	1	No	O	NA	R (23OCT2020)	N/N
16-55/ C4591001 1270 12701025	MUSC	Spinal osteoarthritis/ Osteoarthritis of Spine	2	01OCT2020	14/C	1	No	O	NA/TC	N	N/N
	MUSC	Arthralgia/ Left wrist joint pain	1	15SEP2020	19/8	1	No	O	NA/TC/TCN	R (22SEP2020)	N/N
16-55/ C4591001 1270 12701030	GENRL	Pyrexia/ Fever	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Chills/ Chills	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1270 12701033	NERV	Headache/ Headache	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1270 12701034	GENRL	Chills/ Chills	1	04SEP2020	5/2	1	Yes		NA	R (05SEP2020)	N/N
	RESP	Upper-airway cough syndrome/ Postnasal drip	1	04SEP2020	5/2	1	No	O	NA	R (05SEP2020)	N/N
16-55/ C4591001 1270 12701037	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	INV	Alanine aminotransferase increased/ Increased ALT	2	15OCT2020	24/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1270 12701045	INFEC	Diverticulitis/ Diverticulitis	2	19NOV2020	59/11	1	No	O	NA/TC	R (29NOV2020)	N/N
	MUSC	Arthralgia/ Left shoulder joint pain	2	19NOV2020	59/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1270 12701051	GENRL	Chills/ Chills	1	23SEP2020	22/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1270 12701056	INFEC	Acute sinusitis/ Acute Sinusitis	1	19OCT2020	47/10	1	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C4591001 1270 12701065	REPRO	Postmenopausal haemorrhage/ Post menopausal bleeding	1	11SEP2020	8/12	1	No	O	NA	R (22SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	INV	Blood thyroid stimulating hormone increased/ Elevated Thyroid Stimulating Hormone Lab Test	2	19OCT2020	25/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1270 12701068	GENRL	Injection site pain/ Pain at injection site	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N	
16-55/ C4591001 1270 12701069	INFEC	Appendicitis/ APPENDICITIS	1	20SEP2020	17/3	3	No	O	NA/TC/TCN	R (22SEP2020)	Y/N	
	INV	Blood cholesterol increased/ Elevated Cholesterol	2	08OCT2020	9/C	1	No	O	NA/TCN	N	N/N	
		Low density lipoprotein increased/ Elevated Low-Density Lipoprotein	2	08OCT2020	9/C	1	No	O	NA/TCN	N	N/N	
16-55/ C4591001 1270 12701071	MUSC	Rotator cuff syndrome/ Impingement Syndrome of Bilateral Shoulders	1	18SEP2020	11/C	1	No	O	NA/TC	RG	N/N	
	EYE	Astigmatism/ Bilateral astigmatism	2	31DEC2020	94/C	1	No	O	NA/TCN	N	N/N	
		Hypermetropia/ Bilateral Hyperopia	2	31DEC2020	94/C	1	No	O	NA/TCN	N	N/N	
	GENRL	Chills/ Chills#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N	
		Injection site pain/ Injection site pain#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N	
16-55/ C4591001	SKIN	Rash/ Rash to Chest	1	12SEP2020	5/15	1	Yes		NA	R (26SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day*/ Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1270 12701074											
16-55/ C4591001	GASTR	Nausea/ Nausea*		08SEP2020	1/1	1	No	O	NA	R (08SEP2020)	N/N
1270 12701076											
	GASTR	Nausea/ Nausea	2	30SEP2020	1/2	2	No	O	NA	R (01OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
	METAB	Decreased appetite/ Decreased Appetite	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001	MUSC	Arthralgia/ New joint pains	1	10SEP2020	2/4	2	Yes		NA	R (13SEP2020)	N/N
1270 12701082											
		Myalgia/ New muscle aches	1	10SEP2020	2/4	2	Yes		NA	R (13SEP2020)	N/N
	VASC	Hot flush/ Hot Flashes	1	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	01OCT2020	1/5	1	Yes		NA	R (05OCT2020)	N/N
	SKIN	Hyperhidrosis/ Sweating	2	01OCT2020	1/5	1	Yes		NA	R (05OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1270 12701084	INFEC	Diverticulitis/ Diverticulitis	2	01OCT2020	3/12	1	No	O	NA/TC	R (12OCT2020)	N/N	
16-55/ C4591001 1270 12701085	INFEC	Acute sinusitis/ Acute Sinusitis	1	14SEP2020	5/14	2	No	O	NA/TCN	R (27SEP2020)	N/N	
	REPRO	Uterine haemorrhage/ Worsening abnormal uterine bleeding	2	27OCT2020	29/29	1	No	O	NA/TC	R (24NOV2020)	N/N	
	INV	Serum ferritin decreased/ Decreased ferritin	2	05NOV2020	38/C	1	No	O	NA/TC	N	N/N	
	MUSC	Plantar fasciitis/ Left Plantar fasciitis	2	08JAN2021	102/C	1	No	O	NA/TCN	N	N/N	
	SKIN	Skin lesion/ Skin lesion of scalp	2	08JAN2021	102/C	1	No	O	NA	N	N/N	
	GENRL	Chills/ Intermittent Chills#	4	21FEB2021	3/C	1	Yes		NA	RG	N/N	
16-55/ C4591001 1270 12701086	GENRL	Injection site pain/ Left arm injection site pain	1	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N	
16-55/ C4591001 1270 12701089	IMMUN	Seasonal allergy/ Worsening seasonal allergies	2	15OCT2020	14/14	2	No	O	NA/TC	R (28OCT2020)	N/N	
16-55/ C4591001	GENRL	Chills/ Chills	1	11SEP2020	2/1	2	Yes		NA	R (11SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1270 12701090												
16-55/ C4591001	NERV	Headache/ Headache	1	11SEP2020	1/4	1	Yes		NA/TC	R (14SEP2020)	N/N	
1270 12701097												
	GENRL	Fatigue/ Fatigue	1	12SEP2020	2/11	2	Yes		NA	R (22SEP2020)	N/N	
		Injection site pain/ Left arm pain at injection site	1	12SEP2020	2/3	1	Yes		NA/TC	R (14SEP2020)	N/N	
	MUSC	Myalgia/ Muscle aches	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	
	NERV	Dizziness/ Dizziness	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	
	MUSC	Tendon disorder/ Cystic lesion in medial patellofemoral retinaculum	1	24SEP2020	14/C	1	No	O	NA	N	N/N	
	INFEC	Otitis externa/ Right otitis externa	2	12OCT2020	11/11	1	No	O	NA/TC	R (22OCT2020)	N/N	
		Otitis media/ Right otitis media	2	12OCT2020	11/11	1	No	O	NA/TC	R (22OCT2020)	N/N	
16-55/ C4591001	INFEC	Ophthalmic herpes zoster/ Right eye herpes zoster keratitis (worsening)	2	23OCT2020	19/13	1	No	O	NA/TC/TCN	R (04NOV2020)	N/N	
1270 12701107												
	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/Y	
	GENRL	Fatigue/ Fatigue#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1270 12701119	GENRL	Chills/ Chills	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
		Pain/ Body Aches	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1270 12701121	EAR	Vertigo/ Vertigo	2	04NOV2020	21/9	1	No	O	NA	R (12NOV2020)	N/N
16-55/ C4591001 1270 12701122	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/2	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1270 12701123	GENRL	Fatigue/ Fatigue#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	3	27JAN2021	1/2	2	Yes		NA/TC	R (28JAN2021)	N/N
	NERV	Headache/ Headache#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	19FEB2021	1/4	1	Yes		NA/TC	R (22FEB2021)	N/N
	MUSC	Arthralgia/ Joint Pain#	4	19FEB2021	1/4	2	Yes		NA/TC	R (22FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1270 12701124	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/Y
16-55/ C4591001 1270 12701128	GENRL	Fatigue/ Fatigue	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	METAB	Decreased appetite/ Loss of appetite	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1270 12701129	GENRL	Chills/ Chills	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
		Pain/ Body Aches	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1270 12701132	MUSC	Back pain/ Burning-like back pain (worsening)	1	23SEP2020	6/22	2	No	O	NA	R (14OCT2020)	N/N
		Neck pain/ Increased neck pain (worsening)	1	23SEP2020	6/22	2	No	O	NA	R (14OCT2020)	N/N
	PSYCH	Sleep disorder/ Sleep disturbance	1	23SEP2020	6/22	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C4591001 1270 12701133	INJ&P	Ligament sprain/ Right ankle sprain	2	08NOV2020	31/7	1	No	O	NA/TCN	R (14NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1270 12701135	EAR	Eustachian tube dysfunction/ Left eustachian tube dysfunction	1	02OCT2020	15/27	1	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C4591001 1270 12701136	GENRL	Fatigue/ Fatigue#	3	21DEC2020	1/3	2	Yes		NA	R (23DEC2020)	N/N
		Injection site pain/ Pain at injection site#	3	21DEC2020	1/3	2	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001 1270 12701137	INV	Low density lipoprotein increased/ Elevated low-density lipoprotein	1	23SEP2020	3/C	1	No	O	NA	N	N/N
	INV	Herpes simplex test positive/ Positive Herpes Simplex Virus Test Results	1	24SEP2020	4/1	1	No	O	NA	R (24SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	12OCT2020	1/3	2	Yes		NA/TC	R (14OCT2020)	N/N
	GENRL	Chills/ Chills	2	12OCT2020	1/2	2	Yes		NA	R (13OCT2020)	N/N
		Pyrexia/ Fever	2	12OCT2020	1/3	2	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1270 12701141	INJ&P	Joint dislocation/ Left Temporomandibular Joint Subluxation	2	17DEC2020	66/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1270 12701142	BLOOD	Lymphadenopathy/ Swollen left superficial cervical lymph node	1	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1270 12701147	GENRL	Pyrexia/ Fever	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	3	04FEB2021	1/4	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1270 12701148	GENRL	Chills/ CHLLS	1	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1270 12701150		Pain/ BODY ACHES	1	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
	REPRO	Uterine haemorrhage/ Abnormal Uterine Bleeding#	3	03FEB2021	2/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1270 12701152	GENRL	Chills/ Chills#	3	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/N
		Fatigue/ Fatigue#	3	03FEB2021	1/7	1	Yes		NA	R (09FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
	GASTR	Nausea/ Nausea#	3	06FEB2021	4/1	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1270 12701154	PSYCH	Generalised anxiety disorder/ Generalized Anxiety Disorder	2	14JAN2021	39/C	1	No	O	NA/TCN	N	N/N	
	MUSC	Back pain/ Chronic Low back pain	2	19JAN2021	44/C	1	No	O	NA/TCN	N	N/N	
16-55/ C4591001 1270 12701155	GENRL	Chills/ Chills#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N	
		Injection site pain/ Injection Site Pain#	3	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N	
	MUSC	Myalgia/ Muscle pain, generalized#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N	
16-55/ C4591001 1270 12701164	MUSC	Pain in extremity/ Right antecubital pain#	2	02FEB2021	51/1	1	No	O	NA/TCN	R (02FEB2021)	N/N	
	NERV	Headache/ Headache#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N	
16-55/ C4591001 1270 12701175	GENRL	Injection site pain/ Left Arm Injection Site Pain	1	01DEC2020	1/7	2	Yes		NA	R (07DEC2020)	N/N	
16-55/ C4591001 1270 12701178	SKIN	Seborrhoeic dermatitis/ Seborrhoeic Dermatitis of Scalp	2	10JAN2021	20/C	1	No	O	NA/TC	N	N/N	
	GENRL	Injection site pain/ Injection Site Pain#	3	03FEB2021	1/2	1	Yes		NA/TC	R (04FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1270 12701186	SKIN	Rash/ Rash to trunk	2	21JAN2021	31/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1270 12701190	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
16-55/ C4591001 4444 44441003	GENRL	Pyrexia/ fever	2	13OCT2020	2/2	2	Yes		NA/TC	R (14OCT2020)	N/N	
	NERV	Headache/ headache	2	13OCT2020	2/C	2	Yes		NA/TC	N	N/N	
16-55/ C4591001 4444 44441007	INJ&P	Procedural haemorrhage/ Intraoperative hemorrhage during an elective laparoscopic ovarian cystectomy	1	03OCT2020	13/5	3	No	O	NA/TC	R (07OCT2020)	Y/N	
	REPRO	Haemorrhagic ovarian cyst/ Hemorrhagic cyst of the right ovary	1	21OCT2020	31/30	1	No	O	NA/TC	R (19NOV2020)	N/N	
16-55/ C4591001 4444 44441012	INFEC	Oral herpes/ cold sore	2	02NOV2020	21/8	1	No	O	NA/TC	R (09NOV2020)	N/N	
16-55/ C4591001 4444 44441015	MUSC	Myalgia/ left arm muscle pain	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 4444 44441016	NERV	Syncope/ Vasovagal syncope	2	13NOV2020	32/1	1	No	O	NA	R (13NOV2020)	N/N	
16-55/ C4591001 4444 44441017	MUSC	Back pain/ Low back pain	2	29OCT2020	17/40	2	No	O	NA/TC	R (07DEC2020)	N/N	
16-55/ C4591001 4444 44441026	GENRL	Injection site swelling/ Swelling at injection site	2	12OCT2020	1/9	1	Yes		NA	R (20OCT2020)	N/N	
	GENRL	Asthenia/ asthenia	2	13OCT2020	2/33	2	Yes		NA	R (14NOV2020)	N/N	
		Pyrexia/ fever	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N	
16-55/ C4591001 4444 44441028	GENRL	Pyrexia/ Fever	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N	
	NERV	Headache/ Headache	2	13OCT2020	2/1	2	Yes		NA	R (13OCT2020)	N/N	
16-55/ C4591001 4444 44441045	GENRL	Injection site pain/ injection site pain#	4	11MAR2021	1/1	1	Yes		NA	R (11MAR2021)	N/N	
	GENRL	Pyrexia/ Fever#	4	12MAR2021	2/1	1	Yes		NA/TC	R (12MAR2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 4444 44441056	INFEC	Oral candidiasis/ Oral thrush	2	14NOV2020	33/7	1	No	O	NA/TC/TCN	R (20NOV2020)	N/N	
	INJ&P	Skin laceration/ Cutting wound on the little finger of the right hand#	3	06MAR2021	15/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 4444 44441060	GENRL	Pyrexia/ Fever#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N	
	MUSC	Arthralgia/ joint pain#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N	
		Myalgia/ muscle pain#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N	
	GENRL	Axillary pain/ Bilateral axillary pain#	4	11MAR2021	22/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 4444 44441071	GASTR	Diarrhoea/ Diarrhea	1	28SEP2020	8/3	1	No	O	NA/TCN	R (30SEP2020)	N/N	
	GASTR	Abdominal pain upper/ Left upper quadrant abdominal pain	1	01OCT2020	11/20	2	No	O	NA/TC	R (20OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	23OCT2020	1/105	1	Yes		NA/TC	R (04FEB2021)	N/Y	
16-55/ C4591001 4444 44441095	MUSC	Neck pain/ Neck pain	1	29SEP2020	9/3	1	No	O	NA/TC	R (01OCT2020)	N/N	
16-55/ C4591001	RENAL	Dysuria/ dysuria	2	27OCT2020	15/14	1	No	O	NA/TC	R (09NOV2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
4444 44441100	GASTR	Toothache/ toothache	1	30SEP2020	10/7	1	No	O	NA/TC	R (06OCT2020)	N/N	
16-55/ C4591001 4444 44441113	INFEC	Gingivitis/ Gingivitis	1	30SEP2020	10/7	1	No	O	NA/TC	R (06OCT2020)	N/N	
	MUSC	Arthralgia/ Right omalgia	2	14NOV2020	32/6	1	No	O	NA/TC	R (19NOV2020)	N/N	
16-55/ C4591001 4444 44441121	MUSC	Arthralgia/ Arthralgia of elbows and knees	2	14OCT2020	2/4	1	Yes		NA	R (17OCT2020)	N/N	
	MUSC	Costochondritis/ mild acute chostochodritis	2	07NOV2020	26/11	1	No	O	NA	R (17NOV2020)	N/N	
16-55/ C4591001 4444 44441125	NERV	Headache/ headache	2	14OCT2020	2/1	2	Yes		NA/TC	R (14OCT2020)	N/N	
16-55/ C4591001 4444 44441134	MUSC	Back pain/ Worsening low back pain	1	03OCT2020	13/2	1	No	O	NA/TC	R (04OCT2020)	N/N	
16-55/ C4591001 4444 44441139	MUSC	Plantar fasciitis/ Plantar fasciitis	2	15DEC2020	64/C	1	No	O	NA/TCN	RG	N/N	
16-55/ C4591001	GASTR	Diarrhoea/ diarrhea	1	09OCT2020	19/2	2	No	O	NA	R (10OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44441144 16-55/ C4591001 4444 44441147	BLOOD	Iron deficiency anaemia/ Iron deficiency anemia	2	08FEB2021	119/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 4444 44441149	MUSC	Arthralgia/ Left omalgia	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	NERV	Headache/ Headache	1	22SEP2020	2/1	1	No	O	NA	R (22SEP2020)	N/N
	GASTR	Odynophagia/ Odynophagia	1	23SEP2020	3/1	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Chills/ Shaking chills	1	24SEP2020	4/1	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 4444 44441150	SKIN	Rash/ Generalized skin rash.	2	26NOV2020	46/12	1	No	O	NA/TC	R (07DEC2020)	N/N
16-55/ C4591001 4444 44441154	GENRL	Pyrexia/ 38.0 C fever	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 4444 44441157	METAB	Dyslipidaemia/ Dyslipidemia	1	07OCT2020	17/36	1	No	O	NA/TC	R (11NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441160	VASC	Arteriosclerosis/ Atherosclerosis of vessels of the neck	1	07OCT2020	17/14	1	No	O	NA/TC	R (20OCT2020)	N/N
	GENRL	Pyrexia/ fever	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 4444 44441166	NEOPL	Lipoma/ worsening of soft tissue tumor resembling lipoma	1	01OCT2020	11/42	1	No	O	NA	R (11NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	13OCT2020	1/5	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 4444 44441169	GENRL	Injection site pain/ injection site pain	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
	16-55/ C4591001 4444 44441175	GASTR	Pyrexia/ Fever Abdominal pain lower/ hypogastric pain#	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)
2				20FEB2021	131/20	2	No	O	NA/TC	R (11MAR2021)	N/N
16-55/ C4591001 4444 44441176	GENRL	Pyrexia/ Fever	2	14OCT2020	1/1	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 4444 44441192	GENRL	Asthenia/ Asthenia	2	13OCT2020	2/3	2	Yes		NA/TC	R (15OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 4444 44441203	MUSC	Injection site pain/ Injection site pain	2	13OCT2020	2/3	3	Yes		NA/TC	R (15OCT2020)	N/N	
		Pyrexia/ Fever	2	13OCT2020	2/1	2	Yes		NA/TC	R (13OCT2020)	N/N	
		Muscular weakness/ arm weakness	2	13OCT2020	2/3	2	Yes		NA/TC	R (15OCT2020)	N/N	
	GENRL	Injection site pruritus/ Itching at injection site	2	14OCT2020	3/4	1	Yes		NA	R (17OCT2020)	N/N	
	16-55/ C4591001 4444 44441205	VASC	Hypertension/ Exacerbation of arterial hypertension	2	16FEB2021	128/C	1	No	O	NA/TC	RG	N/N
	16-55/ C4591001 4444 44441209	NERV	Headache/ Headache	1	25SEP2020	5/2	1	Yes		NA	R (26SEP2020)	N/N
	16-55/ C4591001 4444 44441232	GENRL	Pyrexia/ Fever	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
	16-55/ C4591001 4444 44441243	GENRL	Pyrexia/ fever	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
		NERV	Headache/ headache	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001	GASTR	Incarcerated inguinal hernia/ Incarcerated right inguinal hernia	1	05OCT2020	15/18	3	No	O	NA/TC/TCN	R (22OCT2020)	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
4444 44441249 16-55/ C4591001 4444 44441268	NERV	Presyncope/ Vasovagal pre-syncope	2	26NOV2020	35/1	1	No	O	NA/TCN	R (26NOV2020)	N/N	
16-55/ C4591001 4444 44441275	INFEC	Periodontitis/ periodontal infection	2	22OCT2020	10/15	1	No	O	NA/TC	R (05NOV2020)	N/N	
16-55/ C4591001 4444 44441297	INFEC	Postoperative wound infection/ Surgical site infection	2	16NOV2020	36/12	2	No	O	NA/TC	R (27NOV2020)	Y/N	
16-55/ C4591001 4444 44441300	GENRL	Injection site pain/ Injection site pain	1	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N	
		Pyrexia/ low-grade fever	1	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N	
	NERV	Headache/ headache	1	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N	
	GENRL	Pyrexia/ low-grade fever (37.5 C) with chills	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N	
	NERV	Headache/ Headache	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N	
16-55/ C4591001 4444 44441310	MUSC	Muscle spasms/ Cramps in upper limbs	1	25SEP2020	4/14	1	No	O	NA	R (08OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 4444 44441311	METAB	Dyslipidaemia/ dyslipidemia	2	14OCT2020	3/C	1	No	O	NA	N	N/N	
16-55/ C4591001 4444 44441321	VASC	Varicose vein/ Worsening varicose veins in lower limbs	1	01OCT2020	10/30	1	No	O	NA	R (30OCT2020)	N/N	
	GENRL	Pyrexia/ fever	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N	
	SKIN	Rash/ facial skin rash	2	22OCT2020	11/3	1	No	O	NA/TC	R (24OCT2020)	N/N	
16-55/ C4591001 4444 44441325	GASTR	Gastritis/ Gastritis	2	21OCT2020	8/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 4444 44441326	GENRL	Injection site pain/ Injection site pain	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N	
16-55/ C4591001 4444 44441330	MUSC	Myalgia/ Generalized myalgia	2	13OCT2020	1/2	2	Yes		NA	R (14OCT2020)	N/N	
16-55/ C4591001 4444 44441360	REPRO	Testicular pain/ Pain in left testicle	1	24SEP2020	3/4	2	No	O	NA	R (27SEP2020)	N/N	
	GASTR	Rectal haemorrhage/ Proctorrhagia	1	06OCT2020	15/2	2	No	O	NA/TC	R (07OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441361	GENRL	Fatigue/ Tiredness	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ mild muscle pain.	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 4444 44441384	MUSC	Rotator cuff syndrome/ Rotator cuff syndrome	1	05OCT2020	14/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 4444 44441388	INFEC	Periodontitis/ Periodontal infection	2	06NOV2020	25/7	1	No	O	NA/TCN	R (12NOV2020)	N/N
16-55/ C4591001 4444 44441390	GENRL	Injection site pain/ injection site pain	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N
		Pyrexia/ fever	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 4444 44441400	GENRL	Injection site pain/ injection site pain	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 4444 44441402	INJ&P	Ligament sprain/ Type 1 sprain on right ankle mild intensity	1	25SEP2020	4/20	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever	2	13OCT2020	1/2	2	Yes		NA/TC	R (14OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
4444 44441408 16-55/ C4591001 4444 44441413	GENRL	Chills/ Shaking chills	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 4444 44441432	INFEC	Sinusitis/ Sinusitis	1	23SEP2020	2/7	2	No	O	NA	R (29SEP2020)	N/N	
16-55/ C4591001 4444 44441433	MUSC	Arthralgia/ arthralgia	2	14OCT2020	2/2	2	No	O	NA/TC	R (15OCT2020)	N/N	
16-55/ C4591001 4444 44441435	REPRO	Myalgia/ myalgia Pelvic pain/ Pelvic pain	2	14OCT2020	2/2	2	No	O	NA/TC	R (15OCT2020)	N/N	
16-55/ C4591001 4444 44441436	REPRO	Pelvic pain/ Pelvic pain	2	06NOV2020	24/10	1	No	O	NA	R (15NOV2020)	N/N	
16-55/ C4591001 4444 44441437	GENRL	Pyrexia/ Fever	2	13OCT2020	2/1	2	Yes		NA/TC	R (13OCT2020)	N/N	
16-55/ C4591001 4444 44441438	INJ&P	Contusion/ Cutaneous bruises	1	06OCT2020	15/C	1	No	O	NA	N	N/N	
	REPRO	Haemorrhagic ovarian cyst/ hemorrhagic ovarian cyst	2	17NOV2020	27/44	1	No	O	NA	R (30DEC2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 4444 44441442	INFEC	Urinary tract infection/ Urinary infection	2	26OCT2020	14/8	1	No	O	NA/TC	R (02NOV2020)	N/N	
16-55/ C4591001 4444 44441452	INJ&P	Animal bite/ Cat bite on right hand with a puncture wound.	2	22OCT2020	10/30	1	No	O	NA/TC	R (20NOV2020)	N/N	
16-55/ C4591001 4444 44441457	INFEC	Tooth infection/ Dental infection	2	07NOV2020	24/6	2	No	O	NA/TC/TCN	R (12NOV2020)	N/N	
16-55/ C4591001 4444 44441483	GENRL	Pyrexia/ fever	2	13OCT2020	1/3	2	Yes		NA/TC	R (15OCT2020)	N/N	
16-55/ C4591001 4444 44441487	NERV	Headache/ headache	1	24SEP2020	3/6	1	No	O	NA/TC	R (29SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N	
	EYE	Ulcerative keratitis/ RIGHT EYE CORNEAL ULCER	2	15NOV2020	35/9	2	No	O	NA/TC	R (23NOV2020)	N/N	
16-55/ C4591001 4444 44441494	GASTR	Gastritis/ Gastritis	1	24SEP2020	3/65	1	No	O	NA/TC	R (27NOV2020)	N/N	
	NEOPL	Colon adenoma/ Colonic Polyp (Histologic analysis: tubular adenoma. Low-grade dysplasia)	1	24SEP2020	3/1	1	No	O	NA/TCN	R (24SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 4444 44441499	PSYCH	Depression/ Worsening Depression	2	11NOV2020	30/17	2	No	O	NA/TC	R (27NOV2020)	N/N	
	MUSC	Myalgia/ GENERALIZED MYALGIA	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 4444 44441503	MUSC	Myalgia/ myalgia	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N	
	NERV	Migraine/ Worsening of migraine.	1	06OCT2020	15/4	2	No	O	NA/TC	R (09OCT2020)	N/N	
16-55/ C4591001 4444 44441505	GENRL	Injection site pain/ right arm pain at injection site	1	24SEP2020	3/1	1	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001 4444 44441506	GENRL	Injection site pain/ Pain at the injection site	2	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/N	
	GENRL	Asthenia/ Asthenia	1	03OCT2020	12/16	1	No	O	NA/TCN	R (18OCT2020)	N/N	
16-55/ C4591001 4444 44441514	GENRL	Injection site pain/ Injection site pain	2	12OCT2020	1/5	1	Yes		NA	R (16OCT2020)	N/N	
	GENRL	Asthenia/ Asthenia	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N	
		Pyrexia/ fever	2	13OCT2020	2/1	2	Yes		NA/TC	R (13OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441518	GENRL	Asthenia/ asthenia	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
		Pyrexia/ fever	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
	NERV	Headache/ headache	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 4444 44441528	GENRL	Injection site pain/ Pain at injection site#	3	09MAR2021	2/1	1	Yes		NA	R (09MAR2021)	N/N
16-55/ C4591001 4444 44441536	GENRL	Pyrexia/ Fever	2	14OCT2020	2/1	2	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 4444 44441539	GENRL	Asthenia/ asthenia	2	17OCT2020	4/6	1	Yes		NA	R (22OCT2020)	N/N
		Pyrexia/ Low grade fever	2	17OCT2020	4/2	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C4591001 4444 44441542	INFEC	Tooth infection/ Dental infection	1	30SEP2020	8/11	1	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 4444 44441544	NERV	Headache/ Headache	1	01OCT2020	9/3	2	No	O	NA/TC	R (03OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441546	INJ&P	Skin laceration/ Cutting skin lesion on left index finger	1	10OCT2020	18/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 4444 44441550	GASTR	Intestinal perforation/ Intestinal perforation	2	23DEC2020	70/22	3	No	O	NA/TC/TCN	R (13JAN2021)	Y/N
	INFEC	Pneumonia/ Hospital-acquired pneumonia	2	30DEC2020	77/15	3	No	O	NA/TC	R (13JAN2021)	Y/N
16-55/ C4591001 4444 44441553	METAB	Insulin resistance/ Insulin resistance	1	30SEP2020	8/45	2	No	O	NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 4444 44441556	GENRL	Pyrexia/ 38C Fever	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 4444 44441561	GENRL	Injection site pain/ injection site Pain	2	15OCT2020	2/3	2	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 4444 44441566	GENRL	Injection site pain/ Pain at the injection site	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001	MUSC	Back pain/ low back pain	1	19OCT2020	27/3	1	No	O	NA	R (21OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
4444 44441572	GENRL	Asthenia/ Asthenia	1	23SEP2020	1/9	1	Yes		NA	R (01OCT2020)	N/N	
16-55/ C4591001 4444 44441573	GENRL	Chills/ chills	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Asthenia/ Asthenia	2	14OCT2020	1/6	1	Yes		NA	R (19OCT2020)	N/N	
		Injection site pain/ Pain at the injection site (left arm)	2	14OCT2020	1/5	1	Yes		NA	R (18OCT2020)	N/N	
16-55/ C4591001 4444 44441577	SURG	Endodontic procedure/ Root canal treatment	1	14OCT2020	22/1	1	No	O	NA/TC	R (14OCT2020)	N/N	
16-55/ C4591001 4444 44441583	GASTR	Toothache/ Right lower molar pain	2	30OCT2020	19/4	2	No	O	NA/TC	R (02NOV2020)	N/N	
16-55/ C4591001 4444 44441586	INFEC	Tooth infection/ Odontogenic infection	1	02OCT2020	10/5	1	No	O	NA	R (06OCT2020)	N/N	
16-55/ C4591001 4444 44441594	GENRL	Injection site pain/ Injection site pain	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N	
		Pyrexia/ Fever	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Myalgia	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N
	NERV	Headache/ Headache	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 4444 44441603	GASTR	Dental caries/ Dental cavity	2	30OCT2020	17/11	1	No	O	NA/TC/TCN	R (09NOV2020)	N/N
16-55/ C4591001 4444 44441612	GENRL	Pyrexia/ Fever	1	15OCT2020	23/2	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 4444 44441614	MUSC	Myalgia/ right back myalgia	1	29SEP2020	7/4	1	No	O	NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 4444 44441616	GASTR	Vomiting/ Vomiting	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
	NERV	Headache/ Headache	2	13OCT2020	2/3	2	Yes		NA/TC	R (15OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	14OCT2020	3/1	2	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 4444 44441618	MUSC	Intervertebral disc protrusion/ herniated disc	2	02NOV2020	20/29	2	No	O	NA/TC	R (30NOV2020)	N/N
16-55/ C4591001	INFEC	Acarodermatitis/ Scabies	1	07OCT2020	15/17	1	No	O	NA/TC	R (23OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
4444 44441624 16-55/ C4591001 4444 44441634	HEPAT	Cholecystitis acute/ Acute cholecystitis	2	28DEC2020	76/8	3	No	O	NA/TC/TCN	R (04JAN2021)	Y/N	
16-55/ C4591001 4444 44441643	MUSC	Osteoporosis/ Osteoporosis	2	26OCT2020	11/117	1	No	O	NA/TC	RS (19FEB2021)	N/N	
16-55/ C4591001 4444 44441658	GENRL	Pyrexia/ fever	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N	
16-55/ C4591001 4444 44441673	GENRL	Pyrexia/ Fever	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N	
16-55/ C4591001 4444 44441679	MUSC	Myalgia/ Myalgia	2	15OCT2020	2/4	1	Yes		NA/TC	R (18OCT2020)	N/N	
16-55/ C4591001 4444 44441679	GENRL	Application site pain/ pain at the application site	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N	
	MUSC	Myalgia/ Generalized Myalgia	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N	
	NERV	Headache/ Headache	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001	GENRL	Pyrexia/ fever	2	14OCT2020	1/2	1	Yes		NA/TC	R (15OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44441680 16-55/ C4591001 4444 44441682	INJ&P	Joint injury/ Mild trauma to the left knee while doing regular physical activity	2	07NOV2020	25/1	1	No	O	NA	R (07NOV2020)	N/N
4444 44441682	MUSC	Arthralgia/ Left knee pain	2	07NOV2020	25/4	1	No	O	NA/TC	R (10NOV2020)	N/N
16-55/ C4591001 4444 44441700	GASTR	Diarrhoea/ Diarrhea	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N
	GENRL	Illness/ Sickness	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 4444 44441716	MUSC	Myalgia/ myalgia	2	14OCT2020	1/2	2	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 4444 44441719	MUSC	Myalgia/ generalized myalgias	1	26SEP2020	4/3	2	Yes		NA/TC	R (28SEP2020)	N/N
16-55/ C4591001 4444 44441725	MUSC	Muscular weakness/ Generalized muscle weakness	1	09OCT2020	17/1	1	No	O	NA	R (09OCT2020)	N/N
		Myalgia/ Dorsal muscle pain	1	09OCT2020	17/1	1	No	O	NA/TC	R (09OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441733	INJ&P	Head injury/ Head injury without loss of consciousness.	2	25OCT2020	12/8	1	No	O	NA/TC/TCN	R (01NOV2020)	N/N
16-55/ C4591001 4444 44441735	SKIN	Skin lesion/ indurated lesion on left arm	1	30SEP2020	8/18	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 4444 44441744	NERV	Headache/ intermittent headache	1	24SEP2020	2/22	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 4444 44441746	GENRL	Injection site oedema/ Edema at the injection site.	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 4444 44441748	GASTR	Oesophageal food impaction/ esophageal impaction with food	1	28SEP2020	6/2	3	No	O	NA/TCN	R (29SEP2020)	Y/N
16-55/ C4591001 4444 44441756	GASTR	Nausea/ Nausea	1	24SEP2020	2/4	2	Yes		NA	R (27SEP2020)	N/N
	GENRL	Pyrexia/ Fever	1	24SEP2020	2/4	2	Yes		NA/TC	R (27SEP2020)	N/N
	MUSC	Myalgia/ Generalized myalgia	1	24SEP2020	2/4	2	Yes		NA/TC	R (27SEP2020)	N/N
	GASTR	Abdominal pain upper/ epigastralgia	1	11OCT2020	19/2	1	No	O	NA/TC	R (12OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 4444 44441761	MUSC	Neck pain/ cervicalgia	1	11OCT2020	19/3	2	No	O	NA	R (13OCT2020)	N/N	
	MUSC	Arthralgia/ Right knee pain	2	04NOV2020	21/8	2	No	O	NA/TC	R (11NOV2020)	N/N	
	GENRL	Application site rash/ Rash in the arm contralateral to the application of the research product	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N	
	BLOOD	Lymphadenopathy/ Right axillary adenopathy#	3	10MAR2021	2/C	1	No	O	NA	RG	N/N	
	GENRL	Pyrexia/ fever	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N	
	MUSC	Back pain/ Exacerbation of low back pain	2	02NOV2020	19/C	3	No	O	NA/TC/TCN	N	Y/N	
	BLOOD	Iron deficiency anaemia/ Iron deficiency anemia	1	29SEP2020	7/C	1	No	O	NA/TC	RG	N/N	
	METAB	Vitamin D deficiency/ Hypovitaminosis D	2	29OCT2020	15/C	1	No	O	NA/TC	N	N/N	
	MUSC	Back pain/ Low back pain	2	07NOV2020	24/4	1	No	O	NA/TC	R (10NOV2020)	N/N	
	METAB	Vitamin D deficiency/ Hypovitaminosis D	2	26OCT2020	13/C	1	No	O	NA/TC	RG	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441785	GASTR	Vomiting/ Vomiting, 2 episodes	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Pyrexia/ FEVER	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 4444 44441786	INFEC	Urinary tract infection/ Urinary infection#	3	11MAR2021	17/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 4444 44441788	MUSC	Muscle contracture/ cervical contracture	2	01NOV2020	20/34	1	No	O	NA/TCN	R (04DEC2020)	N/N
16-55/ C4591001 4444 44441796	GENRL	Pyrexia/ Fever	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 4444 44441797	GENRL	Pyrexia/ Fever	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C4591001 4444 44441801	GENRL	Chest pain/ chest pain	2	28OCT2020	15/3	2	No	O	NA/TC	R (30OCT2020)	N/N
	VASC	Diastolic hypertension/ Diastolic arterial hypertension	2	29OCT2020	16/C	1	No	O	NA	N	N/N
	GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux	2	03NOV2020	21/C	1	No	O	NA/TC	RG	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441808	INFEC	Tooth infection/ odontogenic infection	2	07NOV2020	24/7	1	No	O	NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 4444 44441810	GENRL	Pyrexia/ FEVER	1	28SEP2020	4/2	2	Yes		NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 4444 44441815	GASTR	Diarrhoea/ diarrhea	2	17OCT2020	3/2	1	Yes		NA	R (18OCT2020)	N/N
		Vomiting/ Vomits.	2	17OCT2020	3/2	2	Yes		NA/TC	R (18OCT2020)	N/N
	NERV	Headache/ Headache	2	17OCT2020	3/4	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 4444 44441824	MUSC	Arthralgia/ Left shoulder pain	1	26SEP2020	2/24	1	No	O	NA	R (19OCT2020)	N/N
16-55/ C4591001 4444 44441825	MUSC	Back pain/ Back pain	1	11OCT2020	17/29	1	No	O	NA/TC	R (08NOV2020)	N/N
		Neck pain/ CERVICALGIA	1	11OCT2020	17/29	1	No	O	NA/TC	R (08NOV2020)	N/N
	MUSC	Back pain/ LUMBALGIA	1	26OCT2020	32/14	1	No	O	NA	R (08NOV2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
4444 44441840 16-55/ C4591001 4444 44441841	NERV	Sciatica/ Lumbociatalgia#	3	24FEB2021	2/4	2	No	O	NA/TC	R (27FEB2021)	N/N	
16-55/ C4591001 4444 44441851	INJ&P	Craniocerebral injury/ Polychontusion plus cranial brain trauma without loss of consciousness	2	06NOV2020	23/1	2	No	O	NA/TC/TCN	R (06NOV2020)	N/N	
16-55/ C4591001 4444 44441854	GENRL	Fatigue/ FATIGUE	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N	
		Injection site pain/ injection site pain	2	16OCT2020	2/5	1	Yes		NA	R (20OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia generalized	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N	
	NERV	Headache/ Headache	2	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N	
16-55/ C4591001 4444 44441859	GENRL	Asthenia/ Asthenia	2	16OCT2020	1/5	1	Yes		NA	R (20OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	16OCT2020	1/5	1	Yes		NA/TC	R (20OCT2020)	N/N	
16-55/ C4591001 4444 44441861	GENRL	Fatigue/ FATIGUE	2	16OCT2020	2/3	2	Yes		NA	R (18OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441872 16-55/ C4591001 4444 44441874 16-55/ C4591001 4444 44441881 16-55/ C4591001 4444 44441896 16-55/ C4591001 4444 44441900 16-55/ C4591001	MUSC	Injection site pain/ Injection site pain.	2	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N
		Pyrexia/ Fever	2	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
		Myalgia/ MYALGIAS	2	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N
	NERV	Headache/ Headache	2	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
	NERV	Headache/ headache	1	07OCT2020	13/3	1	No	O	NA/TC	R (09OCT2020)	N/N
	NERV	Headache/ headache	1	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N
	MUSC	Back pain/ Back pain	2	05NOV2020	23/C	1	No	O	NA/TC	RG	N/N
	GENRL	Pyrexia/ Fever	2	17OCT2020	3/2	1	Yes		NA/TC	R (18OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
MUSC	Myalgia/ Myalgia	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
4444 44441903	NERV	Headache/ Headache	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001 4444 44441909	INFEC	Infected dermal cyst/ Left preauricular epidermal cyst infection*		25SEP2020	1/40	2	No	O	NA/TC	R (03NOV2020)	N/N	
	SKIN	Dermal cyst/ Epidermal cyst on right and left preauricular region*		25SEP2020	1/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 4444 44441910	GENRL	Pyrexia/ Fever	2	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001 4444 44441916	MUSC	Muscle contracture/ Cervical contracture	1	02OCT2020	8/3	1	No	O	NA/TC	R (04OCT2020)	N/N	
16-55/ C4591001 4444 44441918	MUSC	Back pain/ Low back pain#	3	10FEB2021	17/19	1	No	O	NA/TC	R (28FEB2021)	N/N	
16-55/ C4591001 4444 44441933	GENRL	Axillary pain/ pain in right armpit	1	13OCT2020	19/3	1	No	O	NA	R (15OCT2020)	N/N	
16-55/ C4591001 4444 44441934	INFEC	Urinary tract infection/ Lower urinary tract infection	2	11NOV2020	28/6	1	No	CND	NA/TC	R (16NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 4444 44441937	MUSC	Back pain/ Low back pain	2	08NOV2020	26/13	2	No	O	NA/TC/TCN	R (20NOV2020)	N/N	
16-55/ C4591001 4444 44441949	NERV	Paraesthesia/ Paresthesia in the anterior aspect of the left thigh	2	11NOV2020	29/5	1	No	O	NA	R (15NOV2020)	N/N	
	INJ&P	Limb injury/ Right index finger injury#	4	13MAR2021	24/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 4444 44441953	PSYCH	Anxiety disorder/ Anxiety disorder	1	10OCT2020	16/2	1	No	O	NA/TC	R (11OCT2020)	N/N	
16-55/ C4591001 4444 44441955	GASTR	Gastritis/ Gastritis	1	04OCT2020	10/14	1	No	O	NA/TC	R (17OCT2020)	N/N	
16-55/ C4591001 4444 44441963	GENRL	Asthenia/ asthenia	2	17OCT2020	2/4	1	Yes		NA/TC	R (20OCT2020)	N/N	
		Pyrexia/ fever	2	17OCT2020	2/4	1	Yes		NA/TC	R (20OCT2020)	N/N	
	NERV	Headache/ headache	2	17OCT2020	2/4	1	Yes		NA/TC	R (20OCT2020)	N/N	
	NERV	Tremor/ BOTH HANDS FINE TREMOR	2	19OCT2020	4/2	1	Yes		NA	R (20OCT2020)	N/N	
16-55/ C4591001	GENRL	Asthenia/ Asthenia	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
4444 44441965		Pyrexia/ Fever	2	17OCT2020	2/2	2	Yes		NA/TC	R (18OCT2020)	N/N	
16-55/ C4591001 4444 44441967	SURG	Wisdom teeth removal/ Retained wisdom tooth extraction	1	09OCT2020	15/1	1	No	CND	NA	R (09OCT2020)	N/N	
16-55/ C4591001 4444 44441973	GENRL	Asthenia/ Asthenia	2	29OCT2020	1/2	2	Yes		NA/TCN	R (30OCT2020)	N/N	
16-55/ C4591001 4444 44441979	INJ&P	Injection site pain/ Injection site pain Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	2 1	29OCT2020 25SEP2020	1/2 1/C	1	Yes No	 O	NA/TC P	R (30OCT2020) UNK	N/N N/N	
16-55/ C4591001 4444 44441988	INFEC	Diverticulitis/ Diverticulitis	1	30SEP2020	6/22	2	No	O	NA/TC/TCN	R (21OCT2020)	N/N	
16-55/ C4591001 4444 44442007	GENRL	Injection site rash/ Erythematous rash at injection site#	4	01MAR2021	4/3	1	Yes		NA/TC	R (03MAR2021)	N/N	
16-55/ C4591001 4444 44442009	BLOOD	Lymphadenopathy/ left axillary adenopathy	2	15OCT2020	2/4	1	Yes		NA	R (18OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 4444 44442015	GASTR	Toothache/ Tooth pain	2	04NOV2020	20/3	1	No	O	NA/TC/TCN	R (06NOV2020)	N/N	
	SURG	Tooth extraction/ Tooth extraction	2	06NOV2020	22/1	1	No	O	NA	R (06NOV2020)	N/N	
16-55/ C4591001 4444 44442021	INJ&P	Ankle fracture/ Right ankle fracture	2	15NOV2020	32/68	3	No	O	NA/TC/TCN	R (21JAN2021)	Y/N	
		Fall/ fall from a bicycle	2	15NOV2020	32/1	2	No	O	NA/TCN	RS (15NOV2020)	N/N	
16-55/ C4591001 4444 44442032	MUSC	Arthralgia/ Worsening of Hands arthralgia episode	1	04OCT2020	10/27	1	No	O	NA	R (30OCT2020)	N/N	
16-55/ C4591001 4444 44442033	GENRL	Pyrexia/ fever	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N	
	MUSC	Myalgia/ myalgia	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N	
16-55/ C4591001 4444 44442035	GENRL	Injection site erythema/ injection site erythema	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N	
		Pyrexia/ Fever	2	17OCT2020	2/3	1	Yes		NA/TC	R (19OCT2020)	N/N	
	MUSC	Myalgia/ generalized Muscle pain	2	17OCT2020	2/19	1	Yes		NA	R (04NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 4444 44442037	NERV	Headache/ Headache	2	17OCT2020	2/3	1	Yes		NA/TC	R (19OCT2020)	N/N	
	NERV	Headache/ Headache	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N	
16-55/ C4591001 4444 44442041	INJ&P	Fall/ Fall down stairs	2	05DEC2020	51/1	1	No	O	NA	R (05DEC2020)	N/N	
		Humerus fracture/ Right displaced proximal humeral fracture	2	05DEC2020	51/41	2	No	O	NA/TC/TCN	R (14JAN2021)	Y/N	
	PSYCH	Adjustment disorder with depressed mood/ Reactive depression	2	25JAN2021	102/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 4444 44442047	GENRL	Pyrexia/ fever	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N	
	NERV	Headache/ headache	2	18OCT2020	3/2	1	Yes		NA/TC	R (19OCT2020)	N/N	
16-55/ C4591001 4444 44442050	GENRL	Asthenia/ Asthenia	2	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N	
		Pyrexia/ Fever	2	16OCT2020	1/3	2	Yes		NA/TC	R (18OCT2020)	N/N	
16-55/ C4591001	INFEC	Tonsillitis bacterial/ Bacterial tonsillitis	1	02OCT2020	8/8	1	No	O	NA/TC	R (09OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
4444 44442053 16-55/ C4591001 4444 44442062	GENRL	Pyrexia/ fever	2	15OCT2020	1/1	1	Yes		NA/TC	R (15OCT2020)	N/N	
4444 44442065 16-55/ C4591001 4444 44442069	REPRO	Metrorrhagia/ mild metrorrhagia	2	16OCT2020	2/C	1	No	O	NA	N	N/N	
4444 44442065 16-55/ C4591001 4444 44442071	VASC	Hypertension/ Arterial hypertension	2	17NOV2020	34/6	2	No	O	NA/TC	R (22NOV2020)	N/N	
4444 44442069 16-55/ C4591001 4444 44442081	ENDO	Hypothyroidism/ Worsening of hypothyroidism#	3	05MAR2021	9/C	1	No	O	NA/TC	N	N/N	
4444 44442071 16-55/ C4591001 4444 44442084	INFEC	Tooth infection/ odontogenic infection	1	10OCT2020	14/3	1	No	O	NA/TC	R (12OCT2020)	N/N	
4444 44442081 16-55/ C4591001 4444 44442084	GASTR	Constipation/ Constipation	1	28SEP2020	2/19	1	No	O	NA	R (16OCT2020)	N/N	
4444 44442084 16-55/ C4591001 4444 44442084	NERV	Sciatica/ lumbosciatalgia	1	07OCT2020	11/3	2	No	O	NA/TC	R (09OCT2020)	N/N	
4444 44442084 16-55/ C4591001	MUSC	Neck pain/ cervicalgia	2	19NOV2020	36/9	1	No	O	NA/TC/TCN	R (27NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
4444 44442101	GENRL	Pyrexia/ fever	2	16OCT2020	1/2	1	Yes		NA/TC	R (17OCT2020)	N/N	
16-55/ C4591001 4444 44442102	GENRL	Chills/ shaking chills	1	27SEP2020	1/2	2	Yes		NA/TC	R (28SEP2020)	N/N	
16-55/ C4591001 4444 44442105	MUSC	Myalgia/ Muscle pain	1	27SEP2020	1/3	2	Yes		NA/TC	R (29SEP2020)	N/N	
16-55/ C4591001 4444 44442106	MUSC	Myalgia/ generalized myalgia	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N	
16-55/ C4591001 4444 44442113	EYE	Conjunctivitis allergic/ worsening of allergic conjunctivitis	1	01OCT2020	5/6	1	No	O	NA	R (06OCT2020)	N/N	
16-55/ C4591001 4444 44442117	NERV	Headache/ headache	2	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001 4444 44442119	MUSC	Back pain/ Lumbar pain	2	13NOV2020	30/1	1	No	O	NA/TC	R (13NOV2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	2	16OCT2020	1/2	2	Yes		NA	R (17OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44442122	MUSC	Arthralgia/ generalized arthralgia	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
	NERV	Headache/ headache	2	17OCT2020	2/1	2	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 4444 44442124	SKIN	Rash maculo-papular/ maculopapular rash on the face, upper limbs and abdomen	2	14NOV2020	30/7	1	No	O	NA/TC	R (20NOV2020)	N/N
16-55/ C4591001 4444 44442135	GENRL	Pyrexia/ fever of 38 degrees Celsius	2	15OCT2020	1/2	1	Yes		NA/TCN	R (16OCT2020)	N/N
	GENRL	Injection site swelling/ injection site swelling	2	16OCT2020	2/6	1	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C4591001 4444 44442146	GENRL	Pyrexia/ fever	2	17OCT2020	2/3	2	Yes		NA/TC/TCN	R (19OCT2020)	N/N
16-55/ C4591001 4444 44442151	MUSC	Neck pain/ Acute Cervicalgia	2	16NOV2020	33/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 4444 44442154	GENRL	Pyrexia/ low grade fever	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	NERV	Headache/ headache	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N	
16-55/ C4591001 4444 44442157	GENRL	Injection site pain/ injection site pain	2	14NOV2020	1/2	1	Yes		NA	R (15NOV2020)	N/N	
16-55/ C4591001 4444 44442159	MUSC	Myalgia/ myalgia.	2	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N	
	NERV	Headache/ headache.	2	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001 4444 44442160	INFEC	Vaginal infection/ vaginal infection	2	11NOV2020	28/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 4444 44442163	MUSC	Back pain/ back pain	2	16OCT2020	1/C	1	No	O	NA	RG	N/N	
	GENRL	Pyrexia/ fever	2	17OCT2020	2/1	2	Yes		NA/TC/TCN	R (17OCT2020)	N/N	
16-55/ C4591001 4444 44442167	GENRL	Injection site erythema/ Injection site erythema	2	17OCT2020	2/4	1	Yes		NA/TCN	R (20OCT2020)	N/N	
		Injection site pain/ Injection site pain (left arm)	2	17OCT2020	2/3	1	Yes		NA	R (19OCT2020)	N/N	
16-55/ C4591001	GENRL	Asthenia/ Asthenia	2	17OCT2020	2/4	2	Yes		NA/TC	R (20OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44442171		Pyrexia/ Fever 39,2 c	2	17OCT2020	2/1	3	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 4444 44442182	GENRL	Pyrexia/ Fever	2	16OCT2020	1/2	1	Yes		NA/TCN	R (17OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 4444 44442193	GENRL	Injection site pain/ Pain at injection site	1	27SEP2020	1/16	1	Yes		NA	R (12OCT2020)	N/Y
	GENRL	Asthenia/ Asthenia	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
		Injection site pain/ Right arm pain at the injection site of the research product	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 4444 44442203	MUSC	Myalgia/ Myalgia	2	16OCT2020	1/2	2	Yes		NA/TC	R (17OCT2020)	N/N
	NERV	Dizziness/ Dizziness	2	09NOV2020	25/1	1	No	O	NA	R (09NOV2020)	N/N
16-55/ C4591001 4444 44442215	NERV	Headache/ headache	2	16OCT2020	2/6	2	Yes		NA/TC	R (21OCT2020)	N/N
	PSYCH	Insomnia/ Insomnia	2	04DEC2020	51/C	1	No	O	NA/TC	N	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 4444 44442221	GENRL	Pyrexia/ Febrile syndrome	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N	
16-55/ C4591001 4444 44442226	INFEC	Paronychia/ Periungual infection of the index finger	2	09NOV2020	26/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 4444 44442230	GENRL	Pyrexia/ Isolated feverish record	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N	
	MUSC	Myalgia/ generalized myalgia	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N	
16-55/ C4591001 4444 44442232	MUSC	Back pain/ Low back pain	1	12OCT2020	16/2	2	No	O	NA/TC	R (13OCT2020)	N/N	
16-55/ C4591001 4444 44442237	GENRL	Injection site pain/ Pain at injection site	2	15OCT2020	1/1	1	Yes		NA/TC	R (15OCT2020)	N/N	
16-55/ C4591001 4444 44442241	NERV	Headache/ headache	2	18OCT2020	4/1	1	No	O	NA/TC/TCN	R (18OCT2020)	N/N	
16-55/ C4591001 4444 44442268	REPRO	Amenorrhoea/ amenorrhoea	2	10NOV2020	27/13	1	No	O	NA	R (22NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 4444 44442274	MUSC	Back pain/ back pain	1	13OCT2020	17/2	2	No	O	NA/TC	R (14OCT2020)	N/N	
	GASTR	Diarrhoea/ diarrhea	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N	
16-55/ C4591001 4444 44442278	GENRL	Pyrexia/ Fever	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N	
	VASC	Hypertensive urgency/ Hypertensive urgency	2	04MAR2021	141/1	3	No	O	NA/TC	R (04MAR2021)	Y/N	
16-55/ C4591001 4444 44442281	GASTR	Toothache/ Odontalgia	1	10OCT2020	14/5	1	No	O	NA/TC	R (14OCT2020)	N/N	
	INFEC	Gingivitis/ gingivitis	1	10OCT2020	14/5	1	No	O	NA/TC	R (14OCT2020)	N/N	
		Tooth infection/ odontogenic infection	1	10OCT2020	14/5	1	No	O	NA/TC	R (14OCT2020)	N/N	
16-55/ C4591001 4444 44442299	GENRL	Injection site pain/ Post vaccination injection site pain.	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N	
16-55/ C4591001 4444 44442304	METAB	Hyperglycaemia/ hyperglycemia	2	29OCT2020	15/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001	MUSC	Myalgia/ Myalgia	2	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
4444 44442306	NERV	Headache/ Headache with mild retro ocular pain	2	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N	
16-55/ C4591001 4444 44442311	GENRL	Pyrexia/ Fever	2	24OCT2020	2/3	1	Yes		NA/TC	R (26OCT2020)	N/N	
16-55/ C4591001 4444 44442314	VASC	Hypotension/ Mild arterial hypotension	2	12FEB2021	121/1	1	No	O	NA	R (12FEB2021)	N/N	
16-55/ C4591001 4444 44442317	GENRL	Injection site pain/ pain at the injection site	2	16OCT2020	1/1	1	Yes		NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001 4444 44442319	PSYCH	Pyrexia/ fever Panic attack/ Worsening of panic attacks	2	16OCT2020	1/1	1	Yes		NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001 4444 44442319	PSYCH	Panic attack/ Worsening of panic attacks	1	15OCT2020	19/C	3	No	O	P/W	N	N/N	
>55/ C4591001 1001 10011093	GENRL	Chest pain/ Chest Pain	2	10JAN2021	145/6	2	No	O	NA/TC/TCN	R (15JAN2021)	Y/N	
>55/ C4591001 1001 10011099	GENRL	Chills/ Chills	1	15AUG2020	17/2	1	No	O	NA	R (16AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1001 10011100	SKIN	Dermatitis contact/ poison ivy	1	11AUG2020	13/21	2	No	O	NA/TC	R (31AUG2020)	N/N	
	SKIN	Dermatitis/ Dermatitis of trunk	2	25AUG2020	8/10	2	No	O	NA/TC	R (03SEP2020)	N/N	
	INJ&P	Fall/ fall	2	12DEC2020	117/1	2	No	O	NA	R (12DEC2020)	N/N	
		Foot fracture/ R 5th metatarsal fracture	2	12DEC2020	117/C	2	No	O	NA/TC/TCN	RG	Y/N	
		Radius fracture/ L radial head fracture	2	12DEC2020	117/C	2	No	O	NA/TC/TCN	RG	Y/N	
	MUSC	Trigger finger/ R pinky finger trigger finger	2	01JAN2021	137/C	2	No	O	NA/TCN	N	N/N	
>55/ C4591001 1001 10011110	VASC	Raynaud's phenomenon/ exacerbation of raynaud's disease	2	02SEP2020	13/C	1	No	O	NA	N	N/N	
>55/ C4591001 1001 10011114	GASTR	Gingival discomfort/ gum irritation	1	17AUG2020	15/2	1	Yes		NA/TC	R (18AUG2020)	N/N	
>55/ C4591001 1001 10011118	EAR	Vertigo/ exacerbation of vertigo	2	25AUG2020	2/7	1	Yes		NA	R (31AUG2020)	N/N	
>55/ C4591001 1001 10011120	SKIN	Rash/ Rash on back	2	28DEC2020	126/C	2	No	O	NA/TC	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1001 10011121	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	2	10SEP2020	17/11	1	No	O	NA	R (20SEP2020)	N/N	
>55/ C4591001 1001 10011133	EYE	Cataract/ worsening bilateral cataracts	1	2020	1/C	2	No	O	NA	RG	N/N	
	GASTR	Nausea/ Nausea	1	22AUG2020	18/2	1	No	O	NA/TC	R (23AUG2020)	N/N	
	EYE	Cataract/ Worsened cataract right eye	2	09NOV2020	75/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1001 10011142	GASTR	Diarrhoea/ diarrhea	2	01SEP2020	8/3	1	Yes		NA	R (03SEP2020)	N/N	
>55/ C4591001 1001 10011144	GENRL	Injection site discomfort/ injection site discomfort	2	07SEP2020	11/1	1	Yes		NA	R (07SEP2020)	N/N	
>55/ C4591001 1001 10011147	MUSC	Osteoarthritis/ Exacerbation of degenerative joint disease	2	31AUG2020	4/77	1	No	O	NA	R (15NOV2020)	N/N	
>55/ C4591001 1001 10011148	GENRL	Injection site pain/ muscle tenderness at injection site	2	04SEP2020	8/8	1	Yes		NA	R (11SEP2020)	N/N	
>55/ C4591001	INJ&P	Contusion/ Bruising on the upper left arm deltoid region	1	05AUG2020	10/28	1	Yes		NA	R (01SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1003 10031091	INJ&P	Tendon rupture/ Torn Lateral Epicondyle tendon	1	09AUG2020	13/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1003 10031092	GENRL	Injection site swelling/ Swelling at injection site	1	31JUL2020	4/10	1	Yes		NA	R (09AUG2020)	N/N	
>55/ C4591001 1003 10031099	GASTR	Odynophagia/ occasional odynophagia	1	12AUG2020	15/6	1	No	O	NA	R (17AUG2020)	N/N	
1003 10031105	MUSC	Neck pain/ Left sided neck pain	1	12AUG2020	15/6	1	No	O	NA	R (17AUG2020)	N/N	
>55/ C4591001 1003 10031107	GASTR	Diarrhoea/ Diarrhea	1	05AUG2020	8/2	1	No	O	NA	R (06AUG2020)	N/N	
>55/ C4591001 1003 10031109	INJ&P	Muscle rupture/ Torn Right Bicep Muscle	1	13AUG2020	15/15	2	No	O	NA	R (27AUG2020)	N/N	
>55/ C4591001 1003 10031113	RESP	Interstitial lung disease/ worsening of interstitial lung disease	2	17OCT2020	59/C	4	No	O	NA/TC/TCN	RG	Y/N	
	INV	Autoantibody positive/ positive autoantibody status	2	20OCT2020	62/C	3	No	O	NA/TC/TCN	RG	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	RESP	Respiratory failure/ respiratory failure	2	11JAN2021	145/C	2	No	O	NA/TC	RG	Y/N	
>55/ C4591001 1003 10031120	INFEC	Diverticulitis/ Possible Flare Up of Diverticulitis	1	11AUG2020	12/2	1	No	O	NA/TC	R (12AUG2020)	N/N	
>55/ C4591001 1003 10031130	INJ&P	Skin laceration/ L middle finger sliced while fixing food	1	08AUG2020	6/7	1	No	O	NA/TC	R (14AUG2020)	N/N	
>55/ C4591001 1003 10031131	VASC	Hypertension/ worsening of hypertension*		03AUG2020	1/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1003 10031135	MUSC	Muscular weakness/ episodic muscle weakness arm	2	19OCT2020	57/C	1	No	O	NA	N	N/N	
>55/ C4591001 1003 10031139	EAR	Vertigo positional/ worsening of benign paroxysmal positional vertigo	1	12AUG2020	9/27	3	No	O	NA/TC	R (07SEP2020)	N/N	
	SKIN	Dermatitis contact/ poison ivy - Righ arm, both hands and legs	1	22AUG2020	19/11	2	No	O	NA/TC	R (01SEP2020)	N/N	
	GASTR	Hiatus hernia/ hiatal hernia#	3	03FEB2021	7/C	2	No	O	NA/TC	RG	N/N	
	INFEC	Diverticulitis/ rule out diverticulitis#	3	16FEB2021	20/C	3	No	O	NA/TC	N	N/N	
>55/ C4591001	GASTR	Small intestinal obstruction/ small bowel obstruction	1	08AUG2020	4/3	4	No	O	NA/TC/TCN	R (10AUG2020)	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1003 10031149	PSYCH	Panic attack/ suspected panic attack	2	28DEC2020	125/2	3	No	O	NA	R (29DEC2020)	Y/N	
>55/ C4591001 1003 10031167	GENRL	Pyrexia/ Low Grade Fever - 100.0F	1	08AUG2020	2/1	1	Yes		NA/TC	R (08AUG2020)	N/N	
>55/ C4591001 1003 10031182	MUSC	Myalgia/ Myalgia	1	08AUG2020	2/5	2	Yes		NA/TC	R (12AUG2020)	N/N	
>55/ C4591001 1003 10031182	GASTR	Inguinal hernia/ right inguinal hernia	1	25AUG2020	15/32	2	No	O	NA/TCN	R (25SEP2020)	N/N	
>55/ C4591001 1003 10031195	SURG	Inguinal hernia repair/ laparoscopic right inguinal hernia repair	2	24SEP2020	24/2	3	No	O	NA/TC/TCN	R (25SEP2020)	N/N	
>55/ C4591001 1003 10031195	INFEC	Diverticulitis/ Diverticulitis	2	28SEP2020	26/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1003 10031208	GASTR	Abdominal rigidity/ Abdominal Spasms	2	16SEP2020	13/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001	MUSC	Muscle spasms/ Back Pain Spasms	2	16SEP2020	13/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001	GASTR	Constipation/ constipation	2	21SEP2020	18/C	3	No	O	NA/TC	N	N/N	
>55/ C4591001	INJ&P	Arthropod bite/ Tick bite	1	28AUG2020	19/1	1	No	O	NA	R (28AUG2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1005 10051006 >55/ C4591001 1005 10051009	GENRL	Injection site pain/ injection site pain#	4	09FEB2021	1/4	2	Yes		NA	R (12FEB2021)	N/N
		Pyrexia/ fever 101F#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1005 10051011	INJ&P	Arthropod bite/ TICK BITE	1	12AUG2020	3/15	1	No	O	NA/TC	R (26AUG2020)	N/N
	MUSC	Pain in extremity/ BILATERAL LEG PAIN	2	01SEP2020	2/2	1	Yes		NA/TC	R (02SEP2020)	N/N
	MUSC	Pain in extremity/ left arm pain	2	14OCT2020	45/C	2	No	O	NA	N	N/N
	MUSC	Pain in extremity/ right arm pain#	3	14JAN2021	1/C	2	Yes		NA	N	N/N
>55/ C4591001 1005 10051021	GASTR	Parotid duct obstruction/ LEFT PAROTID GLAND OBSTRUCTION	2	05SEP2020	6/6	1	No	O	NA/TC	R (10SEP2020)	N/N
>55/ C4591001 1005 10051022	GASTR	Diarrhoea/ DIARRHEA	1	17AUG2020	7/2	1	No	O	NA	R (18AUG2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	06SEP2020	7/4	1	Yes		NA/TC	R (09SEP2020)	N/N
>55/ C4591001	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	22SEP2020	23/5	1	No	O	NA/TC	R (26SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1005 10051023 >55/ C4591001 1005 10051025	GENRL	Fatigue/ FATIGUE	2	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
>55/ C4591001 1005 10051047	PSYCH	Irritability/ IRRITABLE	2	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
>55/ C4591001 1005 10051049	VASC	Aortic aneurysm/ AORTIC ANEURYSM	2	20NOV2020	81/70	3	No	O	NA/TC	R (28JAN2021)	Y/N
>55/ C4591001 1005 10051049	GENRL	Chills/ chills#	4	08MAR2021	1/2	1	Yes		NA	R (09MAR2021)	N/N
>55/ C4591001 1005 10051069	MUSC	Pyrexia/ fever 101F# Myalgia/ generalized myalgia#	4	08MAR2021	1/2	2	Yes		NA/TC	R (09MAR2021)	N/N
>55/ C4591001 1005 10051078	NEOPL	Breast cancer/ LEFT BREAST CANCER	2	04SEP2020	3/131	2	No	O	NA/TC	R (12JAN2021)	Y/N
>55/ C4591001 1005 10051078	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
>55/ C4591001 1005 10051078	SKIN	Dermal cyst/ CYST ON LOWER BACK	1	22AUG2020	4/12	1	No	O	NA/TC	R (02SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1005 10051083	GENRL	Injection site pain/ INJECTION SITE PAIN	1	20AUG2020	2/2	1	Yes		NA/TC	R (21AUG2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	GASTR	Nausea/ NAUSEA	2	14SEP2020	6/2	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	14SEP2020	6/2	2	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	14SEP2020	6/2	2	Yes		NA/TC	R (15SEP2020)	N/N
>55/ C4591001 1005 10051088	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N
	GENRL	Pyrexia/ FEVER 102F	2	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1005 10051090	NERV	Headache/ HEADACHE	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N
	RESP	Oropharyngeal pain/ SORE THROAT	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N
	RESP	Cough/ COUGH	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 10051005 10051091	GENRL	Oropharyngeal pain/ SORE THROAT	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	1	20AUG2020	1/2	2	Yes		NA/TC	R (21AUG2020)	N/N
>55/ C4591001 10051005 10051098	GENRL	Injection site pain/ INJECTION SITE PAIN	1	21AUG2020	2/3	1	Yes		NA	R (23AUG2020)	N/N
>55/ C4591001 10051005 10051102	GENRL	Fatigue/ FATIGUE	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
	PSYCH	Injection site pain/ INJECTION SITE PAIN	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
		Abnormal dreams/ VIVID DREAMS	1	23AUG2020	4/2	1	Yes		NA	R (24AUG2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	MUSC	Myalgia/ GENERALIZED MYALGIA	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Injection site erythema/ INJECTION SITE REDNESS	2	13SEP2020	4/1	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site warmth/ WARMTH AT INJECTION SITE	2	13SEP2020	4/1	1	Yes		NA	R (13SEP2020)	N/N
		Injection site pruritus/ INJECTION SITE PRURITUS	2	14SEP2020	5/2	1	Yes		NA	R (15SEP2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1005 10051103	GASTR	Nausea/ NAUSEA	2	09SEP2020	1/3	2	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	09SEP2020	1/6	2	Yes		NA	R (14SEP2020)	N/N
		Pyrexia/ FEVER	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
	MUSC	Arthralgia/ GENERALIZED JOINT PAIN	2	09SEP2020	1/6	2	Yes		NA	R (14SEP2020)	N/N
		Myalgia/ GENERALIZED MYALGIA	2	09SEP2020	1/3	2	Yes		NA	R (11SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	09SEP2020	1/37	3	Yes		NA/TC	R (15OCT2020)	N/N
>55/ C4591001 1005 10051104	GENRL	Injection site pain/ INJECTION SITE PAIN	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	10SEP2020	1/3	2	Yes		NA	R (12SEP2020)	N/N
	MUSC	Myalgia/ MYALGIA	2	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
>55/ C4591001 1005 10051114	GENRL	Chills/ CHILLS	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		Fatigue/ FATIGUE	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	MUSC	Myalgia/ GENERALIZED MYALGIA	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1005 10051116	GENRL	Injection site pain/ soreness at injection site	1	21AUG2020	1/3	1	Yes		NA/TC	R (23AUG2020)	N/N	
	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	21SEP2020	12/11	2	No	O	NA/TC	R (01OCT2020)	N/N	
>55/ C4591001 1005 10051124	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N	
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N	
	GENRL	Chills/ CHILLS	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
		Pyrexia/ FEVER 101F	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
>55/ C4591001 1005 10051130	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	25AUG2020	2/8	1	Yes		NA	R (01SEP2020)	N/N	
	GENRL	Chills/ CHILLS	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	
		Pyrexia/ FEVER 100.5	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	
>55/ C4591001 1005 10051131	GENRL	Injection site pain/ Injection site pain	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N	
>55/ C4591001	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1005 10051136	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
	NERV	Headache/ HEADACHE	2	16SEP2020	2/1	2	Yes		NA/TC	R (16SEP2020)	N/N	
>55/ C4591001 1005 10051137	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N	
>55/ C4591001 1005 10051138	GENRL	Injection site pain/ INJECTION SITE PAIN	1	25AUG2020	1/2	2	Yes		NA/TC	R (26AUG2020)	N/N	
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	16SEP2020	1/3	1	Yes		NA/TC	R (18SEP2020)	N/N	
>55/ C4591001 1005 10051143	ENDO	Hyperthyroidism/ hyperthyroidism	2	25NOV2020	71/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1005 10051152	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N	
>55/ C4591001 1005 10051155	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	15JAN2021	1/3	1	Yes		NA	R (17JAN2021)	N/N	
>55/ C4591001	RESP	Paranasal sinus discomfort/ SINUS PRESSURE	2	14OCT2020	29/2	1	No	O	NA/TC	R (15OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1005 10051156 >55/ C4591001 1005 10051158	GENRL	Injection site pain/ INJECTION SITE PAIN	2	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N
		Malaise/ MALAISE	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001 1005 10051160	GENRL	Fatigue/ FATIGUE	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Myalgia/ GENERALIZED MYALGIA	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1005 10051162	GENRL	Injection site pain/ INJECTION SITE PAIN	1	27AUG2020	2/1	1	Yes		NA	R (27AUG2020)	N/N
>55/ C4591001 1005 10051173	GENRL	Injection site pain/ INJECTION SITE PAIN IN LEFT ARM	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
		Injection site pain/ INJECTION SITE TENDERNESS IN LEFT ARM	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1005 10051177	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	27AUG2020	1/4	1	Yes		NA	R (30AUG2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Malaise/ MALAISE	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N	
	MUSC	Myalgia/ GENERALIZED MYALGIA	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N	
	NERV	Headache/ HEADACHE	1	12SEP2020	17/2	1	No	O	NA/TC	R (13SEP2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N	
	GENRL	Fatigue/ FATIGUE	2	17SEP2020	2/3	2	Yes		NA	R (19SEP2020)	N/N	
		Malaise/ MALAISE	2	17SEP2020	2/3	2	Yes		NA	R (19SEP2020)	N/N	
	MUSC	Myalgia/ GENERALIZED MYALGIA	2	17SEP2020	2/3	2	Yes		NA	R (19SEP2020)	N/N	
>55/ C4591001 1005 10051180	GENRL	Fatigue/ FATIGUE	2	19SEP2020	3/2	1	Yes		NA	R (20SEP2020)	N/N	
	MUSC	Myalgia/ MYALGIA	2	19SEP2020	3/2	1	Yes		NA	R (20SEP2020)	N/N	
>55/ C4591001 1005 10051185	INFEC	Tooth infection/ DENTAL INFECTION	1	09SEP2020	10/156	2	No	O	NA/TC	R (11FEB2021)	N/N	
	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	1	17SEP2020	18/17	2	No	O	NA	R (03OCT2020)	N/N	
>55/ C4591001 1005 10051186	GENRL	Fatigue/ FATIGUE	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1005 10051191	GENRL	Injection site pain/ INJECTION SITE PAIN	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N	
		Injection site pain/ INJECTION SITE PAIN	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	21SEP2020	1/5	1	Yes		NA	R (25SEP2020)	N/N	
	GENRL	Chills/ CHILLS	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
		Fatigue/ FATIGUE	2	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N	
>55/ C4591001 1005 10051193	INFEC	Gastroenteritis/ GASTROENTERITIS	1	18SEP2020	17/2	2	No	O	NA	R (19SEP2020)	N/N	
	INFEC	Herpes zoster/ shingles#	4	02MAR2021	27/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1005 10051196	INFEC	Tooth infection/ TOOTH INFECTION	2	22OCT2020	28/5	2	No	O	NA/TC	R (26OCT2020)	N/N	
>55/ C4591001 1005 10051201	MUSC	Myalgia/ GENERALIZED MYALGIA	1	05SEP2020	3/8	2	Yes		NA	R (12SEP2020)	N/N	
	NERV	Headache/ HEADACHE	1	05SEP2020	3/2	1	Yes		NA	R (06SEP2020)	N/N	
	MUSC	Myalgia/ GENERALIZED MYALGIA	2	22SEP2020	1/3	2	Yes		NA/TC	R (24SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1005 10051202	NERV	Headache/ HEADACHE	2	22SEP2020	1/5	2	Yes		NA/TC	R (26SEP2020)	N/N
	MUSC	Arthralgia/ KNEE PAIN	2	29SEP2020	8/C	1	No	O	NA	N	N/N
	RESP	Sleep apnoea syndrome/ sleep apnea	2	18DEC2020	86/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1005 10051204	INJ&P	Muscle strain/ right neck muscle strain	2	28DEC2020	96/55	1	No	O	NA/TC	R (20FEB2021)	N/N
	GENRL	Fatigue/ FATIGUE	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	22SEP2020	1/6	2	Yes		NA	R (27SEP2020)	N/N
>55/ C4591001 1005 10051206		Pyrexia/ FEVER 100.5	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ MYALGIA	2	22SEP2020	1/2	2	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	18OCT2020	25/4	2	No	O	NA	R (21OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	4	05FEB2021	2/3	1	Yes		NA	R (07FEB2021)	N/N
		Injection site pain/ injection site pain#	4	05FEB2021	2/3	1	Yes		NA	R (07FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1005 10051211	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
>55/ C4591001 1005 10051213	SURG	Toe amputation/ PARTIAL LEFT 3RD TOE AMPUTATION	2	27NOV2020	65/1	2	No	O	NA	R (27NOV2020)	N/N
>55/ C4591001 1005 10051214	GENRL	Injection site pain/ INJECTION SITE PAIN	1	04SEP2020	2/4	2	Yes		NA	R (07SEP2020)	N/N
	GENRL	Facial pain/ FACIAL TENDERNESS	1	06SEP2020	4/11	2	No	O	P/TC	R (16SEP2020)	N/N
		Swelling face/ FACIAL SWELLING	1	06SEP2020	4/11	2	No	O	P/TC	R (16SEP2020)	N/N
	INFEC	Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	1	06SEP2020	4/11	2	No	O	NA/TC	R (16SEP2020)	N/N
>55/ C4591001 1005 10051227	GENRL	Chills/ CHILLS#	4	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
	MUSC	Myalgia/ GENERALIZED MYALGIA#	4	08JAN2021	1/3	2	Yes		NA/TC	R (10JAN2021)	N/N
>55/ C4591001 1005 10051231	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	26JAN2021	1/6	1	Yes		NA	R (31JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Nausea/ NAUSEA#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1005 10051247	MUSC	Back pain/ BACK PAIN	1	16OCT2020	4/47	1	No	O	NA/TC	R (01DEC2020)	N/N
>55/ C4591001 1005 10051250	INFEC	Tooth abscess/ LEFT UPPER DENTAL ABCESS	2	05NOV2020	2/62	2	No	O	NA/TC/TCN	R (05JAN2021)	N/N
>55/ C4591001 1005 10051262	MUSC	Neck pain/ NECK ACHE	1	15OCT2020	1/4	1	Yes		NA	R (18OCT2020)	N/N
>55/ C4591001 1005 10051263	GENRL	Chills/ CHILLS	2	05NOV2020	1/2	2	Yes		NA	R (06NOV2020)	N/N
		Fatigue/ FATIGUE	2	05NOV2020	1/5	2	Yes		NA	R (09NOV2020)	N/N
	MUSC	Myalgia/ MYALGIA	2	05NOV2020	1/5	2	Yes		NA/TC	R (09NOV2020)	N/N
>55/ C4591001 1005 10051265	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	15OCT2020	1/4	1	Yes		NA	R (18OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	METAB	Decreased appetite/ LOSS OF APPETITE	1	15OCT2020	1/68	1	Yes		NA	R (21DEC2020)	N/N
>55/ C4591001 1005 10051266	GENRL	Fatigue/ FATIGUE#	3	28JAN2021	3/4	2	Yes		NA	R (31JAN2021)	N/N
	NERV	Dizziness/ DIZZINESS#	3	30JAN2021	5/2	2	Yes		NA	R (31JAN2021)	N/N
>55/ C4591001 1005 10051272	GENRL	Chills/ CHILLS	2	03NOV2020	1/2	2	Yes		NA	R (04NOV2020)	N/N
		Fatigue/ FATIGUE	2	03NOV2020	1/2	2	Yes		NA	R (04NOV2020)	N/N
	MUSC	Myalgia/ MYALGIA	2	03NOV2020	1/2	2	Yes		NA	R (04NOV2020)	N/N
>55/ C4591001 1005 10051275	GENRL	Malaise/ MALAISE	1	18OCT2020	4/3	2	Yes		NA	R (20OCT2020)	N/N
>55/ C4591001 1005 10051282	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
>55/ C4591001 1005 10051293	CARD	Cardiac arrest/ CARDIAC ARREST	1	08NOV2020	21/1	4	No	O	NA/TC	R (08NOV2020)	Y/N
	INJ&P	Overdose/ Overdose	1	08NOV2020	21/1	4	No	O	NA	R (08NOV2020)	Y/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	RESP	Acute respiratory failure/ Acute Respiratory Failure	1	08NOV2020	21/C	4	No	O	NA	RG	Y/N	
>55/ C4591001 1005 10051304	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N	
	GENRL	Injection site pain/ TENDERNESS AT INJECTION SITE	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N	
	PSYCH	Insomnia/ INSOMNIA	2	09NOV2020	1/2	2	Yes		NA	R (10NOV2020)	N/N	
	GENRL	Pain/ GENERALIZED BODY ACHES	2	10NOV2020	2/2	2	Yes		NA/TC	R (11NOV2020)	N/N	
>55/ C4591001 1005 10051320	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	21OCT2020	2/20	1	Yes		NA	R (09NOV2020)	N/N	
>55/ C4591001 1005 10051321	GENRL	Injection site pain/ MILD INJECTION SITE PAIN	2	11NOV2020	1/4	1	Yes		NA	R (14NOV2020)	N/N	
>55/ C4591001 1005 10051336	PSYCH	Libido decreased/ LOW LIBIDO	1	06NOV2020	17/C	1	No	O	NA	N	N/N	
>55/ C4591001 1005 10051347	BLOOD	Lymphadenopathy/ ENLARGED LYMPH NODE LEFT AXILLA#	4	12JAN2021	2/15	1	Yes		NA	R (26JAN2021)	N/N	
	GENRL	Chills/ CHILLS#	4	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1005 10051348	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Pyrexia/ FEVER	2	13NOV2020	2/1	1	Yes		NA/TC	R (13NOV2020)	N/N
>55/ C4591001 1005 10051351	MUSC	Myalgia/ GENERALIZED MYALGIA	2	13NOV2020	2/1	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	10NOV2020	1/4	1	Yes		NA	R (13NOV2020)	N/N
>55/ C4591001 1005 10051355	GENRL	Injection site pain/ TENDERNESS AT INJECTION SITE	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
>55/ C4591001 1005 10051360	GENRL	Chills/ chills#	3	09MAR2021	1/2	1	Yes		NA	R (10MAR2021)	N/N
	MUSC	Myalgia/ generalized myalgia#	3	09MAR2021	1/2	1	Yes		NA	R (10MAR2021)	N/N
>55/ C4591001 1005 10051373	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	17NOV2020	2/2	1	Yes		NA	RS (18NOV2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	26OCT2020	1/3	2	Yes		NA	R (28OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1005 10051374	NERV	Headache/ HEADACHE	1	26OCT2020	1/2	2	Yes		NA/TC	R (27OCT2020)	N/N
>55/ C4591001 1005 10051382	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	29OCT2020	2/3	1	Yes		NA	R (31OCT2020)	N/N
>55/ C4591001 1005 10051387	GENRL	Injection site pain/ INJECTION SITE PAIN	1	30OCT2020	2/2	1	Yes		NA	R (31OCT2020)	N/N
	MUSC	Myalgia/ MYALGIA	2	17NOV2020	1/2	2	Yes		NA	R (18NOV2020)	N/N
	BLOOD	Lymphadenopathy/ SWOLLEN LYMPH NODE UNDER LEFT ARM	2	18NOV2020	2/32	1	Yes		NA	R (19DEC2020)	N/N
>55/ C4591001 1005 10051389	GENRL	Pyrexia/ FEVER 100.5	2	18NOV2020	2/1	1	Yes		NA	R (18NOV2020)	N/N
	MUSC	Myalgia/ MYALGIA	2	18NOV2020	2/1	1	Yes		NA	R (18NOV2020)	N/N
	NERV	Headache/ HEADACHES	2	18NOV2020	2/1	2	Yes		NA/TC	R (18NOV2020)	N/N
>55/ C4591001 1005 10051395	GENRL	Injection site pain/ INJECTION SITE TENDERNESS	1	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ GENERALIZED MYALGIA	2	23NOV2020	1/2	2	Yes		NA/TC	R (24NOV2020)	N/N
	VASC	Flushing/ FACIAL FLUSHING	2	23NOV2020	1/1	1	Yes		NA	R (23NOV2020)	N/N
>55/ C4591001 1005 10051399	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	24NOV2020	1/2	1	Yes		NA	R (25NOV2020)	N/N
>55/ C4591001 1005 10051402	GENRL	Injection site pain/ INJECTION SITE PAIN	2	24NOV2020	2/2	1	Yes		NA	R (25NOV2020)	N/N
	MUSC	Myalgia/ WORSENING OF GENERALIZED MUSCLE ACHES	2	24NOV2020	2/1	2	Yes		NA/TC	R (24NOV2020)	N/N
>55/ C4591001 1005 10051403	GENRL	Injection site pain/ INJECTION SITE PAIN	1	04NOV2020	1/4	2	Yes		NA/TC	R (07NOV2020)	N/N
>55/ C4591001 1005 10051406	GENRL	Fatigue/ fatigue	1	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N
		Injection site pain/ Injection site pain	1	09NOV2020	1/8	1	Yes		NA	R (16NOV2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	30NOV2020	1/3	1	Yes		NA/TC	R (02DEC2020)	N/N
	GENRL	Malaise/ MALAISE	2	01DEC2020	2/3	1	Yes		NA/TC	R (03DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1006 10061006	SURG	Postoperative care/ RIGHT CATARACT REPAIR AFTERCARE	1	14AUG2020	5/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1006 10061017	GENRL	Injection site pain/ Injection Site Tenderness#	4	01FEB2021	1/4	1	Yes		NA	R (04FEB2021)	N/N	
		Malaise/ Malaise#	4	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N	
>55/ C4591001 1006 10061020	CARD	Angina pectoris/ ANGINA	1	21AUG2020	10/7	2	No	O	NA/TCN	R (27AUG2020)	N/N	
	CARD	Acute myocardial infarction/ NON-ST ELEVATED MYOCARDIAL INFARCTION	1	25AUG2020	14/3	3	No	O	NA/TC/TCN	R (27AUG2020)	N/N	
		Coronary artery occlusion/ CORONARY ARTERY OCCLUSION	1	25AUG2020	14/3	4	No	O	P/TC/TCN/W	R (27AUG2020)	Y/N	
		Mitral valve incompetence/ MITRAL VALVE REGURGITATION	1	25AUG2020	14/3	3	No	O	NA/TCN	R (27AUG2020)	N/N	
	RESP	Dyspnoea exertional/ DYSPNEA ON EXERTION	1	25AUG2020	14/3	2	No	O	NA/TCN	R (27AUG2020)	N/N	
>55/ C4591001 1006 10061025	IMMUN	Seasonal allergy/ WORSENING SEASONAL ALLERGIES	1	30AUG2020	19/94	1	No	O	NA/TC	R (01DEC2020)	N/N	
>55/ C4591001 1006 10061030	INJ&P	Tooth fracture/ Broken Tooth	2	15SEP2020	13/C	2	No	O	NA/TC/TCN	RG	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1006 10061035	INFEC	Tooth abscess/ Abscessed Tooth	2	29JAN2021	148/4	2	No	O	NA/TC/TCN	R (01FEB2021)	N/N
>55/ C4591001 1006 10061046	GENRL	Pain/ Body Aches#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1006 10061047	GENRL	Pain/ Body Aches#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1006 10061064	GENRL	Chills/ Chills#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1006 10061086	GENRL	Injection site pain/ INJECTION SITE PAIN LEFT ARM#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
>55/ C4591001 1006 10061097	MUSC	Arthralgia/ BILATERAL HAND JOINT PAIN	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
		Muscular weakness/ LEFT LEG MUSCLE WEAKNESS	2	16SEP2020	2/3	3	Yes		NA	R (18SEP2020)	N/N
	NERV	Hypoaesthesia/ LEFT LEG MUSCLE NUMBNESS	2	16SEP2020	2/3	3	Yes		NA	R (18SEP2020)	N/N
	INJ&P	Procedural pain/ Post Sinus Surgery Pain#	2	12FEB2021	151/3	2	No	O	NA/TC	R (14FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1006 10061098	NERV	Headache/ Headache	1	24AUG2020	1/2	2	Yes		NA/TC	R (25AUG2020)	N/N
	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	03OCT2020	19/10	3	No	O	NA/TC	R (12OCT2020)	N/N
	CARD	Atrial fibrillation/ ATRIAL FIBRILLATION INTERMITTENT	2	06OCT2020	22/7	2	No	CD	NA/TC/TCN	R (12OCT2020)	Y/N
>55/ C4591001 1006 10061101	GASTR	Vomiting/ VOMITING	1	26AUG2020	3/7	3	Yes		NA/TC	R (01SEP2020)	N/N
	GENRL	Chills/ CHILLS	1	26AUG2020	3/5	2	Yes		NA	R (30AUG2020)	N/N
	MUSC	Flank pain/ RIGHT FLANK PAIN	1	26AUG2020	3/5	3	Yes		NA/TC	R (30AUG2020)	N/N
>55/ C4591001 1006 10061135	GENRL	Injection site pain/ Injection Site Pain#	3	19JAN2021	1/4	2	Yes		NA/TC	R (22JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	4	10FEB2021	2/1	3	Yes		NA/TC	R (10FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	11FEB2021	3/2	2	Yes		NA	R (12FEB2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	4	11FEB2021	3/2	2	Yes		NA/TC	R (12FEB2021)	N/N
	NERV	Disturbance in attention/ Difficulty Concentrating#	4	11FEB2021	3/2	2	Yes		NA	R (12FEB2021)	N/N
	MUSC	Plantar fasciitis/ Plantar Fasciitis of Right Foot#	4	01MAR2021	21/C	2	No	O	NA/TC	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1006 10061139	GENRL	Injection site pain/ Injection site soreness	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
	INJ&P	Arthropod bite/ Spider Bite	2	19OCT2020	26/1	1	No	O	NA/TC	R (19OCT2020)	N/N
>55/ C4591001 1006 10061145	INJ&P	Contusion/ HEAD CONTUSION#	4	16FEB2021	7/18	2	No	O	NA/TC	R (05MAR2021)	N/N
		Fall/ FELL ON ICE#	4	16FEB2021	7/1	2	No	O	NA	R (16FEB2021)	N/N
		Muscle strain/ Muscle strain torso#	4	16FEB2021	7/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1006 10061157	GASTR	Hiatus hernia/ Worsening hiatal hernia	2	16NOV2020	34/108	1	No	O	NA/TC	R (03MAR2021)	N/N
	INJ&P	Procedural pain/ Post-surgical Pain#	4	03MAR2021	28/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1006 10061158	GENRL	Chills/ Chills	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N
		Pyrexia/ Fever	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Aches	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N
	NERV	Headache/ Headache	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1006 10061168	GENRL	Malaise/ General Malaise#	3	18JAN2021	1/1	2	Yes		NA/TC	R (18JAN2021)	N/N
		Pain/ Generalized Body Aches#	3	18JAN2021	1/2	2	Yes		NA/TC	R (19JAN2021)	N/N
>55/ C4591001 1006 10061177	GENRL	Injection site pain/ Injection Site Pain	1	21OCT2020	1/5	1	Yes		NA	R (25OCT2020)	N/N
>55/ C4591001 1007 10071081	IMMUN	Seasonal allergy/ Exacerbation of Seasonal Allergies	2	20AUG2020	2/4	2	No	O	NA/TC	R (23AUG2020)	N/N
	EYE	Lacrimation increased/ Watery left eye#	3	27FEB2021	5/C	1	Yes		NA	N	N/N
	GENRL	Facial pain/ L sided facial pain#	3	27FEB2021	5/C	2	Yes		NA/TC	N	N/N
>55/ C4591001 1007 10071090	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1007 10071098	GENRL	Fatigue/ Fatigue#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ injection site soreness#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ myalgias#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Chills/ chills#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
>55/ C4591001 1007 10071101	CARD	Cardiac arrest/ Cardiac Arrest	2	18OCT2020	60/4	4	No	O	NA/W	F (21OCT2020)	Y/N
>55/ C4591001 1007 10071104	GENRL	Fatigue/ Fatigue#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
		Injection site pain/ Injection site tenderness#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
>55/ C4591001 1007 10071124	GENRL	Chills/ chills#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	MUSC	Myalgia/ generalized myalgia#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ headache#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
	BLOOD	Lymphadenopathy/ axillary lymphadenopathy#	4	10FEB2021	2/3	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1007 10071127	MUSC	Pain in extremity/ Right foot pain	2	20SEP2020	26/107	2	No	O	NA/TC	R (04JAN2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1007 10071128	INJ&P	Fall/ Fall while running	1	12AUG2020	8/1	2	No	O	NA	R (12AUG2020)	N/N	
		Humerus fracture/ humeral fracture	1	12AUG2020	8/51	2	No	O	NA/TC	R (01OCT2020)	N/N	
>55/ C4591001 1007 10071144	SKIN	Pruritus/ pruritus face, shoulder arms and torso	2	02SEP2020	7/1	2	No	O	NA/TC	R (02SEP2020)	N/N	
	SKIN	Pruritus/ pruritic face, shoulder arms and torso	2	10SEP2020	15/1	2	No	O	NA/TC	R (10SEP2020)	N/N	
>55/ C4591001 1007 10071147	GENRL	Injection site pain/ Injection Site Soreness#	3	11JAN2021	1/4	1	Yes		NA	R (14JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	3	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N	
>55/ C4591001 1007 10071149	GENRL	Fatigue/ fatigue#	3	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N	
>55/ C4591001 1007 10071161	PSYCH	Sleep disorder/ sleep disturbance	1	24AUG2020	15/4	1	No	O	NA/TC	R (27AUG2020)	N/N	
	EYE	Vision blurred/ Right eye blurred vision	1	26AUG2020	17/132	2	No	O	NA	R (04JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	METAB	Decreased appetite/ Loss of appetite	2	01SEP2020	2/29	2	No	O	NA	R (29SEP2020)	N/N	
>55/ C4591001 1007 10071166	GASTR	Nausea/ nausea#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N	
	GENRL	Chills/ chills#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N	
	MUSC	Myalgia/ myalgias#	4	28JAN2021	1/2	2	Yes		NA/TC	R (29JAN2021)	N/N	
	NERV	Headache/ headache#	4	28JAN2021	1/3	2	Yes		NA/TC	R (30JAN2021)	N/N	
>55/ C4591001 1007 10071174	INFEC	Urinary tract infection/ Urinary tract infection	1	17AUG2020	6/6	1	No	O	NA	R (22AUG2020)	N/N	
>55/ C4591001 1007 10071182	GENRL	Injection site pain/ Injection Site soreness#	3	12JAN2021	1/2	2	Yes		NA/TC	R (13JAN2021)	N/N	
>55/ C4591001 1007 10071183	GASTR	Nausea/ nausea	2	03SEP2020	1/2	2	Yes		NA	R (04SEP2020)	N/N	
>55/ C4591001 1007 10071189	GENRL	Fatigue/ Fatigue#	3	23JAN2021	3/2	1	Yes		NA	R (24JAN2021)	N/N	
	INJ&P	Upper limb fracture/ Fractured Left Arm#	3	05FEB2021	16/C	2	No	O	NA/TC	RG	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1007 10071192	INJ&P	Tendon rupture/ right gluteus medius tendon tear	2	27SEP2020	25/68	2	No	O	NA/TCN	R (03DEC2020)	N/N
	GASTR	Gastrointestinal haemorrhage/ Gastrointestinal Bleed	2	09DEC2020	98/30	3	No	O	NA/TC/TCN	R (07JAN2021)	Y/N
	GASTR	Gastric ulcer/ Gastric ulcer	2	11DEC2020	100/C	2	No	O	NA/TC	RG	N/N
	GASTR	Duodenal ulcer/ Duodenal ulcer	2	17DEC2020	106/57	2	No	O	NA/TC	R (11FEB2021)	N/N
>55/ C4591001 1007 10071199	GENRL	Chills/ chills	2	08SEP2020	1/2	2	Yes		NA	R (09SEP2020)	N/N
		Fatigue/ Fatigue	2	08SEP2020	1/2	2	Yes		NA	R (09SEP2020)	N/N
>55/ C4591001 1007 10071200	GENRL	Chills/ chills	1	20AUG2020	4/2	1	Yes		NA	R (21AUG2020)	N/N
		Fatigue/ fatigue	1	20AUG2020	4/2	1	Yes		NA	R (21AUG2020)	N/N
	RESP	Throat irritation/ scratchy throat	1	20AUG2020	4/2	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Chills/ Chills	2	08SEP2020	1/3	1	Yes		NA/TCN	R (10SEP2020)	N/N
		Injection site pain/ Injection site pain	2	08SEP2020	1/3	1	Yes		NA/TC	R (10SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1007 10071205	METAB	Polydipsia/ Polydipsia	2	09SEP2020	2/2	1	Yes		NA/TCN	R (10SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ injection site soreness	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Chills/ chills	1	08SEP2020	23/2	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	08SEP2020	23/2	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ arm soreness at injection site	2	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N
	METAB	Hypercholesterolaemia/ hypercholesteremia	2	22SEP2020	15/C	2	No	O	NA/TC	N	N/N
	>55/ C4591001 1007 10071209	GENRL	Injection site pain/ injection site soreness	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)
>55/ C4591001 1007 10071213	INFEC	Gingival abscess/ gum abscess	1	02SEP2020	17/30	2	No	O	NA/TC	R (01OCT2020)	N/N
	SURG	Apicectomy/ apicoectomy	1	01OCT2020	46/1	2	No	O	NA/TC	R (01OCT2020)	N/N
	GENRL	Injection site induration/ induration at injection site	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
>55/ C4591001 1007 10071215											

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1007 10071222	GENRL	Induration/ Induration	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/Y
	SKIN	Ecchymosis/ Ecchymosis	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/N
>55/ C4591001 1007 10071226	GENRL	Injection site pain/ Muscle Soreness around injection site#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N
>55/ C4591001 1007 10071242	NERV	Headache/ Intermittent Headache	2	08OCT2020	29/2	1	No	O	NA/TC	R (09OCT2020)	N/N
>55/ C4591001 1007 10071244	GENRL	Injection site pain/ Injection site pain#	3	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
>55/ C4591001 1007 10071245	GENRL	Fatigue/ fatigue	1	21AUG2020	2/2	2	Yes		NA	R (22AUG2020)	N/N
	MUSC	Myalgia/ Myalgia	1	21AUG2020	2/2	2	Yes		NA	R (22AUG2020)	N/N
>55/ C4591001 1007 10071248	GENRL	Chills/ chills#	4	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1007 10071255	SKIN	Dermatitis contact/ Contact Dermatitis	1	29AUG2020	6/2	2	No	O	NA/TC	R (30AUG2020)	N/N
>55/ C4591001 1007 10071257	GENRL	Fatigue/ fatigue	1	24AUG2020	1/2	1	Yes		NA	R (25AUG2020)	N/N
>55/ C4591001 1007 10071259	NERV	Headache/ headache	2	16SEP2020	1/3	1	No	O	NA	R (18SEP2020)	N/N
>55/ C4591001 1007 10071260	GENRL	Injection site pain/ injection site soreness	1	24AUG2020	1/2	2	Yes		NA/TC	R (25AUG2020)	N/N
>55/ C4591001 1007 10071262	GENRL	Injection site pain/ Injection site pain#	3	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
>55/ C4591001 1007 10071265	GENRL	Malaise/ Malaise#	2	18FEB2021	156/2	1	Yes		NA/TC	R (19FEB2021)	N/N
>55/ C4591001 1007 10071267	GENRL	Injection site pain/ Right Arm Injection Site Pain#	3	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
>55/ C4591001 1007 10071277	NERV	Headache/ headache#	3	14JAN2021	1/7	1	Yes		NA/TC	R (20JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1007 10071283	GENRL	Chills/ chills	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
		Fatigue/ fatigue	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
>55/ C4591001 1007 10071294	GENRL	Injection site haematoma/ injection site hematoma	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/Y
	MUSC	Myalgia/ muscle soreness	1	28AUG2020	2/3	1	Yes		NA	R (30AUG2020)	N/N
>55/ C4591001 1007 10071297	GENRL	Injection site pain/ Injection site arm soreness#	3	28JAN2021	2/3	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Chills/ chills#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
>55/ C4591001 1007 10071298	GENRL	Injection site paraesthesia/ Tingling at injection site	1	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/Y
>55/ C4591001 1007 10071301	GENRL	Injection site pain/ injection site pain	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
>55/ C4591001 1007 10071303	GENRL	Chills/ chills#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1007 10071305	NERV	Headache/ headache#	4	18FEB2021	1/4	3	Yes		NA/TC	R (21FEB2021)	N/N	
	MUSC	Myalgia/ Myalgias#	3	20JAN2021	2/4	2	Yes		NA	R (23JAN2021)	N/N	
>55/ C4591001 1007 10071306	NERV	Headache/ Headache#	3	20JAN2021	2/3	1	Yes		NA	R (22JAN2021)	N/N	
	INFEC	Pneumonia/ left lower lobe pneumonia#	2	19FEB2021	110/C	3	No	O	NA/TC/TCN	RG	Y/N	
>55/ C4591001 1007 10071310		Sepsis/ sepsis#	2	19FEB2021	110/16	3	No	O	NA/TC/TCN	R (06MAR2021)	Y/N	
	GENRL	Fatigue/ fatigue	1	14OCT2020	3/3	1	Yes		NA	R (16OCT2020)	N/N	
>55/ C4591001 1007 10071311	MUSC	Myalgia/ exacerbation of bilateral hand myalgia	1	14OCT2020	3/15	1	Yes		NA	R (28OCT2020)	N/N	
	GENRL	Injection site pain/ injection site tenderness	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N	
		Pyrexia/ fever	2	03NOV2020	2/2	2	Yes		NA/TC	R (04NOV2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N	
>55/ C4591001	GENRL	Injection site pain/ Injection Site Pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1007 10071312											
>55/ C4591001 1007 10071313	GENRL	Injection site pain/ Injection site pain	1	13OCT2020	1/5	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	03NOV2020	1/3	1	Yes		NA	R (05NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
>55/ C4591001 1007 10071314	GENRL	Injection site pain/ Injection site pain	1	13OCT2020	1/1	1	Yes		NA	R (13OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	03NOV2020	1/9	1	Yes		NA	R (11NOV2020)	N/N
>55/ C4591001 1007 10071315	EAR	Deafness/ hearing loss	1	01NOV2020	20/81	2	No	O	NA/TC	RS (20JAN2021)	N/N
	GENRL	Injection site pain/ Injection site soreness#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
>55/ C4591001 1007 10071318	GENRL	Fatigue/ Tiredness	1	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
>55/ C4591001 1007 10071319	RESP	Cough/ Coughing	1	13OCT2020	1/1	1	Yes		NA	R (13OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1007 10071320	MUSC	Pain in extremity/ left arm soreness	1	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C4591001 1007 10071321	GENRL	Injection site erythema/ Injection site erythema	2	03NOV2020	1/22	1	Yes		NA	R (24NOV2020)	N/N
		Injection site induration/ Injection site induration	2	03NOV2020	1/22	1	Yes		NA	R (24NOV2020)	N/N
		Injection site pain/ Injection site tenderness	2	03NOV2020	1/22	1	Yes		NA	R (24NOV2020)	N/N
	GENRL	Chills/ chills#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
		Pyrexia/ fever#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
	MUSC	Myalgia/ myalgias#	4	24FEB2021	2/1	2	Yes		NA	R (24FEB2021)	N/N
	NERV	Headache/ headache#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
>55/ C4591001 1007 10071322	GENRL	Injection site pain/ Tenderness at injection site	1	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
		Injection site swelling/ swelling at injection site	1	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Injection site pain/ Tenderness at Injection Site	2	03NOV2020	1/2	1	Yes		NA	R (04NOV2020)	N/N
>55/ C4591001	GENRL	Chills/ chills#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1007 10071323		Fatigue/ fatigue#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
	MUSC	Myalgia/ myalgias#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1007 10071327	GENRL	Malaise/ General Malaise	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
	MUSC	Pain in extremity/ Soreness of the arm	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Chills/ chills#	3	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
		Pain/ Body Aches#	3	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
>55/ C4591001 1007 10071329	NERV	Headache/ Headache	1	14OCT2020	1/1	2	Yes		NA/TC	R (14OCT2020)	N/N
>55/ C4591001 1007 10071333	GENRL	Injection site erythema/ Erythema at injection site	1	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
		Injection site pain/ Pain at injection site	1	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
		Malaise/ Malaise	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
	METAB	Decreased appetite/ Loss of appetite	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
>55/ C4591001 1007 10071343	GENRL	Pyrexia/ low grade fever#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	3	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	22JAN2021	4/1	1	Yes		NA	R (22JAN2021)	N/N
>55/ C4591001 1007 10071346	GENRL	Chills/ Chills	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
	MUSC	Arthralgia/ Generalized Arthralgia	2	05NOV2020	1/3	1	Yes		NA/TC	R (07NOV2020)	N/N
		Myalgia/ myalgia	2	05NOV2020	1/3	1	Yes		NA/TC	R (07NOV2020)	N/N
>55/ C4591001 1007 10071347	CARD	Atrial fibrillation/ atrial fibrillation	1	25OCT2020	11/2	3	No	O	P/TC	R (26OCT2020)	Y/N
>55/ C4591001	GENRL	Chills/ chills#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Investigational Vaccine Dose/ Subject	Action: Outcome (End Date)	SAE/Imm AE (Yes/No)
1007 10071348		Fatigue/ fatigue#	3	21JAN2021	1/2	1	Yes	NA	R (22JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	3	21JAN2021	1/2	1	Yes	NA	R (22JAN2021)	N/N
>55/ C4591001 1007 10071349	GENRL	Fatigue/ fatigue	1	16OCT2020	2/2	1	Yes	NA	R (17OCT2020)	N/N
>55/ C4591001 1007 10071354	GENRL	Injection site haemorrhage/ Ecchymosis at injection site	1	15OCT2020	1/15	1	Yes	NA	R (29OCT2020)	N/N
		Injection site induration/ Induration at injection site	1	15OCT2020	1/10	1	Yes	NA	R (24OCT2020)	N/Y
		Injection site pain/ Injection site pain	1	15OCT2020	1/15	1	Yes	NA	R (29OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/2	1	Yes	NA	R (09FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	09FEB2021	2/1	1	Yes	NA	R (09FEB2021)	N/N
>55/ C4591001 1007 10071355	GENRL	Injection site pain/ tenderness at injection site	1	15OCT2020	1/2	2	Yes	NA	R (16OCT2020)	N/Y
	MUSC	Pain in extremity/ left Arm soreness	2	06NOV2020	2/5	1	Yes	NA	R (10NOV2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	19FEB2021	2/1	1	Yes	NA	R (19FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1007 10071356 >55/ C4591001 1007 10071371	GASTR	Toothache/ tooth pain	2	24NOV2020	15/57	1	No	O	NA/TC	R (19JAN2021)	N/N
	INJ&P	Fall/ fall	2	01DEC2020	22/1	2	No	O	NA/TCN	R (01DEC2020)	N/N
		Joint injury/ left wrist injury	2	01DEC2020	22/C	2	No	O	NA/TCN	RG	N/N
>55/ C4591001 1007 10071372	MUSC	Myalgia/ myalgias#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
>55/ C4591001 1007 10071379	GENRL	Injection site pain/ pain extending from injection site to elbow	1	20OCT2020	1/2	1	Yes		NA/TC	R (21OCT2020)	N/N
>55/ C4591001 1007 10071384	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Chills/ Chills	2	11NOV2020	2/1	2	Yes		NA/TC	R (11NOV2020)	N/N
		Injection site pain/ Injection site pain	2	11NOV2020	2/7	2	Yes		NA/TC	R (17NOV2020)	N/N
		Pyrexia/ Fever	2	11NOV2020	2/1	2	Yes		NA/TC	R (11NOV2020)	N/N
	NERV	Headache/ Headache	2	11NOV2020	2/1	2	Yes		NA/TC	R (11NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1007 10071411	GENRL	Injection site pain/ Muscle Soreness in arm of injection site#	3	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
>55/ C4591001 1007 10071412	GENRL	Chills/ Chills	2	13NOV2020	2/1	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Injection site pain/ Muscle Soreness in Arm of Injection site#	3	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
>55/ C4591001 1007 10071430	GENRL	Injection site pain/ Achiness at injection site	1	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/Y
	GASTR	Nausea/ nausea	2	17NOV2020	2/2	1	Yes		NA	R (18NOV2020)	N/N
	GENRL	Chills/ chills	2	17NOV2020	2/2	1	Yes		NA	R (18NOV2020)	N/N
>55/ C4591001 1007 10071432	GENRL	Injection site pain/ Soreness at injection site	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
		Injection site swelling/ Swelling at injection site	1	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
	INFEC	Urinary tract infection/ urinary tract infection	1	06NOV2020	12/8	2	No	O	NA	R (13NOV2020)	N/N
	GENRL	Pain/ Body Aches	2	17NOV2020	2/1	1	Yes		NA/TC	R (17NOV2020)	N/N
	INFEC	Urinary tract infection/ Urinary Tract Infection	2	15JAN2021	61/C	2	No	O	NA/TC	RG	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ injection site soreness#	4	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
		Pyrexia/ fever#	4	12FEB2021	2/2	2	Yes		NA/TC	R (13FEB2021)	N/N
	MUSC	Myalgia/ myalgias#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1008 10081003	GENRL	Injection site pain/ injection site pain#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
>55/ C4591001 1008 10081010	GENRL	Injection site pain/ injection site pain#	3	15JAN2021	1/6	1	Yes		NA	R (20JAN2021)	N/N
	MUSC	Arthralgia/ Generalized joint pain#	3	16JAN2021	2/5	2	Yes		NA	R (20JAN2021)	N/N
>55/ C4591001 1008 10081020	GENRL	Injection site pain/ injection site pain#	3	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
>55/ C4591001 1008 10081039	GENRL	Injection site pain/ injection site pain#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N
		Pain/ body aches#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
>55/ C4591001	GENRL	Injection site erythema/ injection site redness#	3	19JAN2021	1/5	1	Yes		NA	R (23JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1008 10081044											
>55/ C4591001 1008 10081050	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	8/2	1	Yes		NA	R (16SEP2020)	N/N
	INFEC	Gastroenteritis/ Gastroenteritis	2	16SEP2020	9/2	1	No	O	NA	R (17SEP2020)	N/N
>55/ C4591001 1008 10081056	GENRL	Injection site pain/ Injection site pain#	3	20JAN2021	1/5	1	Yes		NA	R (24JAN2021)	N/N
	RESP	Dyspnoea/ Shortness of breath#	4	MAR2021	20/C	3	No	O	NA/TC	N	Y/N
>55/ C4591001 1008 10081057	GENRL	Injection site pain/ injection site pain#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Pain/ body aches#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1008 10081062	GENRL	Pain/ Body aches	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
>55/ C4591001 1008 10081070	GENRL	Chills/ chills	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ fever	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1008 10081073	NERV	Headache/ headache	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N	
		Pain/ body aches	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N	
>55/ C4591001 1008 10081082	GENRL	Fatigue/ fatigue	2	11SEP2020	2/C	1	Yes		NA	N	N/N	
	GENRL	Chills/ chills	1	24AUG2020	1/2	1	Yes		NA	R (25AUG2020)	N/N	
>55/ C4591001 1008 10081083	RESP	Oropharyngeal pain/ Sore throat	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/N	
>55/ C4591001 1008 10081090	GENRL	Chills/ Chills	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
		Fatigue/ Fatigue	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
>55/ C4591001 1008 10081092	INFEC	Gastroenteritis/ Gastroenteritis	2	03OCT2020	19/2	1	No	O	NA	R (04OCT2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	29JAN2021	1/4	1	Yes		NA	R (01FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1008 10081093	NERV	Headache/ headache#	3	20JAN2021	2/3	1	Yes		NA/TC	R (22JAN2021)	N/N
	GENRL	Pyrexia/ fever#	4	10FEB2021	2/3	2	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1008 10081094	GENRL	Chills/ chills	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
	GENRL	Chills/ chills	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
		Pain/ body aches	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
		Pyrexia/ fever	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ headache	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
	INFEC	Urinary tract infection/ UTI	2	23OCT2020	39/4	2	No	O	NA/TC	R (26OCT2020)	N/N
>55/ C4591001 1008 10081097	INFEC	Urinary tract infection/ Urinary tract infection	2	05JAN2021	113/10	1	No	O	NA/TC	R (14JAN2021)	N/N
>55/ C4591001 1008 10081100	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1008 10081106	GENRL	Injection site pain/ injection site pain	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001 1008 10081107	GENRL	Fatigue/ Fatigue#	3	22JAN2021	2/2	2	Yes		NA	R (23JAN2021)	N/N
>55/ C4591001 1008 10081110	GENRL	Injection site pain/ injection site pain#	3	21JAN2021	2/5	1	Yes		NA	R (25JAN2021)	N/N
>55/ C4591001 1008 10081114	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	2/4	2	Yes		NA	R (29JAN2021)	N/N
>55/ C4591001 1008 10081125	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1008 10081131	GENRL	Injection site erythema/ Grade 2 injection site redness	2	18SEP2020	2/3	2	Yes		NA	R (20SEP2020)	N/N
>55/ C4591001 1008 10081139	GENRL	Injection site pain/ injection site pain#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue#	3	29JAN2021	2/2	2	Yes		NA	R (30JAN2021)	N/N
>55/ C4591001 1008 10081146	INFEC	Tooth infection/ Tooth infection#	3	09FEB2021	15/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1008 10081157	GENRL	Pain/ Body aches	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1008 10081164	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
		Injection site pain/ Injection site pain Left deltoid	2	23SEP2020	2/4	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1008 10081165	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ Injection site pain Left arm	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1008 10081168	NERV	Headache/ Headache	2	29SEP2020	7/3	1	No	O	NA	R (01OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1008 10081173	GENRL	Chills/ Chills	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ Fever	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N
>55/ C4591001 1008 10081174	GENRL	Injection site pain/ Injection site pain left arm	2	24SEP2020	2/6	1	Yes		NA	R (29SEP2020)	N/N
>55/ C4591001 1008 10081175	GENRL	Fatigue/ Fatigue	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N
		Pain/ Body aches	1	03SEP2020	2/1	1	Yes		NA/TC	R (03SEP2020)	N/N
		Pyrexia/ Fever	1	03SEP2020	2/1	1	Yes		NA/TC	R (03SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Pain/ Body aches	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C4591001 1008 10081180	INFEC	Urinary tract infection/ urinary tract infection#	4	27FEB2021	25/5	1	No	O	NA/TC	R (03MAR2021)	N/N
>55/ C4591001	EYE	Keratitis/ Corneal inflammation left eye	1	17SEP2020	15/8	1	No	O	NA/TC	R (24SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1008 10081182	GENRL	Pyrexia/ Fever	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1008 10081184	NEOPL	Prostate cancer/ Prostate cancer	2	30SEP2020	7/C	2	No	O	NA/TCN	N	Y/N
>55/ C4591001 1008 10081185	GASTR	Diarrhoea/ Diarrhea	2	02OCT2020	8/1	1	No	O	NA	R (02OCT2020)	N/N
>55/ C4591001 1008 10081186	GENRL	Injection site pain/ Injection site pain left arm	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1008 10081190	GENRL	Injection site pain/ injection site pain#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/Y
>55/ C4591001 1008 10081192	GENRL	Chills/ Chills	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		Fatigue/ Fatigue	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		Pyrexia/ Fever	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
	NERV	Headache/ Headache	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1008 10081195	GENRL	Injection site pain/ injection site pain#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
>55/ C4591001 1008 10081208	GENRL	Asthenia/ Weakness	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
		Chills/ Chills	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
		Fatigue/ Fatigue	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1008 10081209	GENRL	Chills/ Chills	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
		Pain/ Body aches	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1008 10081210	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/4	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1008 10081211	NERV	Sciatica/ sciatica	1	16SEP2020	9/C	2	No	O	NA/TC	N	N/N
	GENRL	Chills/ Chills	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1008 10081213	GENRL	Pain/ Body aches	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ injection site pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
		Chills/ Chills#	4	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
		Headache/ headache#	4	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N
		Nausea/ Nausea#	4	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1008 10081214	GENRL	Pain/ body aches#	4	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
		Chills/ chills#	3	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N
		Pyrexia/ fever#	3	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N
		Vomiting/ Vomiting	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
		Chills/ Chills	2	29SEP2020	2/3	1	Yes		NA/TC	R (01OCT2020)	N/N
>55/ C4591001 1008 10081222	GENRL	Injection site pain/ Injection site pain	2	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N
		Pain/ Body aches	2	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1008 10081226	NERV	Headache/ Headache	2	29SEP2020	2/3	1	Yes		NA/TC	R (01OCT2020)	N/N
	METAB	Decreased appetite/ Loss of appetite	2	30SEP2020	3/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ Injection site pain left deltoid	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C4591001 1008 10081227		Pain/ Body aches	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Injection site erythema/ redness at injection site#	3	10FEB2021	3/6	1	Yes		NA	R (15FEB2021)	N/N
>55/ C4591001 1008 10081228		Injection site swelling/ swelling at injection site#	3	10FEB2021	3/6	1	Yes		NA	R (15FEB2021)	N/N
	SKIN	Rash/ Rash extremities unknown etiology	1	11SEP2020	4/47	1	No	O	NA/TC	R (27OCT2020)	N/N
>55/ C4591001 1008 10081237	GASTR	Diarrhoea/ Diarrhea	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
>55/ C4591001 1008 10081242	GENRL	Chills/ Chills	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Fatigue/ Fatigue	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1008 10081243	INFEC	Localised infection/ Infection right middle finger#	3	30JAN2021	10/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1008 10081246	GENRL	Pyrexia/ Fever	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	NERV	Dizziness/ Dizziness	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1008 10081248	GASTR	Diarrhoea/ Diarrhea	1	13SEP2020	5/2	1	Yes		NA	R (14SEP2020)	N/N
		Nausea/ Nausea	1	13SEP2020	5/2	1	Yes		NA	R (14SEP2020)	N/N
		Vomiting/ Vomiting	1	13SEP2020	5/2	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Chills/ Chills	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	NERV	Headache/ Headache	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	3	15JAN2021	2/4	2	Yes		NA	R (18JAN2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine Subject	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1008 10081249	GENRL	Chills/ chills#	4	04FEB2021	2/1	1	Yes	NA	NA	R (04FEB2021)	N/N
	NERV	Headache/ headache#	4	04FEB2021	2/1	1	Yes	NA	NA	R (04FEB2021)	N/N
>55/ C4591001 1008 10081250	GENRL	Injection site pain/ Injection site pain	2	01OCT2020	2/2	1	Yes	NA	NA	R (02OCT2020)	N/N
		Pyrexia/ Fever	2	01OCT2020	2/2	1	Yes	NA/TC	NA/TC	R (02OCT2020)	N/N
>55/ C4591001 1008 10081252	GENRL	Chills/ Chills	2	03OCT2020	2/2	1	Yes	NA	NA	R (04OCT2020)	N/N
>55/ C4591001 1008 10081262	GENRL	Injection site pain/ injection site pain#	3	23JAN2021	2/1	1	Yes	NA	NA	R (23JAN2021)	N/N
		Pain/ body aches#	3	23JAN2021	2/1	2	Yes	NA	NA	R (23JAN2021)	N/N
	NERV	Headache/ headache#	3	23JAN2021	2/1	2	Yes	NA	NA	R (23JAN2021)	N/N
>55/ C4591001 1008 10081269	GENRL	Chills/ Chills	2	01OCT2020	1/2	1	Yes	NA	NA	R (02OCT2020)	N/N
		Fatigue/ Fatigue	2	01OCT2020	1/3	1	Yes	NA	NA	R (03OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site pain	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
		Pain/ Body aches	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C4591001 1008 10081270	GENRL	Chills/ Chills	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
		Pain/ Body aches	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C4591001 1008 10081272	GENRL	Fatigue/ fatigue#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
>55/ C4591001 1008 10081275	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N
>55/ C4591001 1008 10081278	GENRL	Injection site pain/ Injection site pain#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
>55/ C4591001 1008 10081282	NERV	Headache/ Headache#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N
>55/ C4591001 1008 10081285	GENRL	Chills/ Chills#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1008 10081296	GENRL	Injection site pain/ injection site pain#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
>55/ C4591001 1008 10081298	GENRL	Injection site pain/ Injection site pain	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		Malaise/ Malaise	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		Pain/ Body aches	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
>55/ C4591001 1008 10081299	GENRL	Chills/ Chills	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
		Fatigue/ Fatigue	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
		Pyrexia/ Fever	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
>55/ C4591001 1008 10081303	GENRL	Pain/ Body aches	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
>55/ C4591001 1008 10081305	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/3	1	Yes		NA/TC	R (19DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1008 10081307	GENRL	Chills/ Chills	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
		Pain/ Body aches	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
>55/ C4591001 1008 10081308	GENRL	Pyrexia/ Fever#	4	09JAN2021	2/1	1	Yes		NA/TC	R (09JAN2021)	N/N
>55/ C4591001 1008 10081309	GASTR	Diarrhoea/ Diarrhea	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
>55/ C4591001 1008 10081318	GENRL	Injection site pain/ Injection site pain	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
>55/ C4591001 1008 10081319	GENRL	Injection site pain/ injection site pain#	3	13JAN2021	1/4	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Injection site erythema/ injection site redness#	3	16JAN2021	4/6	2	Yes		NA	R (21JAN2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1008 10081322											
>55/ C4591001 1008 10081332	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Pain/ Body aches	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Pyrexia/ Fever	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
>55/ C4591001 1008 10081335	GENRL	Injection site pain/ Injection site pain	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
>55/ C4591001 1008 10081339	GASTR	Nausea/ Nausea#	4	08JAN2021	2/4	2	Yes		NA	R (11JAN2021)	N/N
	GENRL	Chills/ Chills#	4	08JAN2021	2/4	2	Yes		NA	R (11JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	08JAN2021	2/7	2	Yes		NA/TC	R (14JAN2021)	N/N
		Pyrexia/ Fever#	4	08JAN2021	2/4	2	Yes		NA/TC	R (11JAN2021)	N/N
	NERV	Headache/ Headache#	4	08JAN2021	2/C	2	Yes		NA/TC	N	N/N
	GENRL	Injection site pain/ Injection site pain#	4	09JAN2021	3/C	3	Yes		NA/TC	RG	N/N
>55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	28DEC2020	1/2	1	Yes		NA	R (29DEC2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1008 10081340 >55/ C4591001 1008 10081345	GENRL	Injection site pain/ injection site pain#	3	15JAN2021	1/3	1	Yes		NA	R (17JAN2021)	N/N
>55/ C4591001 1008 10081355	GASTR	Diarrhoea/ Diarrhea	1	18SEP2020	3/3	1	Yes		NA	R (20SEP2020)	N/N
>55/ C4591001 1008 10081362	GASTR	Nausea/ intermittent nausea#	3	22JAN2021	2/13	2	Yes		NA	R (03FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	22JAN2021	2/13	1	Yes		NA	R (03FEB2021)	N/N
	NERV	Headache/ headache#	3	22JAN2021	2/21	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1008 10081363	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	07OCT2020	1/4	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Chills/ Chills	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
		Pain/ Body aches	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1008 10081376	GENRL	Fatigue/ Fatigue	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
	NERV	Headache/ Headache	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
>55/ C4591001 1008 10081378	GENRL	Chills/ Chills	1	23SEP2020	7/2	1	Yes		NA	R (24SEP2020)	N/N
	SKIN	Hyperhidrosis/ Sweating	1	23SEP2020	7/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1008 10081380	GENRL	Injection site pain/ Injection site soreness	2	09OCT2020	2/6	1	Yes		NA	R (14OCT2020)	N/N
		Pyrexia/ Fever	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
>55/ C4591001 1008 10081399	GENRL	Pain/ bodyaches#	4	11JAN2021	1/2	2	Yes		NA	R (12JAN2021)	N/N
	GENRL	Pyrexia/ fever#	4	12JAN2021	2/2	2	Yes		NA	R (13JAN2021)	N/N
>55/ C4591001 1008 10081400	INJ&P	Arthropod bite/ Tick bite	2	24OCT2020	17/14	1	No	O	NA/TC	R (06NOV2020)	N/N
>55/ C4591001	GENRL	Fatigue/ Fatigue	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1008 10081412		Injection site pain/ Injection site pain	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Pain/ Body aches	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Fatigue/ Fatigue	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		Injection site pain/ Injection site pain	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		Pain/ Body aches	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
	NERV	Headache/ Headache	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
>55/ C4591001 1008 10081443	NERV	Parosmia/ Olfactory disturbance	1	22SEP2020	1/C	1	Yes		NA	N	N/N
>55/ C4591001 1008 10081445	GENRL	Injection site pain/ injection site soreness#	3	01FEB2021	1/5	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1008 10081454	GASTR	Nausea/ Nausea	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Chills/ Chills	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
	MUSC	Myalgia/ Muscles aches	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1008 10081461	GENRL	Injection site pain/ injection site pain#	3	25JAN2021	1/4	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle aches#	3	26JAN2021	2/2	2	Yes		NA	R (27JAN2021)	N/N
	INFEC	Otitis externa/ External ear infection#	4	18FEB2021	4/11	2	No	O	NA/TC	R (28FEB2021)	N/N
	SKIN	Dermatitis contact/ Contact dermatitis scalp/hands#	4	18FEB2021	4/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1008 10081482	GASTR	Diarrhoea/ Diarrhea	1	05OCT2020	13/1	1	No	O	NA	R (05OCT2020)	N/N
		Vomiting/ Vomiting	1	05OCT2020	13/1	1	No	O	NA	R (05OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	14OCT2020	1/C	1	Yes		NA	RG	N/N
>55/ C4591001 1008 10081489	GENRL	Injection site pain/ injection site pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001 1008 10081490	GENRL	Injection site pain/ Injection site pain	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	14OCT2020	1/8	1	Yes		NA	R (21OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1008 10081495	GENRL	Pyrexia/ Fever	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N	
>55/ C4591001 1008 10081503	GENRL	Chills/ Chills	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N	
>55/ C4591001 1008 10081508	MUSC	Myalgia/ Muscle aches	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N	
>55/ C4591001 1008 10081508	GENRL	Injection site pain/ injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
>55/ C4591001 1008 10081510	GENRL	Injection site pain/ injection site pain#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N	
>55/ C4591001 1008 10081511	GENRL	Injection site swelling/ injections site swelling#	3	19JAN2021	1/3	2	Yes		NA	R (21JAN2021)	N/N	
>55/ C4591001 1008 10081511	GENRL	Pyrexia/ Fever	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
>55/ C4591001 1008 10081523	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N	
	NERV	Headache/ headache#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1008 10081526	SKIN	Dermatitis contact/ Contact dermatitis	2	08NOV2020	25/C	1	No	O	NA	RG	N/N	
	GASTR	Gastric ulcer/ Gastric ulcer#	3	04FEB2021	17/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1008 10081531	GENRL	Chills/ Chills	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N	
		Injection site pain/ Injection site pain	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N	
	METAB	Decreased appetite/ Loss of appetite	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N	
>55/ C4591001 1008 10081538	GENRL	Injection site pain/ injection site pain#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N	
>55/ C4591001 1008 10081550	GENRL	Chills/ chills	1	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N	
		Pain/ bodyaches	1	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N	
	PSYCH	Anxiety/ Anxiety	1	14OCT2020	16/C	2	No	O	NA/TCN	N	N/N	
		Depression/ Depression	1	14OCT2020	16/C	2	No	O	NA/TCN	N	N/N	
	INFEC	Sinusitis/ sinus infection#	4	12FEB2021	4/14	2	No	O	NA/TC	R (25FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1008 10081560	GENRL	Injection site pain/ injection site pain#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N	
>55/ C4591001 1008 10081561	VASC	Hypertension/ Hypertension	2	02DEC2020	38/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1008 10081564	GENRL	Injection site pain/ Injection site pain	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N	
>55/ C4591001 1008 10081566	GENRL	Chills/ Chills	2	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N	
>55/ C4591001 1008 10081569	GENRL	Injection site pain/ Injection site pain#	3	20JAN2021	1/2	2	Yes		NA	R (21JAN2021)	N/N	
>55/ C4591001 1008 10081571	INFEC	Otitis externa/ Otitis externa Left ear	1	08OCT2020	2/8	1	No	O	NA/TC	R (15OCT2020)	N/N	
>55/ C4591001 1008 10081586	GENRL	Injection site pain/ Injection site pain	1	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N	
>55/ C4591001 1008 10081587	GENRL	Chills/ Chills	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1008 10081588	NERV	Headache/ headache	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	04NOV2020	3/2	1	Yes		NA	R (05NOV2020)	N/N
	NERV	Headache/ headache	2	04NOV2020	3/2	1	Yes		NA	R (05NOV2020)	N/N
	GENRL	Chills/ Chills	1	17OCT2020	6/1	1	Yes		NA	R (17OCT2020)	N/N
	NERV	Headache/ headache	1	17OCT2020	6/1	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N
	GENRL	Chills/ chills	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N
>55/ C4591001 1008 10081601	NERV	Headache/ headache	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N
	INFEC	Fungal skin infection/ Yeast infection left axilla#	3	21JAN2021	3/24	2	No	O	NA/TC	R (13FEB2021)	N/N
>55/ C4591001 1008 10081602	GENRL	Fatigue/ Fatigue	2	04NOV2020	1/2	2	Yes		NA	R (05NOV2020)	N/N
	GENRL	Pain/ Body aches	2	04NOV2020	1/2	2	Yes		NA/TC	R (05NOV2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1008 10081603	INFEC	Pyrexia/ Fever	2	04NOV2020	1/2	2	Yes		NA/TC	R (05NOV2020)	N/N
		Cellulitis/ CELLULITIS UPPER BACK	1	26OCT2020	13/8	3	No	O	NA/TC	R (02NOV2020)	Y/N
	INJ&P	Subcutaneous abscess/ SCALP ABCESS	1	26OCT2020	13/2	3	No	O	NA/TC/TCN	R (27OCT2020)	Y/N
		Wound/ Surgical wound scalp	1	27OCT2020	14/87	2	No	O	NA/TC/TCN	R (21JAN2021)	N/N
>55/ C4591001 1008 10081610	GENRL	Chills/ Chills	2	04NOV2020	2/1	2	Yes		NA	R (04NOV2020)	N/N
>55/ C4591001 1008 10081622	GENRL	Pain/ Body aches	2	04NOV2020	2/1	2	Yes		NA/TC	R (04NOV2020)	N/N
		Pyrexia/ Fever	2	04NOV2020	2/1	1	Yes		NA/TC	R (04NOV2020)	N/N
		Chills/ Chills	2	07NOV2020	2/2	1	Yes		NA	R (08NOV2020)	N/N
>55/ C4591001 1008 10081626	NERV	Pain/ Body aches	2	07NOV2020	2/1	1	Yes		NA/TC	R (07NOV2020)	N/N
		Headache/ headache#	3	15JAN2021	2/3	1	Yes		NA	R (17JAN2021)	N/N
	GENRL	Chills/ chills#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1008 10081627	NERV	Pain/ body aches#	4	03FEB2021	2/1	2	Yes		NA/TC	R (03FEB2021)	N/N
		Headache/ headache#	4	03FEB2021	2/2	2	Yes		NA/TC	R (04FEB2021)	N/N
		Migraine/ migraine#	3	01FEB2021	1/4	2	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1008 10081639	GENRL	Injection site pain/ injection site pain#	3	02FEB2021	2/3	2	Yes		NA	R (04FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	29JAN2021	2/2	2	Yes		NA	R (30JAN2021)	N/N
	GASTR	Pain/ body aches#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
Pyrexia/ fever#		3	29JAN2021	2/2	2	Yes		NA/TC	R (30JAN2021)	N/N	
Nausea/ Nausea#		4	23FEB2021	2/3	1	Yes		NA	R (25FEB2021)	N/N	
>55/ C4591001 1008 10081641	GENRL	Pain/ body aches#	4	23FEB2021	2/4	1	Yes		NA	R (26FEB2021)	N/N
	NERV	Pyrexia/ Fever(101)#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
		Headache/ headache#	4	23FEB2021	2/4	1	Yes		NA	R (26FEB2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1008 10081645	GENRL	Fatigue/ Fatigue	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
>55/ C4591001 1008 10081656	GENRL	Fatigue/ Fatigue	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
		Injection site pain/ Injection site pain	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
	NERV	Headache/ Headache	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
>55/ C4591001 1008 10081660	INJ&P	Tooth fracture/ Cracked left lower molar	1	07NOV2020	18/3	1	No	O	NA/TC/TCN	R (09NOV2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
>55/ C4591001 1008 10081667	GENRL	Injection site pain/ injection site are soreness	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
	NEOPL	Hepatic cancer/ liver cancer#	4	25FEB2021	23/C	3	No	O	NA/W	N	Y/N
>55/ C4591001 1008 10081685	GENRL	Fatigue/ Fatigue	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N
	MUSC	Myalgia/ Generalized muscle aches	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1008 10081690	GENRL	Injection site pain/ injection site pain#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
>55/ C4591001 1008 10081694	GENRL	Chills/ Chills	2	17NOV2020	2/2	1	Yes		NA/TC	R (18NOV2020)	N/N
		Pain/ Body aches	2	17NOV2020	2/2	1	Yes		NA/TC	R (18NOV2020)	N/N
>55/ C4591001 1008 10081699	GENRL	Injection site pain/ Injection site pain	1	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N
		Pain/ Body aches	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N
	GENRL	Pyrexia/ Fever	2	18NOV2020	2/2	2	Yes		NA	R (19NOV2020)	N/N
>55/ C4591001 1008 10081701	NERV	Headache/ Headache	1	14NOV2020	19/3	1	No	O	NA/TC	R (16NOV2020)	N/N
	MUSC	Muscle fatigue/ generalized muscle fatigue#	4	12FEB2021	1/4	1	Yes		NA	R (15FEB2021)	N/N
>55/ C4591001 1008 10081705	GENRL	Chills/ chills	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Injection site erythema/ injection site redness	2	18NOV2020	2/5	2	Yes		NA	R (22NOV2020)	N/N
		Injection site pain/ injection site pain	2	18NOV2020	2/5	2	Yes		NA	R (22NOV2020)	N/N
		Injection site swelling/ injection site swelling	2	18NOV2020	2/5	2	Yes		NA	R (22NOV2020)	N/N
		Pain/ body aches	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N
		Pyrexia/ low grade fever	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N
>55/ C4591001 1008 10081711	GENRL	Injection site pain/ injection site pain#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
>55/ C4591001 1008 10081724	GENRL	Injection site pain/ Injection site pain	1	29OCT2020	1/3	1	Yes		NA	R (31OCT2020)	N/N
		Pain/ Body aches	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
>55/ C4591001 1008 10081726	GENRL	Injection site pain/ Injection site pain	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	30OCT2020	2/2	1	Yes		NA	R (31OCT2020)	N/N
>55/ C4591001 1008 10081729	INFEC	Urinary tract infection/ Urinary tract infection	1	04NOV2020	7/6	1	No	O	NA/TC	R (09NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1008 10081730	MUSC	Myalgia/ Generalized muscle aches#	4	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1008 10081732	GENRL	Fatigue/ fatigue	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N
		Pain/ body aches	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N
>55/ C4591001 1008 10081734	GENRL	Injection site pain/ Injection site pain	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N
>55/ C4591001 1009 10091018	SKIN	Rash/ rash on left arm, lower bilateral legs, and lower back	2	01JAN2021	120/C	1	No	O	NA/TC	N	N/N
	SKIN	Rash/ worsening of rash to left arm, bilateral legs, lower back, stomach#	3	04MAR2021	4/7	2	Yes		NA/TC	R (10MAR2021)	N/N
>55/ C4591001 1009 10091019	GASTR	Toothache/ Left upper molar tooth pain	2	24SEP2020	25/C	2	No	O	NA	RG	N/N
	NERV	Headache/ headache	2	18JAN2021	141/1	1	No	O	NA	R (18JAN2021)	N/N
	NERV	Headache/ headache#	2	25JAN2021	148/2	1	No	O	NA	R (26JAN2021)	N/N
>55/ C4591001	INFEC	Skin infection/ skin infection right hand	2	18SEP2020	17/C	2	No	O	NA/TC	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1009 10091029 >55/ C4591001 1009 10091034	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	1	14AUG2020	2/19	2	No	O	NA/TC	R (01SEP2020)	N/N	
>55/ C4591001 1009 10091038	INJ&P	Stress fracture/ Right Foot Stress Fracture	2	23SEP2020	21/C	2	No	O	NA/TC	RG	N/N	
	MUSC	Sinus tarsi syndrome/ Left Sinus Tarsis Syndrome	2	22OCT2020	50/C	2	No	O	NA/TC	RG	N/N	
	PSYCH	Suicidal ideation/ Suicidal Ideation#	3	30JAN2021	13/5	3	No	O	NA/TC	R (03FEB2021)	N/N	
	SKIN	Ingrowing nail/ Ingrown Toenail#	4	10FEB2021	2/1	1	No	O	NA/TCN	R (10FEB2021)	N/N	
>55/ C4591001 1009 10091041	MUSC	Arthralgia/ Intermittent Bilateral Ankle Pain, Unspecified	2	07SEP2020	6/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1009 10091047	GENRL	Pain/ body aches#	3	27JAN2021	2/5	1	Yes		NA	R (31JAN2021)	N/N	
>55/ C4591001 1009 10091048	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	28SEP2020	26/15	1	No	O	NA/TC	R (12OCT2020)	N/N	
>55/ C4591001	GENRL	Peripheral swelling/ RIGHT HAND SWELLING	2	14OCT2020	35/C	3	No	O	NA/TC	RG	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1009 10091067	GASTR	Diarrhoea/ DIARRHEA	1	19AUG2020	2/1	1	No	O	NA	R (19AUG2020)	N/N
>55/ C4591001 1009 10091069	GASTR	Diarrhoea/ DIARRHEA	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE ACHES	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1009 10091077	GENRL	Fatigue/ fatigue	2	09SEP2020	2/4	1	Yes		NA	R (12SEP2020)	N/N
	MUSC	Myalgia/ generalized muscle soreness	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1009 10091089	INJ&P	Skin laceration/ LEFT THUMB LACERATION	1	06SEP2020	18/18	2	No	O	NA/TC	R (23SEP2020)	N/N
	PSYCH	Depression/ Worsening of Depression	2	21OCT2020	15/26	3	No	O	NA	R (15NOV2020)	N/N
	INJ&P	Fall/ fall	2	09DEC2020	64/1	2	No	O	NA	R (09DEC2020)	N/N
		Radius fracture/ left radius fracture	2	09DEC2020	64/36	2	No	O	NA/TC	R (13JAN2021)	N/N
	INFEC	Abscess limb/ abscess left hand	2	27DEC2020	82/30	2	No	O	NA/TC	R (25JAN2021)	N/N
>55/ C4591001	GENRL	Fatigue/ Fatigue#	4	10FEB2021	1/10	2	Yes		NA	R (19FEB2021)	N/Y



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1009 10091119		Malaise/ Malaise#	4	10FEB2021	1/10	2	Yes		NA	R (19FEB2021)	N/Y	
>55/ C4591001 1009 10091120	INFEC	Tooth infection/ tooth infection	1	04SEP2020	9/10	3	No	O	NA/TC/TCN	R (13SEP2020)	N/N	
>55/ C4591001 1009 10091123	NEOPL	Colon adenoma/ TUBULAR ADENOMA OF ASCENDING COLON	2	15DEC2020	92/3	2	No	O	NA/TC/TCN	R (17DEC2020)	Y/N	
>55/ C4591001 1009 10091135	NEOPL	Intraductal proliferative breast lesion/ Right Breast Ductal Carcinoma In Situ	1	02SEP2020	3/C	1	No	O	NA/TCN	N	Y/N	
	REPRO	Breast mass/ right breast lump	1	02SEP2020	3/C	1	No	O	NA	N	N/N	
>55/ C4591001 1009 10091141	INJ&P	Procedural pain/ Right Knee Post Surgical Pain#	2	19JAN2021	121/44	2	No	O	NA/TC	R (03MAR2021)	N/N	
>55/ C4591001 1009 10091143	INFEC	Cystitis/ CYSTITIS	2	06OCT2020	16/9	2	No	O	NA/TC	R (14OCT2020)	N/N	
>55/ C4591001 1009 10091149	INFEC	Diverticulitis/ worsening of diverticulitis	2	31DEC2020	101/3	2	No	O	NA/TC/TCN	R (02JAN2021)	Y/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1009 10091154	GASTR	Nausea/ nausea	1	04SEP2020	1/2	2	Yes		NA	R (05SEP2020)	N/N
	NERV	Headache/ headache	1	04SEP2020	1/2	3	Yes		NA/TC	R (05SEP2020)	N/N
	GENRL	Chills/ Chills	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
		Injection site pain/ soreness at injection site	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1009 10091160	INFEC	Urinary tract infection/ urinary tract infection	1	13SEP2020	6/10	2	No	O	NA/TC	R (22SEP2020)	N/N
>55/ C4591001 1009 10091162	GASTR	Toothache/ Toothache	1	20SEP2020	12/C	2	No	O	NA/TC	N	N/N
	INFEC	Oral herpes/ cold sore to mouth	2	12OCT2020	15/5	1	No	O	NA/TC	R (16OCT2020)	N/N
>55/ C4591001 1009 10091168	SURG	Spinal fusion surgery/ Lumbar Spinal Fusion#	4	03MAR2021	22/C	3	No	O	NA/TC	RG	N/N
>55/ C4591001 1009 10091179	MUSC	Plantar fasciitis/ LEFT FOOT PLANTAR FASCIITIS#	3	08MAR2021	6/C	1	No	O	NA/TCN	RG	N/N
>55/ C4591001	INFEC	Ear infection/ ear infection	1	10OCT2020	17/C	2	No	O	NA/TC	RG	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1009 10091190 >55/ C4591001	REPRO	Cervical polyp/ benign cervical polyp	2	30OCT2020	17/C	1	No	O	NA	N	N/N
1009 10091195 >55/ C4591001	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	18DEC2020	2/3	1	Yes		NA	R (20DEC2020)	N/N
1009 10091196 >55/ C4591001	GENRL	Injection site discomfort/ Left arm muscle tightness at injection site#	3	20JAN2021	1/3	1	No	O	NA	R (22JAN2021)	N/N
1011 10111007 >55/ C4591001	SKIN	Rash erythematous/ Red rash on torso#	4	10FEB2021	3/5	1	Yes		NA	R (14FEB2021)	N/N
1011 10111012 >55/ C4591001	NERV	Headache/ Headache	2	01OCT2020	29/45	1	No	O	NA/TC	R (14NOV2020)	N/N
1011 10111018 >55/ C4591001	RESP	Nasal congestion/ Nasal Congestion	2	01OCT2020	29/45	1	No	O	NA/TC	R (14NOV2020)	N/N
1011 10111029 >55/ C4591001	INFEC	Appendicitis perforated/ Perforated Appendicitis	2	12SEP2020	13/4	3	No	O	NA/TC/TCN	R (15SEP2020)	Y/N
1011 10111029 >55/ C4591001	INFEC	Peritonitis/ Feculant Peritonitis	2	14SEP2020	15/5	3	No	O	NA/TC/TCN	R (18SEP2020)	Y/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1011 10111047	GASTR	Nausea/ Nausea#	4	11FEB2021	1/4	1	Yes		NA	R (14FEB2021)	N/N
	GENRL	Chills/ Chills#	4	11FEB2021	1/4	1	Yes		NA	R (14FEB2021)	N/N
		Fatigue/ Fatigue#	4	11FEB2021	1/4	1	Yes		NA	R (14FEB2021)	N/N
		Pyrexia/ Fever-101.3#	4	11FEB2021	1/4	1	Yes		NA	R (14FEB2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	11FEB2021	1/4	1	Yes		NA	R (14FEB2021)	N/N
NERV	Headache/ Headache#	4	11FEB2021	1/4	1	Yes		NA	R (14FEB2021)	N/N	
>55/ C4591001 1011 10111048	GENRL	Chills/ Chills#	3	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
>55/ C4591001 1011 10111049	INJ&P	Fall/ Fall	2	04OCT2020	27/1	1	No	O	NA	R (04OCT2020)	N/N
		Ligament sprain/ Sprained left ankle	2	04OCT2020	27/C	1	No	O	NA/TC/TCN	N	N/N
>55/ C4591001 1011 10111050	GENRL	Chills/ Chills	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
		Fatigue/ Fatigue	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Pyrexia/ Fever 100.1 F	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1011 10111057	INV	Blood cholesterol increased/ High Cholesterol#	4	24FEB2021	15/C	1	Yes		NA/TC	N	N/N
>55/ C4591001 1011 10111059	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	1/3	1	Yes		NA	R (18FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
	RENAL	Hypertonic bladder/ Overactive Bladder#	4	25FEB2021	10/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1011 10111068	GENRL	Injection site pain/ Injection Site Pain#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1011 10111076	GASTR	Diarrhoea/ Diarrhea#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Injection site swelling/ Injection site swelling#	4	09JAN2021	2/4	1	Yes		NA	R (12JAN2021)	N/N
>55/ C4591001 1011 10111085	GENRL	Chills/ Chills#	3	11FEB2021	1/4	1	Yes		NA	R (14FEB2021)	N/N
		Fatigue/ Fatigue#	2	11FEB2021	155/4	2	Yes		NA	R (14FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1011 10111086	NERV	Dizziness/ Dizziness#	3	11FEB2021	1/4	1	Yes		NA	R (14FEB2021)	N/N	
	MUSC	Myalgia/ Muscle Aches#	3	12FEB2021	2/3	1	Yes		NA	R (14FEB2021)	N/N	
	GENRL	Chills/ Chills#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N	
		Fatigue/ Fatigue#	3	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N	
		Pyrexia/ Fever 100.9#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N	
	MUSC	Myalgia/ Muscle Aches#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N	
	NERV	Headache/ Headache#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N	
	>55/ C4591001 1011 10111120	INFEC	Urinary tract infection/ Urinary Tract Infection#	3	11FEB2021	14/C	1	No	O	NA/TC	RG	N/N
	>55/ C4591001 1011 10111126	MUSC	Myalgia/ Generalized Muscle aches	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
	>55/ C4591001 1011 10111138	INJ&P	Chest injury/ Bruised Ribs	1	15SEP2020	15/C	2	No	O	NA	N	N/N
		Hand fracture/ Left Hand Fracture	1	15SEP2020	15/C	2	No	O	NA/TC	N	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1011 10111139	MUSC	Ligament sprain/ Left Wrist Sprain	1	15SEP2020	15/C	2	No	O	NA/TC	N	N/N
		Ligament sprain/ Sprained left knee	1	15SEP2020	15/C	2	No	O	NA/TC	N	N/N
		Road traffic accident/ Bike accident	1	15SEP2020	15/1	2	No	O	NA	R (15SEP2020)	N/N
		Back pain/ Back pain left medial area	2	JAN2021	102/C	1	No	O	NA	N	N/N
>55/ C4591001 1011 10111145	RESP	Rhinorrhoea/ Runny Nose#	2	21JAN2021	122/1	1	No	O	NA	R (21JAN2021)	N/N
	SKIN	Rash/ Rash on right forearm	1	02SEP2020	1/4	1	No	O	NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site pain#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1011 10111152	MUSC	Myalgia/ Generalized Muscle Aches#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	NERV	Headache/ Headache#	4	09FEB2021	2/1	1	Yes		NA/TC	R (09FEB2021)	N/N
	GASTR	Toothache/ Tooth Pain	1	22SEP2020	21/2	1	No	O	NA/TC	R (23SEP2020)	N/N
>55/ C4591001 1011 10111153	GENRL	Chills/ Chills#	4	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1011 10111157	RESP	Pyrexia/ Fever 100.9#	4	04FEB2021	1/2	1	Yes		NA/TC	R (05FEB2021)	N/N
		Nasal congestion/ Nasal Congestion	1	20SEP2020	18/5	1	No	O	NA/TC	R (24SEP2020)	N/N
	GENRL	Chills/ Chills#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
		Pyrexia/ Fever 100.8#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1011 10111167	NERV	Headache/ Headache#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	04SEP2020	2/3	1	Yes		NA	R (06SEP2020)	N/N
	INFEC	Conjunctivitis/ Left eye conjunctivitis	1	04SEP2020	2/5	1	No	O	NA/TC	R (08SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
>55/ C4591001 1011 10111171	GENRL	Fatigue/ Fatigue	1	06OCT2020	1/1	1	Yes		NA/TCN	R (06OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Chills/ Chills#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
Fatigue/ Fatigue#		4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N	



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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1011 10111172	NERV	Pyrexia/ Fever 101.8#	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
		Headache/ Headache#	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1011 10111172	GASTR	Diarrhoea/ Diarrhea	2	29OCT2020	1/5	1	Yes		NA	R (02NOV2020)	N/N
>55/ C4591001 1011 10111181	GASTR	Paraesthesia oral/ Tingling around the mouth	1	08OCT2020	1/1	1	Yes		P	R (08OCT2020)	N/N
>55/ C4591001 1011 10111188	NERV	Paraesthesia/ Tingling at finger tips	1	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
	GASTR	Toothache/ Toothache	1	30OCT2020	23/19	1	No	O	NA/TC	R (17NOV2020)	N/N
>55/ C4591001 1011 10111188	INV	Body temperature increased/ Increased Body Temperature (99.8F)	2	03NOV2020	1/2	1	Yes		NA/TC	R (04NOV2020)	N/N
>55/ C4591001 1011 10111191	MUSC	Myalgia/ Generalized Muscle Aches	2	03NOV2020	1/2	1	Yes		NA/TC	R (04NOV2020)	N/N
	NERV	Headache/ Headache#	4	19JAN2021	1/2	1	Yes		NA/TC	R (20JAN2021)	N/N
>55/ C4591001 1011 10111201	GENRL	Fatigue/ Fatigue	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1011 10111202		Pyrexia/ Fever 101.0	2	06NOV2020	2/2	2	Yes		NA	R (07NOV2020)	N/N	
	METAB	Decreased appetite/ Loss of Appetite	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N	
	MUSC	Myalgia/ Muscle Aches	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N	
	GENRL	Chills/ Chills#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	
	MUSC	Myalgia/ Generalized Muscle Aches#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	
	NERV	Headache/ Headache#	4	08FEB2021	1/2	2	Yes		NA	R (09FEB2021)	N/N	
	VASC	Hypertension/ Worsening Hypertension#	4	01MAR2021	22/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1011 10111206	GENRL	Injection site pain/ Soreness at injection site	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N	
	NERV	Somnolence/ Drowsiness	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N	
>55/ C4591001 1011 10111217	NERV	Headache/ Headaches	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N	
	NERV	Headache/ Headache	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N	
>55/ C4591001 1011 10111218	NERV	Headache/ Headache	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
		Fatigue/ Fatigue#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
	NERV	Headache/ Headache#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
>55/ C4591001 1011 10111229	GENRL	Injection site pain/ Injection Site Pain#	4	09JAN2021	2/4	1	Yes		NA	R (12JAN2021)	N/N
>55/ C4591001 1011 10111230	GENRL	Injection site pain/ Soreness at injection site	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Chills/ Chills	2	14NOV2020	2/1	1	Yes		NA	R (14NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	14NOV2020	2/1	1	Yes		NA/TC	R (14NOV2020)	N/N
		Pyrexia/ Fever (100.7)	2	14NOV2020	2/1	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Aches	2	14NOV2020	2/1	1	Yes		NA/TC	R (14NOV2020)	N/N
>55/ C4591001 1012 10121004	REPRO	Breast hyperplasia/ Atypical Lobular Hyperplasia Right Breast	2	15JAN2021	145/C	1	No	O	NA/TCN	N	N/N
>55/ C4591001 1012 10121010	GASTR	Nausea/ Nausea	2	26AUG2020	2/1	1	No	O	NA/TC	R (26AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1012 10121029	MUSC	Muscle spasms/ Cramp in left calf	1	16AUG2020	6/2	1	No	CND	NA	R (17AUG2020)	N/N	
	MUSC	Osteoarthritis/ Right Shoulder Osteoarthritis	2	13DEC2020	104/C	2	No	CND	NA	RG	N/N	
	NERV	Head discomfort/ HEAD PRESSURE	2	31JAN2021	153/C	2	No	O	NA	N	N/N	
>55/ C4591001 1012 10121033	HEPAT	Hepatic cirrhosis/ Cirrhotic liver	1	22SEP2020	15/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1012 10121034	GENRL	Injection site pain/ PAIN AT INJECTION SITE LEFT ARM#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N	
>55/ C4591001 1012 10121035	NEOPL	Prostate cancer/ Prostate Cancer (Gleason 8)	2	24DEC2020	115/C	2	No	O	NA/TC	N	N/N	
	NERV	Tremor/ Worsening of Hand Tremors	2	26DEC2020	117/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1012 10121039	GENRL	Injection site pain/ Left Arm Injection Site Pain	1	17AUG2020	1/1	1	Yes		NA	R (17AUG2020)	N/N	
	GENRL	Fatigue/ FATIGUE	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N	
	MUSC	Myalgia/ MUSCLE ACHES	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ HEADACHE	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Injection site pain/ Arm pain at injection site	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1012 10121044	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
>55/ C4591001 1012 10121045	GENRL	Pyrexia/ Fever	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
>55/ C4591001 1012 10121047	GENRL	Chills/ Chills#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
		Malaise/ Generalized malaise#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
		Pyrexia/ Fever#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N
>55/ C4591001 1012 10121048	GENRL	Injection site pain/ Left Arm Pain at Injection Site	1	19AUG2020	1/4	1	Yes		NA	R (22AUG2020)	N/Y
	GENRL	Fatigue/ Fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Pain/ Body Aches	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1012 10121049	GENRL	Pyrexia/ Low Grade Fever	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Pain/ Body Aches	2	12SEP2020	3/4	2	Yes		NA/TC	R (15SEP2020)	N/N
>55/ C4591001 1012 10121056	PSYCH	Nightmare/ Nightmares	2	01OCT2020	22/6	2	No	O	NA	R (06OCT2020)	N/N
	MUSC	Arthralgia/ Worsening of right shoulder pain	2	15DEC2020	96/C	1	No	CND	NA/TC/TCN	N	N/N
>55/ C4591001 1012 10121057	INJ&P	Muscle strain/ Pulled left arm muscle	1	08SEP2020	19/4	1	No	CND	NA	R (11SEP2020)	N/N
	NERV	Dizziness/ Dizziness#	3	11FEB2021	13/1	1	No	CND	NA	R (11FEB2021)	N/N
>55/ C4591001 1012 10121063	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	24AUG2020	1/3	2	Yes		NA	R (26AUG2020)	N/N
	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	16SEP2020	1/6	1	Yes		NA	R (21SEP2020)	N/N
	MUSC	Arthralgia/ JOINT PAIN	2	17SEP2020	2/1	2	Yes		NA	R (17SEP2020)	N/N
		Myalgia/ MUSCLE PAIN	2	17SEP2020	2/1	2	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	17SEP2020	2/1	2	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1012 10121064	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	24AUG2020	1/3	2	Yes		NA	R (26AUG2020)	N/N
	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	16SEP2020	1/5	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Pyrexia/ LOW GRADE FEVER	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Arthralgia/ JOINT PAIN	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		Myalgia/ MUSCLE PAIN	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1012 10121068	GENRL	Injection site pain/ Left arm muscle pain at injection site	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ FEVER	2	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1012 10121071	GENRL	Injection site pain/ Injection site pain#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1012 10121080	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
		Injection site swelling/ SWELLING AT INJECTION SITE LEFT ARM	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
	GASTR	Nausea/ NAUSEA	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	15SEP2020	1/3	3	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1012 10121086	MUSC	Back pain/ LOWER BACK PAIN	1	30AUG2020	3/4	2	Yes		NA/TC	R (02SEP2020)	N/N
		Joint stiffness/ Bilateral Knee Stiffness	1	30AUG2020	3/4	1	No	CND	NA	R (02SEP2020)	N/N
		Musculoskeletal stiffness/ NECK STIFFNESS	1	30AUG2020	3/4	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	16SEP2020	1/1	2	Yes		NA	R (16SEP2020)	N/N
	MUSC	Back pain/ LOW BACK PAIN	2	16SEP2020	1/C	1	Yes		NA	RG	N/N
		Joint stiffness/ Bilateral Knee Stiffness	2	16SEP2020	1/C	1	No	CND	NA	RG	N/N
		Musculoskeletal stiffness/ NECK STIFFNESS	2	16SEP2020	1/C	1	Yes		NA	RG	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Musculoskeletal stiffness/ Left Shoulder Stiffness Intermittent	2	23SEP2020	8/C	1	Yes		NA	RG	N/N
>55/ C4591001 1012 10121088	GASTR	Nausea/ Nausea	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Pain/ Body Aches	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
	EYE	Eye pain/ Bilateral Eye Soreness	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Chills/ Chills	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ Fever	2	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C4591001 1012 10121093	GENRL	Injection site pain/ Left Arm Pain at Injection Site	2	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C4591001 1012 10121094	GENRL	Fatigue/ FATIGUE	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
>55/ C4591001 1012 10121097	GENRL	Injection site pain/ Left arm localized soreness at injection site	1	02SEP2020	3/2	1	Yes		NA	R (03SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Dizziness/ Dizziness#	3	24JAN2021	12/1	1	No	O	NA	R (24JAN2021)	N/N
	GENRL	Chills/ Chills#	4	02FEB2021	1/2	3	Yes		NA	R (03FEB2021)	N/N
	EAR	Vertigo/ Vertigo#	4	03FEB2021	2/3	3	No	O	NA/TC/TCN	R (05FEB2021)	Y/N
	GENRL	Pyrexia/ Fever#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	INJ&P	Skin laceration/ Laceration on Head#	4	03FEB2021	2/9	2	No	O	NA/TC/TCN	R (11FEB2021)	N/N
>55/ C4591001 1012 10121100	VASC	Hypertension/ WORSENING OF HYPERTENSION	2	13JAN2021	115/C	1	No	O	NA/TC	RG	N/N
	NERV	Dizziness/ Worsening of Lightheadedness#	4	01MAR2021	19/C	1	No	O	NA	N	N/N
	METAB	Type 2 diabetes mellitus/ Type II Diabetes Mellitus#	4	11MAR2021	29/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1012 10121106	GENRL	Injection site pain/ RIGHT ARM INJECTION SITE PAIN	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
	EYE	Vision blurred/ Blurred vision	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain Bilateral Arms	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Arthralgia/ Joint Pain Bilateral Legs	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	23SEP2020	3/1	2	Yes		NA/TC	R (23SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	2	23SEP2020	3/2	3	Yes		NA	R (24SEP2020)	N/N
	NERV	Dizziness/ Lightheadedness	2	23SEP2020	3/2	2	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1012 10121109	NEOPL	Infected naevus/ Infection of Mole Lower Right Abdomen	2	14OCT2020	24/76	1	No	CND	NA/TC	R (28DEC2020)	N/N
>55/ C4591001 1012 10121112	CARD	Atrial fibrillation/ PAROXYSMAL ATRIAL FIBRILLATION	2	09DEC2020	80/3	3	No	O	NA/TC	R (11DEC2020)	Y/N
	GENRL	Chills/ BODY CHILLS#	4	03FEB2021	2/4	2	Yes		NA	R (06FEB2021)	N/N
	MUSC	Back pain/ BACK PAIN#	4	03FEB2021	2/C	2	No	O	NA	RG	N/N
	SKIN	Hyperhidrosis/ BODY SWEATS#	4	03FEB2021	2/4	2	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1012 10121113	NERV	Headache/ HEADACHE	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/N
	NERV	Headache/ Headache	2	21SEP2020	1/31	1	Yes		NA	R (21OCT2020)	N/N
>55/ C4591001 1012 10121114	GENRL	Injection site pain/ INJECTION SITE PAIN LEFT ARM	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Chills/ Chills	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1012 10121120	NERV	Pyrexia/ Fever	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
		Headache/ Headache	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ RIGHT ARM INJECTION SITE PAIN	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	INJ&P	Procedural pain/ POST-OP PAIN FROM LEFT ROTATOR CUFF REPAIR	1	18SEP2020	17/C	1	No	CND	NA/TC	RG	N/N
	GENRL	Chills/ BODY CHILLS	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
		Fatigue/ FATIGUE	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1012 10121122	INV	Pyrexia/ FEVER	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		Blood testosterone decreased/ Low Testosterone#	4	25FEB2021	9/C	1	No	CND	NA/TC	N	N/N
>55/ C4591001 1012 10121123	MUSC	Back pain/ Mid Back Pain	1	17SEP2020	15/C	1	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	METAB	Glucose tolerance impaired/ Pre-Diabetes	2	04JAN2021	105/C	1	No	O	NA/TC	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1012 10121125	GENRL	Injection site pain/ RIGHT ARM INJECTION SITE PAIN	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
	EYE	Chalazion/ RIGHT CHALAZION	1	10SEP2020	8/C	2	No	O	NA/TC/TCN	RG	N/N
	INFEC	Hordeolum/ RIGHT STYE	1	10SEP2020	8/C	2	No	O	NA/TC/TCN	RG	N/N
	INFEC	Sinusitis/ SINUS INFECTION	1	11SEP2020	9/12	2	No	O	NA/TC	R (22SEP2020)	N/N
	INFEC	Cellulitis orbital/ RIGHT EYE CELLULITIS	1	12SEP2020	10/5	2	No	O	NA/TC	R (16SEP2020)	N/N
>55/ C4591001 1012 10121126	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
>55/ C4591001 1012 10121127	GENRL	Fatigue/ Fatigue	1	04SEP2020	2/4	1	Yes		NA	R (07SEP2020)	N/N
	MUSC	Pain in extremity/ LEFT ARM PAIN	1	04SEP2020	2/3	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Injection site pain/ Left Arm Injection Site Pain	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
>55/ C4591001 1012 10121128	GENRL	Fatigue/ Fatigue	1	05SEP2020	3/3	1	Yes		NA	R (07SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	25SEP2020	2/3	2	Yes		NA	R (27SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1012 10121135	GENRL	Injection site pain/ Right Arm Injection Site Pain	2	25SEP2020	2/11	1	Yes		NA	R (05OCT2020)	N/N
		Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	04SEP2020	1/5	2	Yes		NA	R (08SEP2020)	N/N
		Injection site pain/ Left Arm Pain at Injection Site	2	25SEP2020	1/6	1	Yes		NA	R (30SEP2020)	N/N
		Chills/ Chills	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		Headache/ Headache	2	26SEP2020	2/2	2	Yes		NA/TC	R (27SEP2020)	N/N
>55/ C4591001 1012 10121139	SKIN	Urticaria/ Hives Bilateral Legs	1	20SEP2020	16/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1012 10121142	EYE	Eye swelling/ Right Swollen Eye#	4	10MAR2021	2/4	2	No	O	NA	R (13MAR2021)	N/N
>55/ C4591001 1012 10121148	INJ&P	Joint dislocation/ Right hip dislocation#	3	22JAN2021	5/1	2	No	O	NA	R (22JAN2021)	N/N
>55/ C4591001	INJ&P	Fall/ Fall#	3	07FEB2021	21/1	2	No	O	NA	R (07FEB2021)	N/N
		Joint dislocation/ RIGHT HIP DISLOCATION#	3	07FEB2021	21/1	2	No	O	NA/TC/TCN	R (07FEB2021)	N/N
	GENRL	Chills/ Chills	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1012 10121160		Pyrexia/ Fever	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pains	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C4591001 1012 10121165	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Chills/ CHILLS	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
		Fatigue/ FATIGUE	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
		Pain/ BODY ACHES	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C4591001 1012 10121168	MUSC	Arthralgia/ LEFT WRIST INSIDE PAIN	1	10SEP2020	1/1	1	No	CND	NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	12SEP2020	3/1	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Dysgeusia/ METALLIC TASTE IN MOUTH	1	12SEP2020	3/1	1	Yes		NA	R (12SEP2020)	N/N
	GASTR	Diarrhoea/ DIARRHEAL EPISODE	2	03OCT2020	4/1	2	No	CND	NA	R (03OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	03OCT2020	4/1	3	Yes		NA/TC	R (03OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1012 10121170	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
>55/ C4591001 1012 10121186	GENRL	Injection site pain/ Pain at Injection Site	1	21SEP2020	1/5	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Chills/ Chills	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		Fatigue/ Fatigue	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		Pain/ Body Aches	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
>55/ C4591001 1013 10131130	NERV	Headache/ Frontal headache	2	03SEP2020	2/1	1	Yes		NA/TC	R (03SEP2020)	N/N
>55/ C4591001 1013 10131133	MUSC	Neck pain/ CERVICAL PAIN	2	09SEP2020	9/C	3	No	O	NA/TC	RG	N/N
>55/ C4591001 1013 10131176	BLOOD	Leukopenia/ LEUKOPENIA	1	29AUG2020	17/10	2	No	O	NA/TCN	R (07SEP2020)	N/N
	GASTR	Abdominal adhesions/ abdominal adhesions	1	29AUG2020	17/2	3	No	O	NA/TC	R (30AUG2020)	Y/N
		Small intestinal obstruction/ SMALL BOWEL OBSTRUCTION	1	29AUG2020	17/2	2	No	O	NA/TCN	R (30AUG2020)	Y/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INFEC	Sepsis/ sepsis	1	29AUG2020	17/19	3	No	O	NA	R (16SEP2020)	N/N
	METAB	Hyponatraemia/ HYPONATREMIA	1	29AUG2020	17/10	2	No	O	NA/TC	R (07SEP2020)	N/N
	PSYCH	Mental status changes/ altered mental status	1	29AUG2020	17/19	3	No	CND	NA	R (16SEP2020)	N/N
	RENAL	Acute kidney injury/ acute renal failure	1	29AUG2020	17/19	3	No	O	NA	R (16SEP2020)	N/N
	BLOOD	Anaemia/ anemia	1	30AUG2020	18/18	3	No	O	NA	R (16SEP2020)	N/N
	CARD	Cardiac failure congestive/ CONGESTIVE HEART FAILURE	1	30AUG2020	18/18	3	No	O	NA	R (16SEP2020)	N/N
	METAB	Hypokalaemia/ hypokalemia	1	30AUG2020	18/18	3	No	O	NA	R (16SEP2020)	N/N
	RESP	Acute respiratory failure/ acute hypoxic respiratory failure	1	30AUG2020	18/13	3	No	O	NA	R (11SEP2020)	Y/N
		Pneumonia aspiration/ ASPIRATION PNEUMONIA	1	30AUG2020	18/18	2	No	O	NA/TCN	R (16SEP2020)	Y/N
	CARD	Left ventricular hypertrophy/ MILD CONCENTRIC LEFT VENTRICULAR HYPERTROPHY	1	16SEP2020	35/C	1	No	O	NA	RG	N/N
	INFEC	Urinary tract infection/ URINARY TRACT INFECTION#	2	13JAN2021	99/10	1	No	O	NA/TC	R (22JAN2021)	N/N
>55/ C4591001 1013 10131186	INFEC	Infected bite/ 2ND TOE OF RIGHT FOOT BUG BITE INFECTION	1	02SEP2020	21/19	2	No	O	NA/TC	R (20SEP2020)	N/N
	INJ&P	Meniscus injury/ TORN MENISCUS RIGHT KNEE	1	02SEP2020	21/C	2	No	O	NA/TC	RG	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1013 10131236	GENRL	Pain/ BODY ACHES	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1013 10131244	PSYCH	Restlessness/ RESTLESSNESS	2	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	2	11SEP2020	2/1	2	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1013 10131248	GENRL	Injection site pain/ INJECTION SITE PAIN	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
		Pyrexia/ LOW GRADE FEVER	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
>55/ C4591001 1013 10131260	GENRL	Injection site pain/ INJECTION SITE PAIN	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1013 10131265	GENRL	Fatigue/ FATIGUE	1	21AUG2020	2/5	1	Yes		NA	R (25AUG2020)	N/N
>55/ C4591001 1013 10131277	GENRL	Chills/ CHILLS	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1013 10131278	GENRL	Fatigue/ FATIGUE	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
		Fatigue/ FATIGUE	2	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1013 10131279	GENRL	Chills/ CHILLS	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C4591001 1013 10131294	MUSC	Musculoskeletal stiffness/ STIFF NECK	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	21SEP2020	8/2	1	Yes		NA	R (22SEP2020)	N/N
>55/ C4591001 1013 10131294	GENRL	Chills/ CHILLS#	4	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
		Fatigue/ FATIGUE#	4	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
		Pyrexia/ FEVER#	4	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1013 10131297	GENRL	Fatigue/ FATIGUE	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C4591001	NERV	Headache/ HEADACHE	2	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131310	GENRL	Pain/ BODY ACHES	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C4591001 1013 10131320	NERV	Dizziness/ LIGHTHEADEDNESS	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1013 10131324	RESP	Dyspnoea/ SHORTNESS OF BREATH	2	16SEP2020	2/2	1	No	O	NA	R (17SEP2020)	N/N
>55/ C4591001 1013 10131326	GENRL	Injection site pain/ INJECTION SITE PAIN	2	23SEP2020	7/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1013 10131326	MUSC	Arthralgia/ JOINT ACHES	1	07SEP2020	13/37	1	No	O	NA	R (13OCT2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ LOW GRADE FEVER	2	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Chills/ CHILLS#	4	13JAN2021	2/1	1	Yes		NA	R (13JAN2021)	N/N
		Fatigue/ FATIGUE#	4	13JAN2021	2/1	1	Yes		NA	R (13JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1013 10131330	NERV	Morton's neuralgia/ UNILATERAL MORTON'S NEUROMA	2	26DEC2020	102/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1013 10131331	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	03NOV2020	49/8	1	No	O	NA/TC	R (10NOV2020)	N/N	
>55/ C4591001 1013 10131333	INJ&P	Radius fracture/ FRACTURE RIGHT DISTAL RADIUS	2	28SEP2020	13/8	2	No	O	NA/TC	R (05OCT2020)	N/N	
		Ulna fracture/ FRACTURE RIGHT DISTAL ULNA	2	28SEP2020	13/8	2	No	O	NA/TC	R (05OCT2020)	N/N	
	SURG	Open reduction of fracture/ OPEN REDUCTION INTERNAL FIXATION RIGHT RADIUS	2	05OCT2020	20/1	2	No	O	NA/TC	R (05OCT2020)	N/N	
>55/ C4591001 1013 10131341	GENRL	Injection site pain/ INJECTION SITE PAIN	2	19SEP2020	3/3	2	Yes		NA/TC	R (21SEP2020)	N/N	
	MUSC	Myalgia/ MUSCLE PAIN	2	19SEP2020	3/3	2	Yes		NA/TC	R (21SEP2020)	N/N	
	GASTR	Gastroesophageal reflux disease/ GASTRO-ESOPHAGEAL REFLUX DISEASE#	2	28JAN2021	134/C	1	No	O	NA/TC	RG	N/N	
	VASC	Hypertension/ HYPERTENSION#	2	28JAN2021	134/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	02SEP2020	7/2	1	Yes		NA	R (03SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131346	METAB	Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2	18JAN2021	125/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1013 10131347	GENRL	Pain/ BODY ACHES	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001 1013 10131350	GENRL	Night sweats/ NIGHT SWEATS	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001 1013 10131350	GENRL	Injection site pain/ INJECTION SITE PAIN	1	28AUG2020	2/3	2	Yes		NA/TC	R (30AUG2020)	N/N
>55/ C4591001 1013 10131354	GENRL	Pyrexia/ LOW GRADE FEVER	2	19SEP2020	3/1	2	Yes		NA/TC	R (19SEP2020)	N/N
>55/ C4591001 1013 10131354	NEOPL	Bladder neoplasm/ BLADDER TUMOR#	4	04MAR2021	29/C	2	No	O	NA/TCN	RG	N/N
>55/ C4591001 1013 10131356	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	31AUG2020	1/4	1	Yes		NA	R (03SEP2020)	N/N
>55/ C4591001	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C4591001	NERV	Headache/ FRONTAL HEADACHE	2	23SEP2020	2/4	2	Yes		NA/TC	R (26SEP2020)	N/N
>55/ C4591001	INJ&P	Fall/ Fall	1	07SEP2020	8/1	2	No	O	NA/TC	R (07SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1013 10131358 >55/ C4591001	MUSC	Arthralgia/ LEFT SHOULDER SORENESS	2	05OCT2020	15/C	2	No	O	NA/TC	RG	N/N	
1013 10131359 >55/ C4591001	GENRL	Fatigue/ FATIGUE	2	21SEP2020	1/4	1	Yes		NA	R (24SEP2020)	N/N	
1013 10131360 >55/ C4591001	VASC	Injection site pain/ INJECTION SITE PAIN Hypertension/ HYPERTENSION#	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N	
1013 10131367 >55/ C4591001	VASC	Hypertension/ HYPERTENSION#	2	11FEB2021	142/C	1	No	O	NA/TC	RG	N/N	
1013 10131368 >55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
1013 10131372 >55/ C4591001	INJ&P	Procedural pain/ POST SURGICAL PAIN#	2	18JAN2021	118/C	2	No	O	NA/TC	RG	N/N	
1013 10131372 >55/ C4591001	RESP	Nasal congestion/ NASAL CONGESTION	2	26SEP2020	4/C	1	Yes		NA	RG	N/N	
1013 10131372 >55/ C4591001	GENRL	Oropharyngeal pain/ SORE THROAT Chills/ CHILLS	2	26SEP2020	4/3	1	Yes		NA/TC	R (28SEP2020)	N/N	
1013 10131372 >55/ C4591001	GENRL	Chills/ CHILLS	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131384	GENRL	Fatigue/ FATIGUE	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	2	22SEP2020	2/4	2	Yes		NA/TC	R (25SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	24SEP2020	4/1	2	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C4591001 1013 10131386	VASC	Arterial occlusive disease/ ARTERY OCCLUSION#	2	13MAR2021	173/C	3	No	O	NA/TC	RG	Y/N
>55/ C4591001 1013 10131402	GENRL	Chills/ CHILLS	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1013 10131415	GENRL	Chills/ CHILLS	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
	GASTR	Nausea/ NAUSEA	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ FEVER	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	INFEC	Paronychia/ PARONYCHIA RIGHT INDEX FINGER	2	14NOV2020	52/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1013 10131428	MUSC	Musculoskeletal discomfort/ RIGHT SHOULDER DISCOMFORT	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N	
>55/ C4591001 1013 10131431	MUSC	Musculoskeletal stiffness/ BODY MUSCLE STIFFNESS	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N	
>55/ C4591001 1013 10131434	GENRL	Chills/ CHILLS	2	25SEP2020	2/2	2	Yes		NA/TC	R (26SEP2020)	N/N	
		Fatigue/ FATIGUE	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
		Injection site pain/ INJECTION SITE PAIN	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N	
		Pyrexia/ LOW GRADE FEVER	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N	
>55/ C4591001 1013 10131457	GENRL	Injection site pain/ INJECTION SITE PAIN	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
>55/ C4591001 1013 10131460	GENRL	Pain/ BODY ACHES	1	08SEP2020	1/2	2	Yes		NA/TC	R (09SEP2020)	N/N	
		Pyrexia/ LOW GRADE FEVER	1	08SEP2020	1/2	2	Yes		NA/TC	R (09SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ FATIGUE	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C4591001 1013 10131461	GENRL	Injection site pain/ INJECTION SITE PAIN	2	30SEP2020	1/7	1	Yes		NA	R (06OCT2020)	N/N
>55/ C4591001 1013 10131462	GENRL	Injection site pain/ INJECTION SITE PAIN	2	29SEP2020	1/3	2	Yes		NA	R (01OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
>55/ C4591001 1013 10131466	INV	Body temperature increased/ ELEVATED TEMPERATURE	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
	MUSC	Pain in extremity/ LEFT ARM PAIN	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Pyrexia/ LOW GRADE FEVER	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	NERV	Headache/ HEADACHE LEFT SIDE	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
>55/ C4591001 1013 10131482	MUSC	Myalgia/ MUSCLE PAIN	1	11SEP2020	3/4	1	Yes		NA	R (14SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	11SEP2020	3/8	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1013 10131488	GENRL	Injection site pain/ INJECTION SITE PAIN	2	02OCT2020	2/4	1	Yes		NA	R (05OCT2020)	N/N
		Pain/ BODY ACHES	2	02OCT2020	2/4	1	Yes		NA	R (05OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	02OCT2020	2/4	1	Yes		NA	R (05OCT2020)	N/N
>55/ C4591001 1013 10131489	GENRL	Injection site pain/ INJECTION SITE PAIN	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
	NERV	Headache/ TEMPORAL HEADACHE	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Pain/ BODY ACHES	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1013 10131505	GENRL	Pyrexia/ Low grade fever	1	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Pain/ BODY ACHES	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N
		Pyrexia/ LOW GRADE FEVER	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1013 10131506	NERV	Headache/ FRONTAL HEADACHE	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N
	GENRL	Pain/ BODY ACHES	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N
		Pyrexia/ LOW GRADE FEVER	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N
>55/ C4591001 1013 10131511	GENRL	Chills/ CHILLS	2	04OCT2020	4/1	1	Yes		NA/TC	R (04OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
>55/ C4591001 1013 10131517	GENRL	Fatigue/ FATIGUE	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN TO LEFT ARM*		10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1013 10131525	CARD	Acute myocardial infarction/ STEMI	2	08NOV2020	40/3	3	No	O	NA	R (10NOV2020)	Y/N
	GENRL	Fatigue/ FATIGUE	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1013 10131536	GASTR	Dry mouth/ DRY MOUTH	1	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N
>55/ C4591001 1013 10131539	SKIN	Rash/ RASH NECK	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	17SEP2020	3/1	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	08OCT2020	3/1	1	Yes		NA	R (08OCT2020)	N/N
>55/ C4591001 1013 10131548	GENRL	Injection site pain/ INJECTION SITE PAIN	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
>55/ C4591001 1013 10131554	GENRL	Injection site pain/ INJECTION SITE PAIN	1	17SEP2020	2/4	1	Yes		NA	R (20SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1013 10131558	GENRL	Injection site pain/ INJECTION PAIN	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
		Pain/ BODY PAIN	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
	GENRL	Chills/ CHILLS	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		Pyrexia/ LOW GRADE FEVER	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
	RESP	Asthma/ acute exacerbation of asthma	2	16DEC2020	73/5	3	No	O	NA/TC	R (20DEC2020)	Y/N
	GENRL	Chills/ CHILLS	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
		Pain/ BODY ACHES	2	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N
		Pyrexia/ LOW GRADE FEVER	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
	NERV	Dizziness/ DIZZINESS	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
	>55/ C4591001 1013 10131560	GENRL	Injection site pain/ INJECTION SITE PAIN	1	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)
	NERV	Headache/ HEADACHE	2	08OCT2020	2/1	2	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	09OCT2020	3/3	1	Yes		NA	R (11OCT2020)	N/N
>55/ C4591001	NERV	Headache/ Headache	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131561	VASC	Hot flush/ Hot flushes	1	17SEP2020	2/5	1	Yes		NA	R (21SEP2020)	N/N
	INJ&P	Procedural pain/ POST SURGICAL PAIN#	4	09MAR2021	27/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1013 10131574	NERV	Headache/ HEADACHE	1	24SEP2020	8/2	2	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Pain/ BODY ACHES	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
		Pyrexia/ LOW GRADE FEVER	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
>55/ C4591001 1013 10131578	GENRL	Injection site pain/ INJECTION SITE PAIN	1	24SEP2020	8/2	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1013 10131583	GENRL	Injection site pain/ INJECTION SITE PAIN	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	08OCT2020	1/2	1	Yes		NA/TCN	R (09OCT2020)	N/N
>55/ C4591001 1013 10131590	GENRL	Injection site pain/ INJECTION SITE PAIN	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine Subject	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131602	GENRL	Chills/ CHILLS	2	13OCT2020	1/2	1	Yes	NA	NA	R (14OCT2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	13OCT2020	1/2	1	Yes	NA	NA	R (14OCT2020)	N/N
>55/ C4591001 1013 10131604	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	22SEP2020	1/4	1	Yes	NA	NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	14OCT2020	1/2	1	Yes	NA	NA	R (15OCT2020)	N/N
>55/ C4591001 1013 10131609	GENRL	Fatigue/ fatigue	1	22SEP2020	1/3	1	Yes	NA	NA	R (24SEP2020)	N/N
>55/ C4591001 1013 10131618	GASTR	Nausea/ NAUSEA	2	14OCT2020	1/2	1	Yes	NA	NA	R (15OCT2020)	N/N
	GENRL	Chills/ CHILLS	2	14OCT2020	1/2	1	Yes	NA	NA	R (15OCT2020)	N/N
		Fatigue/ FATIGUE	2	14OCT2020	1/2	1	Yes	NA	NA	R (15OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	14OCT2020	1/2	1	Yes	NA/TC	NA/TC	R (15OCT2020)	N/N
>55/ C4591001 1013 10131620	GENRL	Injection site pain/ INJECTION SITE PAIN	1	24SEP2020	1/2	2	Yes	NA/TC	NA/TC	R (25SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ FATIGUE	1	10OCT2020	17/7	1	Yes		NA	R (16OCT2020)	N/N
>55/ C4591001 1013 10131640	GENRL	Injection site pain/ INJECTION SITE PAIN	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
	NERV	Headache/ HEADACHE	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
>55/ C4591001 1013 10131686	GENRL	Fatigue/ FATIGUE	2	04NOV2020	3/1	2	Yes		NA	R (04NOV2020)	N/N
>55/ C4591001 1013 10131692	GENRL	Pyrexia/ LOW GRADE FEVER	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
>55/ C4591001 1013 10131698	GENRL	Injection site pain/ INJECTION SITE PAIN	1	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C4591001 1013 10131699	RENAL	Nephrolithiasis/ KKIDNEY STONES#	4	19FEB2021	16/C	3	No	O	NA/TC	RG	Y/N
>55/ C4591001 1013 10131705	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	04NOV2020	1/5	1	Yes		NA	R (08NOV2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	05NOV2020	2/3	3	Yes		NA	R (07NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1013 10131706	MUSC	Arthralgia/ LEFT SHOULDER PAIN#	3	15JAN2021	3/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1013 10131707	GENRL	Pain/ BODY ACHES	1	15OCT2020	3/3	1	Yes		NA	R (17OCT2020)	N/N	
>55/ C4591001 1013 10131715	GENRL	Injection site pain/ INJECTION SITE PAIN	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N	
>55/ C4591001 1013 10131719	GENRL	Injection site pain/ INJECTION SITE PAIN	1	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N	
	GENRL	Fatigue/ FATIGUE	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N	
	INJ&P	Procedural pain/ POST ORAL SURGICAL PAIN	2	04JAN2021	64/3	1	No	O	NA/TC	R (06JAN2021)	N/N	
>55/ C4591001 1013 10131728	GENRL	Injection site pain/ INJECTION SITE PAIN	1	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N	
	GENRL	Chills/ CHILLS	2	05NOV2020	2/2	2	Yes		NA	R (06NOV2020)	N/N	
		Fatigue/ FATIGUE	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N	
		Pain/ BODY ACHES	2	05NOV2020	2/2	2	Yes		NA	R (06NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1013 10131741	NERV	Headache/ FRONTAL HEADACHE	2	05NOV2020	2/1	1	Yes		NA	R (05NOV2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	16OCT2020	2/3	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	05NOV2020	1/5	1	Yes		NA	R (09NOV2020)	N/N
>55/ C4591001 1013 10131743	GENRL	Chills/ CHILLS	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Pain/ BODY ACHES	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
>55/ C4591001 1013 10131751	EYE	Glaucoma/ GLAUCOMA BILATERAL#	2	18JAN2021	75/C	1	No	O	NA/TC	RG	N/N
	GENRL	Fatigue/ FATIGUE	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	2	11NOV2020	1/2	2	Yes		NA	R (12NOV2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131753	GENRL	Fatigue/ FATIGUE	2	12NOV2020	2/1	1	Yes	NA	NA	R (12NOV2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	12NOV2020	2/1	1	Yes	NA/TC	NA/TC	R (12NOV2020)	N/N
	NERV	Headache/ HEADACHE	2	12NOV2020	2/2	1	Yes	NA/TC	NA/TC	R (13NOV2020)	N/N
>55/ C4591001 1013 10131754	GENRL	Chills/ CHILLS	2	11NOV2020	2/1	1	Yes	NA	NA	R (11NOV2020)	N/N
		Fatigue/ FATIGUE	2	11NOV2020	2/1	2	Yes	NA	NA	R (11NOV2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE	2	11NOV2020	2/8	1	Yes	NA	NA	R (18NOV2020)	N/N
		Pyrexia/ LOW GRADE FEVER	2	11NOV2020	2/1	1	Yes	NA/TC	NA/TC	R (11NOV2020)	N/N
>55/ C4591001 1013 10131766	GENRL	Fatigue/ FATIGUE	2	11NOV2020	2/2	2	Yes	NA	NA	R (12NOV2020)	N/N
		Pain/ BODY ACHES	2	11NOV2020	2/2	2	Yes	NA	NA	R (12NOV2020)	N/N
>55/ C4591001 1013 10131768	GENRL	Fatigue/ FATIGUE	2	12NOV2020	1/12	2	Yes	NA	NA	R (23NOV2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	2	16NOV2020	1/7	1	Yes	NA	NA	R (22NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131775 >55/ C4591001 1013 10131786	NERV	Syncope/ SYNCOPAL EPISODE#	3	30JAN2021	6/3	3	No	O	NA/TC	R (01FEB2021)	Y/N
1013 10131786	INFEC	COVID-19 pneumonia/ COVID-19 PNEUMONIA#	3	02FEB2021	9/5	3	No	O	NA/TC	R (06FEB2021)	Y/N
>55/ C4591001 1013 10131798	GENRL	Fatigue/ FATIGUE	1	11NOV2020	21/1	2	Yes		NA	R (11NOV2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	11NOV2020	1/2	2	Yes		NA	R (12NOV2020)	N/N
		Pain/ BODY ACHES	1	11NOV2020	21/10	2	Yes		NA	R (20NOV2020)	N/N
>55/ C4591001 1013 10131805	GENRL	Chills/ CHILLS	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	13NOV2020	3/2	1	Yes		NA	R (14NOV2020)	N/N
>55/ C4591001 1013 10131814	GENRL	Injection site pain/ INJECTION SITE PAIN	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Chills/ CHILLS	2	13NOV2020	2/1	1	Yes		NA	R (13NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Fatigue/ FATIGUE	2	13NOV2020	2/2	2	Yes		NA	R (14NOV2020)	N/N	
>55/ C4591001 1015 10151002	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N	
>55/ C4591001 1015 10151003	GENRL	Fatigue/ Fatigue	2	01SEP2020	1/6	1	Yes		NA/TC	R (06SEP2020)	N/N	
		Injection site erythema/ Redness at injection site	2	01SEP2020	1/6	1	Yes		NA/TC	R (06SEP2020)	N/N	
		Pyrexia/ Low grade fever - 98.9	2	01SEP2020	1/6	1	Yes		NA/TC	R (06SEP2020)	N/N	
>55/ C4591001 1015 10151012	GENRL	Pyrexia/ Fever 101.0 F#	4	08FEB2021	1/3	2	Yes		NA/TC	R (10FEB2021)	N/N	
>55/ C4591001 1015 10151019	MUSC	Arthralgia/ Joint pain in left arm	2	03SEP2020	2/28	1	Yes		NA	R (30SEP2020)	N/N	
>55/ C4591001 1015 10151040	GENRL	Chills/ Chills#	4	07JAN2021	1/3	1	Yes		NA/TC	R (09JAN2021)	N/N	
		Fatigue/ Fatigue#	4	07JAN2021	1/3	1	Yes		NA/TC	R (09JAN2021)	N/N	
		Pyrexia/ Fever 101.2#	4	07JAN2021	1/3	2	Yes		NA/TC	R (09JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1015 10151057	GENRL	Injection site pain/ Pain at injection site	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Malaise/ General Malaise	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ Headache	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1015 10151060	GENRL	Chills/ Chills#	4	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
	INV	Body temperature increased/ Increased body temperature#	4	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
>55/ C4591001 1015 10151065	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/5	1	Yes		NA/TC	R (13SEP2020)	N/N
>55/ C4591001 1015 10151078	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	1/4	1	Yes		NA	R (21DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	08JAN2021	1/3	1	Yes		NA/TC	R (10JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	09JAN2021	2/2	1	Yes		NA/TC	R (10JAN2021)	N/N
>55/ C4591001 1015 10151079	GENRL	Injection site pain/ Injection site pain#	3	21DEC2020	1/2	1	Yes		NA/TC	R (22DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1015 10151096	GENRL	Injection site pain/ Injection site pain#	4	13JAN2021	1/2	1	Yes		NA/TC	R (14JAN2021)	N/N
	NERV	Headache/ Worsening headache#	4	14JAN2021	2/1	1	Yes		NA/TC	R (14JAN2021)	N/N
	MUSC	Pain in extremity/ Whole left arm pain	2	14SEP2020	1/4	1	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C4591001 1015 10151110	GENRL	Malaise/ Malaise	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	04JAN2021	1/4	2	Yes		NA/TC	R (07JAN2021)	N/N
>55/ C4591001 1015 10151111	EAR	Ear pruritus/ Itching of ears	1	08SEP2020	15/2	1	No	O	NA	R (09SEP2020)	N/N
>55/ C4591001 1015 10151127	RESP	Throat irritation/ Itching of throat	1	08SEP2020	15/2	1	No	O	NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	GENRL	Injection site pain/ Injection site soreness	2	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N
	EAR	Ear pain/ Ear pain	2	29OCT2020	42/2	1	No	O	NA/TC	R (30OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1015 10151129	MUSC	Joint stiffness/ Bilateral knee stiffness	2	23SEP2020	7/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1015 10151142	GENRL	Injection site swelling/ 5cm swelling at injection site	1	28AUG2020	1/3	1	Yes		NA/TC	R (30AUG2020)	N/N	
	MUSC	Myalgia/ Myalgia	1	28AUG2020	1/3	1	Yes		NA/TC	R (30AUG2020)	N/N	
	GENRL	Influenza like illness/ Flu-like symptom - fatigue	2	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N	
		Injection site pain/ Pain at injection site	2	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N	
>55/ C4591001 1015 10151144	GENRL	Injection site pain/ Pain at injection site	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/Y	
>55/ C4591001 1015 10151155	GENRL	Injection site pain/ Injection Site Pain#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N	
>55/ C4591001 1015 10151156	GENRL	Malaise/ Malaise	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N	
		Injection site pain/ Injection site pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1015 10151158	NERV	Headache/ Headache#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N	
	GENRL	Fatigue/ Fatigue#	4	13JAN2021	2/2	2	Yes		NA	R (14JAN2021)	N/N	
	NERV	Headache/ Headache#	4	13JAN2021	2/1	2	Yes		NA/TC	R (13JAN2021)	N/N	
	MUSC	Back pain/ Left lower back pain	2	24SEP2020	2/7	2	No	O	NA	R (30SEP2020)	N/N	
			Musculoskeletal pain/ Upper left gluteal pain	2	24SEP2020	2/7	2	No	O	NA	R (30SEP2020)	N/N
	SKIN	Rash/ Bilateral rash on arms and legs#	4	19JAN2021	7/C	2	Yes		NA/TC	RG	N/N	
>55/ C4591001 1015 10151168	EYE	Erythema of eyelid/ Bilateral eyelid erthema#	4	22JAN2021	10/C	2	Yes		NA/TC	RG	N/N	
	GENRL	Fatigue/ Fatigue	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N	
			Injection site pain/ Pain at injection site	1	02SEP2020	1/2	2	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N	
			Injection site pain/ Injection site pain	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
			Pyrexia/ Fever - 101.0	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/Y	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1015 10151169 >55/ C4591001 1015 10151173	GENRL	Injection site pain/ Injection site soreness	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
1015 10151173	GENRL	Injection site pain/ Injection site soreness	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
>55/ C4591001 1015 10151178	MUSC	Pain in extremity/ Left leg pain from hip to ankle	2	21OCT2020	28/2	2	No	O	NA/TC	R (22OCT2020)	N/N
1015 10151178	GENRL	Fatigue/ fatigue#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1015 10151181	MUSC	Arthralgia/ Joint pain (hands, elbows, knees, and hips)	1	05SEP2020	2/5	1	Yes		NA/TC	R (09SEP2020)	N/N
1015 10151181	MUSC	Arthralgia/ Joint pain (hips, fingers, elbows)	1	19SEP2020	16/3	1	Yes		NA	R (21SEP2020)	N/N
1015 10151181	GENRL	Fatigue/ Fatigue#	4	06JAN2021	1/4	2	Yes		NA	R (09JAN2021)	N/N
>55/ C4591001 1015 10151186	GASTR	Nausea/ Nausea	2	28SEP2020	1/2	1	Yes		NA/TC	R (29SEP2020)	N/N
1015 10151186	GENRL	Chills/ Chills	2	28SEP2020	1/2	1	Yes		NA/TC	R (29SEP2020)	N/N
1015 10151186	GENRL	Pyrexia/ Fever 100.4	2	28SEP2020	1/2	1	Yes		NA/TC	R (29SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1015 10151190	MUSC	Myalgia/ Muscle pain in left arm	2	28SEP2020	1/2	1	Yes		NA/TC	R (29SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	30SEP2020	3/1	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	1	07SEP2020	1/2	1	Yes		NA	R (08SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Chills/ Chills#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	MUSC Myalgia/ Muscle aches	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1015 10151215	GENRL	Fatigue/ Fatigue#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1015 10151216	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		Malaise/ Malaise	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ Headache	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
>55/ C4591001 1015 10151219	RESP	Rhinorrhoea/ Nasal discharge	1	26SEP2020	16/2	1	No	O	NA	R (27SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	18DEC2020	1/4	1	Yes		NA	R (21DEC2020)	N/N
		Injection site swelling/ Right arm swollen at injection site#	3	18DEC2020	1/4	1	Yes		NA	R (21DEC2020)	N/N
	INV	Body temperature increased/ Increased body temperature - 99.8F#	3	19DEC2020	2/1	1	Yes		NA	R (19DEC2020)	N/N
	MUSC	Myalgia/ Myalgia#	3	19DEC2020	2/1	1	Yes		NA	R (19DEC2020)	N/N
	NERV	Headache/ Headache#	3	19DEC2020	2/1	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	08JAN2021	1/1	1	Yes		NA	R (08JAN2021)	N/N
	INV	Body temperature increased/ Increased body temperature#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
MUSC	Myalgia/ Myalgia#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache#	4	09JAN2021	2/1	1	Yes		NA/TC	R (09JAN2021)	N/N
>55/ C4591001 1015 10151237	GENRL	Injection site pain/ Injection site soreness - localized achiness	1	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C4591001 1015 10151238†	INFEC	Pneumonia/ Pneumonia	2	20JAN2021	86/8	3	No	O	NA/TC	R (27JAN2021)	Y/N
	GENRL	Oedema peripheral/ Peripheral edema	2	03FEB2021	100/31	2	No	O	NA	R (05MAR2021)	N/N
>55/ C4591001 1015 10151244	GENRL	Pain/ Body aches	1	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	INJ&P	Administration related reaction/ Sore arm - whole arm that received IP	1	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	INV	Body temperature increased/ Increased temperature 99.2	1	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Chills/ Chills	2	04NOV2020	1/C	2	Yes		NA/TC	RG	N/N
		Injection site pain/ Injection site soreness	2	04NOV2020	1/3	2	Yes		NA/TC	R (06NOV2020)	N/N
		Pain/ Body aches	2	04NOV2020	1/C	2	Yes		NA/TC	RG	N/N
		Pyrexia/ Fever	2	04NOV2020	1/3	2	Yes		NA/TC	R (06NOV2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	1/4	1	Yes		NA	R (21DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1015 10151247	MUSC	Back pain/ Back pain#	4	09JAN2021	2/1	1	Yes		NA/TC	R (09JAN2021)	N/N	
		Myalgia/ myalgia#	4	09JAN2021	2/1	1	Yes		NA/TC	R (09JAN2021)	N/N	
>55/ C4591001 1015 10151251	INJ&P	Fall/ Fall	1	07NOV2020	19/1	1	No	O	NA/TC	R (07NOV2020)	N/N	
		Stress fracture/ Hair line fracture of right humerus	1	07NOV2020	19/22	2	No	O	NA/TC	R (28NOV2020)	N/N	
	GENRL	Chills/ Chills#	4	10FEB2021	3/1	1	Yes		NA/TC	R (10FEB2021)	N/N	
>55/ C4591001 1015 10151258	GENRL	Injection site pain/ Injection site pain	1	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N	
>55/ C4591001 1016 10161022	MUSC	Arthralgia/ worsening of right knee pain	1	07AUG2020	8/C	2	No	O	NA/TC/TCN	N	N/N	
>55/ C4591001 1016 10161026	SKIN	Dermatitis contact/ diffuse contact dermatitis	1	23AUG2020	21/8	1	No	O	NA/TC	R (30AUG2020)	N/N	
	INFEC	Parotitis/ Parotitis	1	20SEP2020	49/12	1	No	O	NA/TC	R (01OCT2020)	N/N	
>55/ C4591001	GASTR	Gastroesophageal reflux disease/ Worsening of of Gastroesophageal Reflux Disease	2	09SEP2020	17/C	2	No	O	NA/TC/TCN	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1016 10161035 >55/ C4591001 1016 10161039	GENRL	Chills/ chills#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N	
>55/ C4591001 1016 10161042	MUSC	Pyrexia/ fever, 100.7# Arthritis/ worsening arthritis of right hip	4 2	11FEB2021 10OCT2020	1/2 45/75	1 3	Yes No		NA/TC NA/TCN	R (12FEB2021) R (23DEC2020)	N/N Y/N	
>55/ C4591001 1016 10161052	GENRL	Fatigue/ fatigue#	4	24FEB2021	2/2	1	Yes		NA	R (25FEB2021)	N/N	
>55/ C4591001 1016 10161059	NERV	Pain/ body aches# Headache/ headache#	4 4	24FEB2021 24FEB2021	2/2 2/2	1 1	Yes Yes		NA/TC NA/TC	R (25FEB2021) R (25FEB2021)	N/N N/N	
>55/ C4591001 1016 10161063	INFEC	Sinusitis/ Sinusitis	1	10AUG2020	6/6	1	No	O	NA/TC	R (15AUG2020)	N/N	
>55/ C4591001 1016 10161063	GENRL	Fatigue/ fatigue	2	03SEP2020	9/1	2	Yes		NA	R (03SEP2020)	N/N	
>55/ C4591001	GENRL	Injection site pain/ injection site pain, left deltoid#	4	08FEB2021	1/C	2	Yes		NA	N	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1016 10161099 >55/ C4591001 1016 10161110	GENRL	Fatigue/ fatigue#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
		Injection site pain/ injection site pain, left deltoid#	4	04JAN2021	1/2	1	Yes		NA/TC	R (05JAN2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	04JAN2021	1/2	1	Yes		NA/TC	R (05JAN2021)	N/N
>55/ C4591001 1016 10161111	GENRL	Injection site pain/ injection site pain(left arm)#	3	17DEC2020	2/3	2	Yes		NA	R (19DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
		Injection site pain/ injection site pain, right deltoid#	4	04JAN2021	1/2	1	Yes		NA/TC	R (05JAN2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	04JAN2021	1/2	1	Yes		NA/TC	R (05JAN2021)	N/N
>55/ C4591001 1016 10161116	NERV	Headache/ headache#	3	26JAN2021	2/2	2	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001 1016 10161124	GASTR	Vomiting/ vomiting#	4	12FEB2021	1/2	2	Yes		NA	R (13FEB2021)	N/N
	GENRL	Chills/ chills#	4	12FEB2021	1/3	2	Yes		NA/TC	R (14FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1016 10161131	NERV	Pyrexia/ fever, 102.0#	4	12FEB2021	1/2	2	Yes		NA/TC	R (13FEB2021)	N/N
		Headache/ headache#	4	12FEB2021	1/3	2	Yes		NA/TC	R (14FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
	MUSC	Arthralgia/ joint pain	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
>55/ C4591001 1016 10161141	MUSC	Myalgia/ muscle pain	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
		Myalgia/ muscle pain	2	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N
>55/ C4591001 1016 10161142	MUSC	Myalgia/ muscle pain	2	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1016 10161151	INJ&P	Muscle strain/ strained thigh muscle	2	11SEP2020	2/44	2	No	O	NA/TC	R (24OCT2020)	N/N
>55/ C4591001 1016 10161162	INJ&P	Concussion/ Concussion	1	08SEP2020	19/8	1	No	O	NA/TC	R (15SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1016 10161165	INFEC	Fall/ Fall While Hiking	1	08SEP2020	19/1	1	No	O	NA	R (08SEP2020)	N/N	
		Skin abrasion/ Abrasions to Head	1	08SEP2020	19/8	1	No	O	NA/TC	R (15SEP2020)	N/N	
		Gastroenteritis/ Gastroenteritis	1	25AUG2020	5/2	1	No	O	NA	R (26AUG2020)	N/N	
	RENAL	Obstructive nephropathy/ right kidney obstruction	2	28SEP2020	18/11	2	No	O	NA	R (08OCT2020)	N/N	
		Urinary tract obstruction/ left kidney obstruction	2	28SEP2020	18/5	2	No	O	NA	R (02OCT2020)	N/N	
>55/ C4591001 1016 10161174	MUSC	Costochondritis/ Costochondritis	1	02SEP2020	10/5	1	No	O	NA	R (06SEP2020)	N/N	
>55/ C4591001 1016 10161175	GENRL	Chills/ chills#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N	
		Pain/ generalized body aches#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N	
>55/ C4591001 1016 10161197	GENRL	Oedema peripheral/ Pedal Edema	1	03SEP2020	8/20	1	No	O	NA	R (22SEP2020)	N/N	
>55/ C4591001 1016 10161199	NERV	Facial paralysis/ bell's palsy	2	25DEC2020	102/C	2	No	O	NA/TC	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1016 10161203	GENRL	Chills/ chills	2	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ injection site pain	2	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ headache	2	18SEP2020	1/2	2	Yes		NA/TC	R (19SEP2020)	N/N
>55/ C4591001 1016 10161247	MUSC	Pain in extremity/ leg aches	1	09SEP2020	6/2	1	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1016 10161257	INJ&P	Fall/ Fall, down stair	1	13SEP2020	6/1	2	No	O	NA	R (13SEP2020)	N/N
		Fibula fracture/ Left Fibula Fracture	1	13SEP2020	6/C	2	No	O	NA/TC	N	N/N
		Patella fracture/ Left Patella Fracture	1	13SEP2020	6/C	2	No	O	NA/TC	N	N/N
	GENRL	Chills/ chills#	3	15JAN2021	1/2	2	Yes		NA	R (16JAN2021)	N/N
NERV	Headache/ headache#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N	
GENRL	Pyrexia/ fever#	3	16JAN2021	2/1	1	Yes		NA/TC	R (16JAN2021)	N/N	
>55/ C4591001 1016 10161267	GASTR	Diarrhoea/ diarrhea#	4	04FEB2021	2/C	1	Yes		NA	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1016 10161270	METAB	Vitamin B12 deficiency/ B12 deficiency	2	05OCT2020	6/C	1	No	O	NA	N	N/N	
>55/ C4591001 1016 10161271	GASTR	Nausea/ nausea	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N	
	GENRL	Chills/ chills	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N	
	MUSC	Myalgia/ muscle aches	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N	
	SKIN	Hyperhidrosis/ excessive sweating	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N	
>55/ C4591001 1016 10161274	PSYCH	Suicidal ideation/ fleeting suicidal ideation	2	03OCT2020	3/1	1	No	O	NA	R (03OCT2020)	N/N	
>55/ C4591001 1016 10161282	METAB	Gout/ Worsening of Gout Right Foot, First Digit	1	26SEP2020	16/81	2	No	O	NA/TC	R (15DEC2020)	N/N	
>55/ C4591001 1016 10161283	MUSC	Arthralgia/ joint pain, neck and upper back#	3	18DEC2020	4/3	2	Yes		NA	R (20DEC2020)	N/N	
		Myalgia/ muscle pain#	3	18DEC2020	4/3	2	Yes		NA	R (20DEC2020)	N/N	
>55/ C4591001	GENRL	Fatigue/ Fatigue	2	20AUG2020	2/2	1	No	O	NA	R (21AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1018 10181002 >55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	20AUG2020	2/2	1	Yes		NA/TC	R (21AUG2020)	N/N	
1018 10181005 >55/ C4591001	NERV	Headache/ Headache	2	23SEP2020	29/1	1	No	O	NA/TC	R (23SEP2020)	N/N	
1018 10181073 >55/ C4591001	GENRL	Fatigue/ Fatigue	2	01SEP2020	6/2	1	Yes		NA	R (02SEP2020)	N/N	
1018 10181075 >55/ C4591001	GENRL	Injection site pain/ Injection Site Pain#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N	
1018 10181078	SKIN	Rash pruritic/ Pruritic Rash, Generalized#	4	13FEB2021	3/15	3	Yes		NA/TC	R (27FEB2021)	N/N	
	GENRL	Oedema peripheral/ bilateral lower leg edema#	4	14FEB2021	4/C	1	Yes		NA/TC	N	N/N	
		Swelling face/ Facial Swelling#	4	14FEB2021	4/14	1	Yes		NA/TC	R (27FEB2021)	N/N	
>55/ C4591001 1018 10181110	RENAL	Urinary retention/ Urinary Retention (AE of Botox Injection)	2	16SEP2020	17/C	1	No	CD	NA/TC	N	N/N	
>55/ C4591001	INJ&P	Meniscus injury/ Right Knee Medial Meniscus Tear	2	01SEP2020	2/121	2	No	O	NA/TCN	R (30DEC2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1018 10181112 >55/ C4591001	MUSC	Back pain/ Acute Back Pain (musculoskeletal)	2	23SEP2020	23/C	2	No	O	NA	RG	N/N
1018 10181123 >55/ C4591001	INV	Cardiac stress test abnormal/ CARDIAC STRESS TEST ABNORMAL, HOSPITALIZED	2	08SEP2020	8/C	3	No	O	NA	N	Y/N
1018 10181132 >55/ C4591001	INFEC	Gastroenteritis/ Acute Gastroenteritis	2	26NOV2020	85/2	1	No	O	NA	R (27NOV2020)	N/N
1018 10181155 >55/ C4591001	GENRL	Injection site pain/ Pain at the Injection Side	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
1018 10181175 >55/ C4591001	GENRL	Injection site pain/ Soreness at injection site	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/Y
1018 10181190 >55/ C4591001	SKIN	Actinic keratosis/ Actinic Keratosis flare up	1	08SEP2020	8/1	2	No	O	NA/TC/TCN	R (08SEP2020)	N/N
1018 10181248 >55/ C4591001	GENRL	Injection site pain/ injection site pain#	2	23DEC2020	91/2	1	Yes		NA	R (24DEC2020)	N/N
1018 10181250											

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1018 10181265	NERV	Headache/ headache	1	04SEP2020	1/1	1	Yes		NA	R (04SEP2020)	N/N
	NERV	Headache/ headache	2	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1018 10181270	GENRL	Injection site pain/ injection site pain	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
	GENRL	Chills/ Chills	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
Fatigue/ Fatigue		2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N	
Injection site pain/ Injection site tenderness		2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N	
>55/ C4591001 1018 10181296	GENRL	Pain/ Body aches and pain	1	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
	RESP	Upper-airway cough syndrome/ post-nasal drip	1	01OCT2020	16/6	1	No	O	NA	R (06OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
>55/ C4591001 1018 10181308	GASTR	Diarrhoea/ Diarrhea	1	26SEP2020	3/6	1	Yes		NA/TC	R (01OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site arm pain	1	26SEP2020	3/1	1	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ Fever, low grade	1	26SEP2020	3/2	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ Headache	1	26SEP2020	3/3	2	Yes		NA/TC	R (28SEP2020)	N/N
>55/ C4591001 1018 10181312	INJ&P	Skin laceration/ Left Elbow laceration	1	26OCT2020	15/1	2	No	O	NA	R (26OCT2020)	N/N
>55/ C4591001 1019 10191001	GENRL	Injection site pain/ Mild Injection Site Pain	1	11AUG2020	2/2	1	Yes		NA	R (12AUG2020)	N/N
	GENRL	Injection site pain/ Mild Injection Pain	2	03SEP2020	3/2	1	Yes		NA	R (04SEP2020)	N/N
>55/ C4591001 1019 10191010	GASTR	Diarrhoea/ Diarrhea	1	17AUG2020	7/11	2	No	O	NA	R (27AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	27AUG2020	17/3	4	No	O	NA/TC	R (29AUG2020)	Y/N
	PSYCH	Mental status changes/ Mental State Status Change	2	02OCT2020	32/1	2	No	O	NA	R (02OCT2020)	N/N
>55/ C4591001 1019 10191021	GASTR	Pancreatitis/ Pancreatitis	2	30DEC2020	120/6	3	No	O	NA/TC	RS (04JAN2021)	Y/N
	GASTR	Pancreatic cyst/ Pancreatic Cyst	2	04JAN2021	125/C	1	No	O	NA	N	Y/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1019 10191025	GENRL	Injection site erythema/ Redness Mild Injection Site	1	13AUG2020	1/1	1	Yes		NA	R (13AUG2020)	N/N	
		Injection site pain/ injection pain mild	1	13AUG2020	1/1	1	Yes		NA	R (13AUG2020)	N/N	
		Injection site swelling/ Swelling mild at site Injection	1	13AUG2020	1/1	1	Yes		NA	R (13AUG2020)	N/N	
	GENRL	Fatigue/ fatigue mild	1	14AUG2020	2/1	1	Yes		NA	R (14AUG2020)	N/N	
	NERV	Dizziness postural/ orthostatic dizziness	1	20AUG2020	8/1	1	Yes		NA	R (20AUG2020)	N/N	
>55/ C4591001 1019 10191035	GENRL	Fatigue/ Mild Fatigue	1	14AUG2020	2/1	1	Yes		NA	R (14AUG2020)	N/N	
>55/ C4591001 1019 10191037	SURG	Cardioversion/ Defibrillator Discharge	2	15OCT2020	42/1	2	No	O	NA	R (15OCT2020)	N/N	
	GENRL	Asthenia/ Weakness	2	27OCT2020	54/3	2	No	O	NA	R (29OCT2020)	Y/N	
>55/ C4591001 1019 10191043	GENRL	Injection site pain/ Pain at injection site#	3	05JAN2021	2/3	1	Yes		NA	R (07JAN2021)	N/N	
>55/ C4591001 1019 10191048	MUSC	Pain in extremity/ Left Arm Pain	2	13SEP2020	6/2	1	Yes		NA	R (14SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chest pain/ Chest shooting pain#	2	02MAR2021	176/C	2	No	O	NA	N	N/N
>55/ C4591001 1019 10191071	BLOOD	Anaemia/ Anemia	2	17DEC2020	98/3	3	No	O	NA/TCN	R (19DEC2020)	Y/N
>55/ C4591001 1019 10191082	NERV	Headache/ Headache#	3	06JAN2021	2/1	1	Yes		NA	R (06JAN2021)	N/N
>55/ C4591001 1019 10191087	GENRL	Injection site pain/ Mild pain at injection site#	3	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
>55/ C4591001 1019 10191094	GENRL	Injection site pain/ Injection Arm Soreness#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N
>55/ C4591001 1019 10191111	GENRL	Injection site pain/ Mild Soreness at Injection Site#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
>55/ C4591001 1019 10191118	GASTR	Haemorrhoids/ Worsening of Hemorrhoids	1	10SEP2020	15/27	1	Yes		NA	R (06OCT2020)	N/N
	MUSC	Osteoarthritis/ Worsening of Osteoarthritis	1	10SEP2020	15/C	1	Yes		NA	N	N/N
	INFEC	Ear infection/ Left Ear Infection#	4	22FEB2021	26/12	2	No	O	NA/TC	R (05MAR2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1019 10191135	GENRL	Injection site induration/ Hard Center of at Injection Site	1	28AUG2020	1/26	1	Yes		NA	R (22SEP2020)	N/N
		Injection site swelling/ Swelling at Injection Site	1	28AUG2020	1/6	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site erythema/ Erythema at injection site	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
		Injection site induration/ 6.5 cm Induration at injection site	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1019 10191146	NEOPL	Biliary cancer metastatic/ Biliary Cancer Metastatic	2	27OCT2020	36/52	4	No	O	NA/W	F (17DEC2020)	Y/N
		Metastases to liver/ Metastases to Liver	2	27OCT2020	36/52	4	No	O	NA/W	F (17DEC2020)	Y/N
>55/ C4591001 1019 10191148	GENRL	Injection site pain/ Mild Pain at Injection Site#	3	06JAN2021	1/8	1	Yes		NA	R (13JAN2021)	N/N
>55/ C4591001 1019 10191150	GENRL	Injection site pain/ Muscle Pain Injection Site	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1019 10191169	INJ&P	Ligament sprain/ Sprained Wrist Right	1	22SEP2020	15/7	1	No	O	NA	R (28SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1019 10191176	ENDO	Hypothyroidism/ Hypothyroidism	1	SEP2020	1/	1	No	O	NA/TC	R	N/N	
>55/ C4591001 1019 10191191	GENRL	Pain/ Body Aches General#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N	
		Pyrexia/ Fever (101.9F)#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N	
>55/ C4591001 1019 10191207	GENRL	Pyrexia/ Fever (102.2F)#	4	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N	
	NERV	Headache/ Headache#	4	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N	
>55/ C4591001 1019 10191229	GASTR	Gastrointestinal mucosa hyperaemia/ Hyperemic Bowel	2	04NOV2020	21/2	4	No	O	NA	RS (05NOV2020)	Y/N	
		Volvulus/ Sigmoid Volvulus	2	04NOV2020	21/2	4	No	O	NA	RS (05NOV2020)	Y/N	
	INJ&P	Rib fracture/ Bilateral Rib Fractures	2	04NOV2020	21/C	3	No	O	NA	N	Y/N	
		Road traffic accident/ Injury Secondary to Pedestrian-Car Accident	2	04NOV2020	21/C	4	No	O	NA	N	Y/N	
		Spinal column injury/ Severe T2 Distraction Injury	2	04NOV2020	21/C	3	No	O	NA	N	Y/N	
		Subdural haematoma/ Small Parafalcine Subdural hematoma	2	04NOV2020	21/30	3	No	O	NA	RS (03DEC2020)	Y/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1019 10191241	NERV	Traumatic haemothorax/ Right Hemopneumothorax	2	04NOV2020	21/31	4	No	O	NA	RS (04DEC2020)	Y/N
		Spinal cord compression/ Spinal Cord Compression	2	04NOV2020	21/C	4	No	O	NA	N	Y/N
	RESP	Pneumothorax/ Left Pneumothorax	2	04NOV2020	21/31	4	No	O	NA	RS (04DEC2020)	Y/N
		Pulmonary embolism/ Left Pulmonary Emboli	2	04NOV2020	21/31	3	No	O	NA	RS (04DEC2020)	Y/N
	VASC	Deep vein thrombosis/ Left Superficial Femoral Vein Deep Vein Thrombosis	2	04NOV2020	21/31	3	No	O	NA	RS (04DEC2020)	Y/N
	CARD	Cardiac arrest/ Cardiac Arrest	2	21NOV2020	38/1	4	No	O	NA/TCN	RS (21NOV2020)	Y/N
	CARD	Cardiac arrest/ Cardiac Arrest	2	23NOV2020	40/1	4	No	O	NA/TCN	RS (23NOV2020)	Y/N
	GENRL	Chills/ Mild Chills	1	30SEP2020	3/3	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Fatigue/ Mild Fatigue	1	30SEP2020	3/3	1	Yes		NA	R (02OCT2020)	N/N
		Pain/ Moderate Body Aches	1	30SEP2020	3/3	2	Yes		NA	R (02OCT2020)	N/N
Injection site swelling/ Injection site swelling		2	20OCT2020	2/4	1	Yes		NA	R (23OCT2020)	N/N	
>55/ C4591001 1019 10191258	GENRL	Injection site pain/ Injection Site Pain#	3	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1019 10191271	GENRL	Injection site pain/ Injection site soreness	1	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
>55/ C4591001 1019 10191272	GASTR	Nausea/ Nausea#	4	27JAN2021	3/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Chills/ Chills#	4	27JAN2021	3/2	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1019 10191275	GENRL	Injection site swelling/ Left arm swelling at injection site	2	05NOV2020	2/5	1	Yes		NA	R (09NOV2020)	N/N
>55/ C4591001 1019 10191277	ENDO	Hypothyroidism/ Hypothyroidism	2	01DEC2020	28/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1019 10191278	NERV	Taste disorder/ Taste Aberration	1	18OCT2020	5/2	1	Yes		NA	R (19OCT2020)	N/N
	NERV	Taste disorder/ Taste Aberration	2	08NOV2020	5/2	1	Yes		NA	R (09NOV2020)	N/N
>55/ C4591001 1019 10191302	GENRL	Pyrexia/ Fever (101.6F)	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N
	SKIN	Skin mass/ Cutaneous Nodules Bilateral Extremities	2	01DEC2020	19/C	1	No	O	NA	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1019 10191303	GASTR	Diarrhoea/ Mild Diarrhea	2	14NOV2020	2/1	1	Yes		NA	R (14NOV2020)	N/N
		Nausea/ Mild Nausea	2	14NOV2020	2/1	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Chills/ Moderate Chills	2	14NOV2020	2/1	2	Yes		NA	R (14NOV2020)	N/N
		Pyrexia/ Fever (102.4 F)	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N
	MUSC	Arthralgia/ Moderate Generalized Joint Pain	2	14NOV2020	2/1	2	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ Moderate Headache	2	14NOV2020	2/1	2	Yes		NA	R (14NOV2020)	N/N
>55/ C4591001 1019 10191310	GENRL	Injection site pain/ Injection site soreness mild#	3	30DEC2020	1/3	1	Yes		NA	R (01JAN2021)	N/N
>55/ C4591001 1019 10191311	MUSC	Myalgia/ General Muscle Aches Mild#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1019 10191316	GENRL	Pyrexia/ Fever 100.6F	2	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N
>55/ C4591001 1019 10191317	GASTR	Diarrhoea/ Diarrhea#	3	05JAN2021	1/7	1	Yes		NA	R (11JAN2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection Site Pain#	3	05JAN2021	1/C	1	Yes		NA	N	N/N
>55/ C4591001 1021 10211001	GASTR	Diarrhoea/ Diarrhea	1	11AUG2020	2/4	1	Yes		NA	R (14AUG2020)	N/N
	NERV	Headache/ Headache	1	11AUG2020	2/4	1	Yes		NA	R (14AUG2020)	N/N
	RESP	Rhinorrhoea/ Runny nose	1	11AUG2020	2/4	1	Yes		NA	R (14AUG2020)	N/N
>55/ C4591001 1021 10211003	MUSC	Pain in extremity/ Soreness in left arm#	4	15FEB2021	1/C	1	Yes		NA	N	N/N
>55/ C4591001 1021 10211013	MUSC	Osteoarthritis/ Osteoarthritis (left knee)	2	04JAN2021	127/C	2	No	O	NA	N	N/N
	SKIN	Urticaria/ Hive on back of neck#	4	24FEB2021	1/C	2	Yes		NA/TC	N	N/Y
>55/ C4591001 1021 10211018	NEOPL	Squamous cell carcinoma/ Squamous Cell Carcinoma R Ankle#	3	25JAN2021	4/C	2	No	O	NA/TCN	N	N/N
>55/ C4591001 1021 10211022	METAB	Type 2 diabetes mellitus/ Worsening of Type 2 Diabetes#	3	03FEB2021	8/C	1	No	O	NA/TC	N	N/N
>55/ C4591001	GASTR	Large intestine polyp/ Benign Colon Polyps	1	18AUG2020	7/10	1	No	O	NA	R (27AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1021 10211024 >55/ C4591001	GENRL	Pyrexia/ Fever#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
1021 10211029	NERV	Headache/ Headache#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
>55/ C4591001	RENAL	Dysuria/ Painful Urination	1	16AUG2020	4/4	1	No	O	NA	R (19AUG2020)	N/N
1021 10211030 >55/ C4591001	MUSC	Osteoarthritis/ Worsening of osteoarthritis (left shoulder)#	2	10FEB2021	155/C	2	No	O	NA/TC/TCN	RG	Y/N
1021 10211044 >55/ C4591001	RENAL	Hypertonic bladder/ Overactive Bladder	2	NOV2020	54/C	1	No	O	NA	RG	N/N
1021 10211052 >55/ C4591001	NEOPL	Basal cell carcinoma/ Basal cell skin cancer (head)	1	10SEP2020	23/C	2	No	O	NA	N	N/N
1021 10211057 >55/ C4591001	GENRL	Fatigue/ Fatigue	2	10SEP2020	1/3	2	Yes		NA	R (12SEP2020)	N/N
1021 10211063		Pyrexia/ Fever	2	10SEP2020	1/3	2	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1021 10211064	NERV	Headache/ Headache	2	10SEP2020	1/3	2	Yes		NA	R (12SEP2020)	N/N	
	VASC	Hypertension/ Worsening of hypertension	2	DEC2020	83/C	2	No	O	NA/TC	N	N/N	
	GASTR	Gastroesophageal reflux disease/ GERD#	4	08FEB2021	6/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1021 10211068	GENRL	Injection site mass/ Bump under skin near injection site Left arm	2	09SEP2020	2/19	1	Yes		NA	R (27SEP2020)	N/N	
>55/ C4591001 1021 10211074	GENRL	Pyrexia/ Fever#	4	10FEB2021	1/1	1	Yes		NA/TC	R (10FEB2021)	N/N	
>55/ C4591001 1021 10211078	GENRL	Chills/ Body Chills	2	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N	
>55/ C4591001 1021 10211081	INJ&P	Fatigue/ Fatigue	2	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N	
		Pain/ Body Aches	2	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N	
		Pyrexia/ Fever	2	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N	
		Ligament sprain/ L Knee Sprain	2	14OCT2020	30/8	2	No	O	NA/TC	R (21OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INJ&P	Joint dislocation/ Dislocated right patella	2	NOV2020	48/	2	No	O	NA/TC	R (12MAR2021)	N/N
	MUSC	Osteoarthritis/ Worsening of osteoarthritis (right knee)#	4	12MAR2021	31/C	2	No	O	NA/TC/TCN	RG	Y/N
>55/ C4591001 1021 10211084	INJ&P	Ligament sprain/ R Knee Sprain	1	03SEP2020	11/4	1	No	O	NA/TC	R (06SEP2020)	N/N
	GASTR	Haematemesis/ Vomiting blood#	2	06MAR2021	173/C	3	No	O	NA	RG	Y/N
>55/ C4591001 1021 10211093	GENRL	Fatigue/ Fatigue	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/Y
>55/ C4591001 1021 10211095	MUSC	Plantar fasciitis/ Plantar Fasciitis (right foot)	1	28AUG2020	4/C	1	No	O	NA	N	N/N
	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
		Pyrexia/ Fever (100.6)	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
>55/ C4591001 1021 10211100	GENRL	Injection site pain/ Intermittent Soreness at Injection Site	1	26AUG2020	1/41	2	Yes		NA	R (05OCT2020)	N/Y
>55/ C4591001 1021 10211102	GENRL	Chills/ Chills#	4	17FEB2021	1/1	1	Yes		NA	R (17FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Fatigue/ Fatigue#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N	
		Injection site pain/ left arm injection soreness#	4	17FEB2021	1/3	2	Yes		NA	R (19FEB2021)	N/N	
>55/ C4591001 1021 10211113	GENRL	Injection site pain/ Soreness in left arm at injection site	1	28AUG2020	1/C	2	Yes		NA	RG	N/N	
>55/ C4591001 1021 10211120	GENRL	Swelling face/ Swelling in Face	2	23DEC2020	98/1	2	No	O	NA/TC	R (23DEC2020)	N/N	
	IMMUN	Hypersensitivity/ Allergic Reaction to Hairspray	2	23DEC2020	98/1	2	No	O	NA/TC	R (23DEC2020)	N/N	
>55/ C4591001 1021 10211121	RENAL	Pollakiuria/ Increased Frequency of Urination	2	28SEP2020	8/C	1	No	O	NA	N	N/N	
>55/ C4591001 1021 10211122	GENRL	Injection site pain/ Left arm soreness at injection site#	3	10FEB2021	1/8	2	Yes		NA/TC	R (17FEB2021)	N/N	
	NERV	Headache/ Recurrent headaches#	3	11FEB2021	2/4	1	Yes		NA	R (14FEB2021)	N/N	
>55/ C4591001 1021 10211128	INJ&P	Fall/ Fall	2	02OCT2020	11/1	2	No	O	NA	R (02OCT2020)	N/N	
		Ligament sprain/ L Ankle Sprain	2	02OCT2020	11/42	2	No	O	NA	R (12NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1021 10211129	METAB	Skin laceration/ Forehead Laceration	2	02OCT2020	11/25	2	No	O	NA/TC	R (26OCT2020)	N/N
		Hypoglycaemia/ Hypoglycemia	2	14OCT2020	24/1	3	No	O	NA	R (14OCT2020)	N/N
>55/ C4591001 1021 10211131	INFEC	Bacterial infection/ Bacterial Infection right hand	1	21SEP2020	21/12	2	No	O	NA/TC	R (02OCT2020)	N/N
>55/ C4591001 1021 10211133	REPRO	Prostatitis/ Prostatitis	2	21JAN2021	115/36	2	No	O	NA/TC	R (25FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	01FEB2021	1/3	1	Yes		NA/TC	R (03FEB2021)	N/N
>55/ C4591001 1021 10211134	NERV	Headache/ Headache#	4	01FEB2021	1/3	2	Yes		NA/TC	R (03FEB2021)	N/N
	GENRL	Peripheral swelling/ Swelling in right leg	1	02SEP2020	2/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1021 10211139	GENRL	Pyrexia/ fever	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1021 10211144	MUSC	Tendonitis/ Right Inflamed Achilles Tendon	1	15SEP2020	14/C	2	No	O	NA/TC/TCN	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1021 10211161	GENRL	Injection site pain/ Pain at injection site	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C4591001 1021 10211162	GENRL	Pyrexia/ fever	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Myalgia/ Left arm muscle soreness	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C4591001 1021 10211166	MUSC	Pain in extremity/ Left Arm Soreness	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
>55/ C4591001 1021 10211172	RESP	Nasal congestion/ Nasal congestion	1	10SEP2020	2/15	2	No	O	NA/TC	R (24SEP2020)	N/N
>55/ C4591001 1021 10211176	GENRL	Chills/ Body Chills#	4	17FEB2021	1/3	2	Yes		NA/TC	R (19FEB2021)	N/N
		Pain/ Body Aches#	4	17FEB2021	1/3	2	Yes		NA/TC	R (19FEB2021)	N/N
		Pyrexia/ Fever#	4	17FEB2021	1/3	2	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	17FEB2021	1/3	2	Yes		NA/TC	R (19FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1021 10211178	GENRL	Fatigue/ fatigue	1	09SEP2020	1/4	1	Yes		NA	R (12SEP2020)	N/N
		Injection site pain/ injection site soreness left arm	1	09SEP2020	1/4	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Chills/ Chills	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
		Fatigue/ fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
>55/ C4591001 1021 10211181	NEOPL	Breast cancer/ Breast Cancer (right breast)#	4	11FEB2021	2/C	3	No	O	NA	N	Y/N
>55/ C4591001 1021 10211183	GENRL	Fatigue/ fatigue	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C4591001 1021 10211188	GENRL	Chills/ Chills	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
>55/ C4591001 1021 10211189	SKIN	Alopecia/ Hair Loss	1	18SEP2020	9/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001	NERV	Cerebrovascular accident/ Stroke (CVA)	2	02NOV2020	33/44	3	No	O	NA	R (15DEC2020)	Y/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1021 10211190 >55/ C4591001	MUSC	Osteoarthritis/ Worsening of osteoarthritis- left knee#	3	03FEB2021	15/C	3	No	O	NA/TC/TCN	RG	N/N	
1021 10211193 >55/ C4591001	GENRL	Chills/ Body Chills#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N	
1021 10211194		Pyrexia/ Fever#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N	
	NERV	Headache/ Headache#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N	
>55/ C4591001	GENRL	Injection site rash/ Rash at Injection Site	2	04OCT2020	4/2	2	Yes		NA/TC	R (05OCT2020)	N/N	
1021 10211201 >55/ C4591001	MUSC	Arthralgia/ Joint pain (bilateral shoulders, knees, hips)	1	22SEP2020	5/3	1	No	O	NA/TC	R (24SEP2020)	N/N	
1021 10211234 >55/ C4591001	NERV	Headache/ Intermittent Headaches	1	20SEP2020	3/4	1	Yes		NA	R (23SEP2020)	N/N	
1021 10211238 >55/ C4591001	GENRL	Injection site pain/ Mild Injection Site Pain#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N	
1022 10221002												

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1022 10221005	GENRL	Injection site induration/ Induration around injection site#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Injection site pain/ Moderate Injection Site Pain#	3	05JAN2021	1/2	2	Yes		NA	R (06JAN2021)	N/N
	GASTR	Abdominal pain/ Abdominal Pain#	4	29JAN2021	2/1	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Mild Fatigue#	4	29JAN2021	2/1	1	Yes		NA	R (29JAN2021)	N/N
		Pyrexia/ Fever#	4	29JAN2021	2/1	1	Yes		NA	R (29JAN2021)	N/N
	NERV	Headache/ Moderate Headache#	4	29JAN2021	2/1	2	Yes		NA/TC	R (29JAN2021)	N/N
	CARD	Palpitations/ Heart Palpitations#	4	04FEB2021	8/C	2	No	O	NA/TCN	N	N/N
	GENRL	Chest pain/ Chest Pain#	4	04FEB2021	8/C	1	No	O	NA	N	N/N
	NERV	Dizziness/ Dizziness#	4	04FEB2021	8/C	1	No	O	NA	N	N/N
>55/ C4591001 1022 10221007		Dizziness/ Lightheadedness#	4	04FEB2021	8/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ Mild Injection Site Pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1022 10221008	GENRL	Injection site pain/ Mild Injection Site Pain#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
>55/ C4591001 1022 10221011	GENRL	Injection site pain/ Mild Injection Site Pain	1	17AUG2020	1/1	1	Yes		NA	R (17AUG2020)	N/N
	GENRL	Fatigue/ Mild Fatigue#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
		Injection site pain/ Mild injection site pain#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	MUSC	Musculoskeletal stiffness/ Stiffness in Hands#	4	22JAN2021	12/C	1	No	CD	NA	N	N/N
	NERV	Paraesthesia/ Tingling in hands#	4	22JAN2021	12/C	1	No	CD	NA	N	N/N
>55/ C4591001 1022 10221012	GENRL	Injection site pain/ Injection Site Pain	1	18AUG2020	2/2	2	Yes		NA	R (19AUG2020)	N/N
>55/ C4591001 1022 10221014	GENRL	Injection site pain/ Moderate Injection Site Pain	1	17AUG2020	1/2	2	Yes		NA	R (18AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	2	08SEP2020	1/1	2	Yes		NA	R (08SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1022 10221021	GENRL	Injection site pain/ Mild Injection Site Pain	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Injection site pain/ Mild Injection site pain	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
>55/ C4591001 1022 10221022	GENRL	Pyrexia/ Fever	2	14SEP2020	7/1	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
>55/ C4591001 1022 10221026	GENRL	Chills/ Chills	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		Injection site pain/ Pain at the injection site	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		Pyrexia/ Fever	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
>55/ C4591001 1022 10221029	GENRL	Injection site pain/ Moderate Injection Site Pain#	3	19JAN2021	1/3	2	Yes		NA	R (21JAN2021)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1022 10221032	GASTR	Diarrhoea/ Loose Stools	1	02SEP2020	14/1	1	No	O	NA	R (02SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1022 10221034		Nausea/ Nausea	1	02SEP2020	14/1	1	No	O	NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	20AUG2020	1/3	2	Yes		NA	R (22AUG2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	14SEP2020	26/3	1	Yes		NA	R (16SEP2020)	N/N
>55/ C4591001 1022 10221036		Injection site pain/ Moderate Injection site pain	1	14SEP2020	26/7	2	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Chills/ Chills#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
		Fatigue/ Fatigue#	4	09JAN2021	2/3	2	Yes		NA	R (11JAN2021)	N/N
>55/ C4591001 1022 10221037		Pyrexia/ Low Grade Fever#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Injection site pain/ Moderate Injection Site Pain#	3	18DEC2020	1/2	2	Yes		NA	R (19DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Mild headache#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	08JAN2021	1/1	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Chills/ Chills#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
		Fatigue/ Mild Fatigue#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
>55/ C4591001 1022 10221038	GENRL	Injection site pain/ Mild Injection Site Pain#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Fatigue/ Moderate Fatigue#	4	09FEB2021	2/2	2	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1022 10221039	GENRL	Fatigue/ Moderate Fatigue#	3	20JAN2021	2/1	2	Yes		NA	R (20JAN2021)	N/N
		Injection site pain/ Moderate Injection Site Pain#	3	20JAN2021	2/3	2	Yes		NA	R (22JAN2021)	N/N
	GENRL	Chills/ Mild Chills#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
		Fatigue/ Mild Fatigue#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Mild Injection site pain#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	PSYCH	Abnormal dreams/ Vivid Dreams#	4	15FEB2021	7/C	1	No	O	NA	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1022 10221041	GENRL	Injection site pain/ Injection Site Pain	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Chills/ Chills	2	11SEP2020	1/2	2	Yes		NA	R (12SEP2020)	N/N
		Pyrexia/ Fever	2	11SEP2020	1/2	2	Yes		NA	R (12SEP2020)	N/N
>55/ C4591001 1022 10221042	GENRL	Fatigue/ Fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		Pyrexia/ Low Grade Fever	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ Headache	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N
>55/ C4591001 1022 10221046	GENRL	Injection site pain/ Mild Injection Site Pain#	3	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
	MUSC	Myalgia/ Mild Generalized Myalgias#	3	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Fatigue/ Mild Fatigue#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1022 10221047	NERV	Headache/ Mild Headache#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Fatigue/ Mild Fatigue#	3	15JAN2021	2/3	1	Yes		NA	R (17JAN2021)	N/N
>55/ C4591001 1022 10221050	NERV	Headache/ Mild Headache#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N
>55/ C4591001 1022 10221053	GENRL	Fatigue/ Fatigue	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/Y
		Injection site pain/ Mild Injection Site Pain	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/Y
	GENRL	Chills/ Moderate Chills#	3	01FEB2021	1/3	2	Yes		P	R (03FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	3	01FEB2021	1/4	3	Yes		P	R (04FEB2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	3	01FEB2021	1/3	2	Yes		P	R (03FEB2021)	N/N
>55/ C4591001	NERV	Headache/ Moderate Headache#	3	01FEB2021	1/3	2	Yes		P	R (03FEB2021)	N/N
	GASTR	Diarrhoea/ Moderate Diarrhea#	3	04FEB2021	4/4	2	Yes		P	R (07FEB2021)	N/N
	GENRL	Injection site pain/ Mild Injection site pain	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1022 10221056 >55/ C4591001	GASTR	Diarrhoea/ Diarrhea	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
1022 10221060	GENRL	Chills/ Chills	2	14SEP2020	1/1	2	Yes		NA	R (14SEP2020)	N/N
		Injection site pain/ Injection site pain	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
		Pyrexia/ Fever	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	2	14SEP2020	1/2	2	Yes		NA/TC	R (15SEP2020)	N/N
	NERV	Headache/ Headache	2	14SEP2020	1/2	2	Yes		NA/TC	R (15SEP2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ Mild Injection Site Pain#	3	15JAN2021	2/3	1	Yes		NA	R (17JAN2021)	N/N
1022 10221061	GENRL	Fatigue/ Mild Fatigue#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ Mild Injection site pain*		25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
1022 10221063	GENRL	Fatigue/ Mild Fatigue#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1022 10221065	GENRL	Injection site pain/ Mild Injection Site Pain#	3	18DEC2020	2/3	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	2/C	2	Yes		NA	N	N/N
	MUSC	Myalgia/ Generalized Myalgias	2	17SEP2020	2/C	2	Yes		NA	N	N/N
	NERV	Headache/ Headache	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001 1022 10221067	GENRL	Injection site pain/ Injection Site Pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Chills/ Mild Chills#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
		Fatigue/ Mild Fatigue#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	NERV	Pyrexia/ Fever#	4	02FEB2021	1/2	1	Yes		NA/TC	R (03FEB2021)	N/N
		Headache/ Mild Headache#	4	02FEB2021	1/3	1	Yes		NA/TC	R (04FEB2021)	N/N
	SKIN	Rash erythematous/ Red Rash on Neck and Chest#	4	03FEB2021	2/3	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1022 10221068	GENRL	Injection site pain/ Mild Injection Site Pain	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection Site Pain#	3	14JAN2021	1/2	2	Yes		NA	R (15JAN2021)	N/N
	GENRL	Fatigue/ Mild Fatigue#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
>55/ C4591001 1022 10221071	GENRL	Injection site pain/ Mild Injection site pain	1	27AUG2020	2/6	1	Yes		NA	R (01SEP2020)	N/N
>55/ C4591001 1022 10221073	GENRL	Injection site pain/ Mild Injection Site Pain	1	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/N
	MUSC	Muscle spasms/ Generalized Muscle Cramps	1	27AUG2020	2/1	2	Yes		NA	R (27AUG2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/Y
>55/ C4591001 1022 10221075	GENRL	Injection site pain/ Mild Injection Site pain	1	27AUG2020	1/1	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Injection site pain/ Mild Injection site pain	2	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	09FEB2021	1/1	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ Mild Injection site pain	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1022 10221077 >55/ C4591001	GENRL	Injection site pain/ Mild Injection Site Pain#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
1022 10221079	NERV	Headache/ Mild Headache#	3	18DEC2020	2/2	1	Yes		NA	R (19DEC2020)	N/N
	NERV	Headache/ Mild headache#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ Mild injection site pain#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
1022 10221082	GENRL	Fatigue/ Mild Fatigue#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ Mild Headache#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001	MUSC	Myalgia/ Myalgias (generalized)	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/N
1022 10221085	RESP	Throat irritation/ Mild scratchy throat	2	18SEP2020	3/1	1	No	O	NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Moderate Injection site pain#	3	17DEC2020	2/1	2	Yes		NA	R (17DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/Y
	GENRL	Fatigue/ Fatigue#	4	06JAN2021	2/2	2	Yes		NA	R (07JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Pyrexia/ Low Grade Fever#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
>55/ C4591001 1022 10221086	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
>55/ C4591001 1022 10221089	GENRL	Fatigue/ Fatigue	1	28AUG2020	1/2	2	Yes		NA	R (29AUG2020)	N/N
		Injection site pain/ Pain At the injection site	1	28AUG2020	1/2	2	Yes		NA	R (29AUG2020)	N/N
>55/ C4591001 1022 10221090	GENRL	Chills/ Mild Chills#	3	18JAN2021	1/1	1	Yes		NA	R (18JAN2021)	N/N
	GENRL	Chills/ Mild Chills#	4	08FEB2021	1/1	1	Yes		NA	R (08FEB2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1022 10221091	GENRL	Chills/ Mild Chills	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ Fever	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ Moderate Headache	2	18SEP2020	2/1	2	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001	NERV	Syncope/ Episode of syncope	1	12SEP2020	16/1	3	No	CD	NA	R (12SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1022 10221092	RESP	Hypersensitivity pneumonitis/ Exacerbation of Hypersensitivity Pneumonitis#	2	26JAN2021	133/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1022 10221095	GENRL	Injection site pain/ Mild Injection Site Pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/Y
	GENRL	Chills/ Moderate Chills	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
		Injection site pain/ Moderate injection site pain	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
	NERV	Headache/ Moderate Headache	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
>55/ C4591001 1022 10221096	CARD	Atrial fibrillation/ Exacerbation of Paroxysmal Atrial Fibrillation	2	26SEP2020	4/C	2	No	O	NA/TCN	N	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
>55/ C4591001 1022 10221097	GENRL	Injection site pain/ Moderate Injection site pain	1	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/Y
>55/ C4591001 1022 10221099	GENRL	Injection site pain/ Mild Injection Site Pain#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N
	GENRL	Fatigue/ Mild Fatigue#	3	17DEC2020	2/2	1	Yes		NA	R (18DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Moderate Fatigue#	4	06JAN2021	1/3	2	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	06JAN2021	1/1	1	Yes		NA	R (06JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ Mild headache#	4	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N
>55/ C4591001 1022 10221102	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
>55/ C4591001 1022 10221103	GENRL	Injection site pain/ Mild Injection Site Pain#	3	19JAN2021	2/3	1	Yes		NA	R (21JAN2021)	N/N
	PSYCH	Irritability/ Mild irritability#	3	19JAN2021	2/3	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	GENRL	Fatigue/ Mild Fatigue#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1022 10221104	GENRL	Injection site pain/ Moderate Injection site pain	1	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Mild Injection site pain	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	NERV	Headache/ Mild Headache	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1022 10221107	GENRL	Injection site pain/ Mild Injection site pain	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
>55/ C4591001 1022 10221116	GENRL	Injection site pain/ injection site pain*		02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Fatigue/ Moderate Fatigue	2	23SEP2020	2/C	2	Yes		NA	N	N/N
		Injection site pain/ Moderate injection site pain	2	23SEP2020	2/C	2	Yes		NA	N	N/N
>55/ C4591001 1022 10221118	GENRL	Injection site pain/ Mild Injection site pain*		03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
	NERV	Headache/ Moderate Headache	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	25SEP2020	23/1	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ Mild Headache	1	25SEP2020	23/1	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	NERV	Headache/ Mild Headache#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
>55/ C4591001 1022 10221119	GENRL	Injection site pain/ Mild Injection Site Pain#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1022 10221121	GENRL	Injection site pain/ Mild Injection Site Pain#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Chest pain/ Musculoskeletal pain in sternum#	4	10FEB2021	2/C	1	Yes		NA	N	N/N
		Chills/ Chills#	4	10FEB2021	2/C	2	Yes		NA	N	N/N
		Chills/ Moderate Shivering#	4	10FEB2021	2/1	2	Yes		NA	R (10FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain in right arm#	4	10FEB2021	2/C	1	Yes		NA	N	N/N
	NERV	Headache/ Moderate Headache#	4	10FEB2021	2/C	2	Yes		NA/TC	N	N/N
>55/ C4591001 1022 10221124	GENRL	Injection site pain/ Mild Injection Site Pain#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1022 10221132	GENRL	Chills/ Chills	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
		Fatigue/ Fatigue	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
		Injection site pain/ Mild Injection Site Pain	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ Fever	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Arthralgia/ Arthralgias	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
>55/ C4591001 1022 10221140	GENRL	Injection site pain/ Mild Injection site pain	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ Mild fatigue	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ Mild Fatigue	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ Mild Injection site pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C4591001 1022 10221141	GENRL	Injection site pain/ Mild Injection Site Pain#	3	14JAN2021	1/3	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Fatigue/ Mild Fatigue#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ Low Grade Fever#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Mild Headache#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1022 10221145	GENRL	Chills/ Mild Chills	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/N
		Fatigue/ Moderate Fatigue	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
>55/ C4591001	GENRL	Fatigue/ Mild Fatigue	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1022 10221148		Injection site pain/ Moderate Injection Site Pain	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1022 10221149	NERV	Headache/ Mild Headache#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1022 10221151	INV	Hepatitis C antibody positive/ Positive Hepatitis C antibody test	2	19OCT2020	19/C	1	No	O	NA	N	N/N
>55/ C4591001 1022 10221152	GENRL	Injection site pain/ Injection site pain	1	11SEP2020	1/7	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		Injection site swelling/ Swelling at the injection site	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
>55/ C4591001 1022 10221153	GENRL	Fatigue/ Mild Fatigue#	3	14JAN2021	1/4	1	Yes		NA	R (17JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	3	14JAN2021	1/3	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	02FEB2021	1/4	1	Yes		NA	R (05FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1022 10221154	GENRL	Injection site pain/ Mild Injection Site Pain	2	05OCT2020	1/4	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site erythema/ Mild Erythema injection site	2	06OCT2020	2/4	1	Yes		NA	R (09OCT2020)	N/N
>55/ C4591001 1022 10221155	NERV	Headache/ Headache (worse than baseline)	2	11OCT2020	7/2	1	Yes		NA	R (12OCT2020)	N/N
	GENRL	Fatigue/ Mild fatigue#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1022 10221157	GENRL	Chills/ Chills	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
		Fatigue/ Fatigue	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
		Pyrexia/ Fever	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
	NERV	Balance disorder/ Loss Of Balance	2	06OCT2020	2/2	2	No	O	NA	R (07OCT2020)	N/N
	MUSC	Bursitis/ Left Trochanteric Bursitis	2	10OCT2020	6/C	3	No	O	NA/TC/TCN	N	N/N
>55/ C4591001 1022 10221160	GENRL	Chills/ Moderate Chills	1	17SEP2020	3/2	2	Yes		NA	R (18SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Moderate Headache	1	17SEP2020	3/2	2	Yes		NA	R (18SEP2020)	N/N
	INFEC	Hordeolum/ Hordeolum Right Lower Lid	1	19SEP2020	5/22	1	No	O	NA/TCN	R (10OCT2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	14JAN2021	1/3	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Chills/ Mild Chills#	3	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N
		Fatigue/ Mild Fatigue#	3	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Fatigue/ Mild Fatigue#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
		Pyrexia/ Low Grade Fever#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	NERV	Headache/ Mild Headache#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
>55/ C4591001 1022 10221161	GASTR	Diarrhoea/ Diarrhea	1	04OCT2020	5/4	1	No	CD	NA	R (07OCT2020)	N/N
	NEOPL	Squamous cell carcinoma of skin/ Squamous Cell Carcinoma Right scalp	2	08DEC2020	49/31	1	No	O	NA/TCN	R (07JAN2021)	N/N
		Squamous cell carcinoma of skin/ Squamous Cell Carcinoma left scalp	2	08DEC2020	49/36	1	No	O	NA/TCN	R (12JAN2021)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1022 10221162	GENRL	Injection site pain/ Mild Injection Site Pain#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	NERV	Headache/ Mild Headache#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	15JAN2021	2/4	1	Yes		NA	R (18JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Fatigue/ Moderate Fatigue#	3	02FEB2021	20/3	2	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1022 10221163		Pyrexia/ Fever#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	18DEC2020	2/3	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Chills/ Chills#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
		Fatigue/ Fatigue#	4	06JAN2021	1/4	1	Yes		NA	R (09JAN2021)	N/N
	VASC	Hot flush/ Hot Flashes#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
>55/ C4591001 1022 10221165	GENRL	Injection site pain/ Mild Injection Site Pain	1	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/Y
	GENRL	Injection site pain/ Mild Injection Site Pain	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1022 10221167	GENRL	Injection site pain/ Mild Injection Site Pain#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
>55/ C4591001 1022 10221168	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1022 10221169	GENRL	Injection site pain/ Mild Injection site pain	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1022 10221170	GENRL	Chills/ Mild Chills#	4	02FEB2021	1/2	1	Yes		NA/TC	R (03FEB2021)	N/N
>55/ C4591001 1022 10221171	INJ&P	Fall/ Ground Level Fall#	4	26JAN2021	23/1	2	No	O	NA	R (26JAN2021)	N/N
		Wrist fracture/ Left Wrist fracture#	4	26JAN2021	23/C	2	No	O	NA/TC/TCN	N	N/N
>55/ C4591001 1022 10221173	GENRL	Injection site pain/ Mild Injection Site Pain	1	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Chills/ Mild Chills	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Mild Fatigue	2	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N
>55/ C4591001 1022 10221174	GENRL	Injection site pain/ Mild Injection Site Pain	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C4591001 1022 10221175	GENRL	Injection site pain/ Mild injection Site Pain#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Chills/ Chills#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ Headache#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
	GASTR	Nausea/ Nausea#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1022 10221176	GASTR	Nausea/ Mild Nausea	1	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/Y
	GENRL	Fatigue/ Mild Fatigue	1	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/Y
		Injection site pain/ Mild Injection Site Pain	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/Y
	GENRL	Chills/ Moderate Chills	2	13OCT2020	1/3	2	Yes		NA	R (15OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1022 10221177	MUSC	Fatigue/ Moderate fatigue	2	13OCT2020	1/3	2	Yes		NA	R (15OCT2020)	N/N	
		Myalgia/ Moderate Generalized Myalgias	2	13OCT2020	1/3	2	Yes		NA	R (15OCT2020)	N/N	
	GENRL	Injection site pain/ Mild injection Site Pain	2	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N	
	GENRL	Chills/ Chills	1	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N	
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N	
	GENRL	Chills/ Mild Chills#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N	
	MUSC	Fatigue/ Moderate Fatigue#	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N	
		Myalgia/ Moderate Myalgias#	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N	
	>55/ C4591001 1022 10221178	NERV	Headache/ Mild Headache	2	21OCT2020	1/1	1	Yes		NA	R (21OCT2020)	N/N
		GENRL	Injection site pain/ Mild Injection Site Pain#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
>55/ C4591001 1024 10241007	GENRL	Injection site pain/ Injection site pain LEFT arm#	4	13JAN2021	2/1	1	Yes		NA	R (13JAN2021)	N/N	
>55/ C4591001	GASTR	Diarrhoea/ Diarrhea	1	19AUG2020	3/2	2	Yes		NA	R (20AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1024 10241028	GENRL	Chills/ Chills	1	19AUG2020	3/2	2	Yes		NA	R (20AUG2020)	N/N	
>55/ C4591001 1024 10241031	GENRL	Injection site pain/ Injection Site Pain	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N	
	GENRL	Fatigue/ Tired	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N	
		Pain/ Generalized Aches	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N	
>55/ C4591001 1024 10241034	GENRL	Injection site pain/ Injection site pain	1	18AUG2020	1/1	1	Yes		NA	R (18AUG2020)	N/Y	
>55/ C4591001 1024 10241037	GENRL	Injection site pain/ Injection Site Pain	1	19AUG2020	2/3	1	Yes		NA	R (21AUG2020)	N/N	
>55/ C4591001 1024 10241077	EYE	Retinal detachment/ Retinal Detachment Left eye	1	14SEP2020	21/C	2	No	O	NA	N	N/N	
>55/ C4591001 1024 10241097	GENRL	Pain/ generalized body aches	2	19SEP2020	2/2	1	Yes		NA/TCN	R (20SEP2020)	N/N	
>55/ C4591001	GENRL	Injection site pain/ Left arm Injection Site Pain#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1024 10241099 >55/ C4591001	GASTR	Diarrhoea/ Diarrhea#	4	08JAN2021	1/2	1	No	O	NA	R (09JAN2021)	N/N
1024 10241113 >55/ C4591001	GENRL	Injection site pain/ Injection Site Pain#	4	25FEB2021	8/3	1	Yes		NA	R (27FEB2021)	N/N
1024 10241133† >55/ C4591001	EYE	Cataract/ Bilateral Cataracts	2	SEP2020	1/	2	No	O	NA/TCN	R (17NOV2020)	N/N
1027 10271007 >55/ C4591001	NEOPL	Acute myeloid leukaemia/ Acute Myeloid Leukemia	2	08NOV2020	58/C	3	No	O	NA/TC/TCN	N	Y/N
1027 10271054	VASC	Deep vein thrombosis/ Deep Vein Thrombosis	2	11NOV2020	61/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1027 10271095	GENRL	Injection site pruritus/ Intermittent Itching at Injection Site (Left arm)	2	01OCT2020	15/27	1	Yes		NA	R (27OCT2020)	N/N
>55/ C4591001 1027 10271099	GASTR	Nausea/ NAUSEA	1	07SEP2020	11/1	1	No	O	NA	R (07SEP2020)	N/N
	RESP	Oropharyngeal pain/ MILD SORE THROAT	1	07SEP2020	11/1	1	No	O	NA	R (07SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1027 10271132	NERV	Headache/ Headache	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N	
>55/ C4591001 1027 10271138	MUSC	Osteoporosis/ Osteoporosis	1	18SEP2020	16/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1027 10271144	GENRL	Pyrexia/ Fever	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N	
	MUSC	Myalgia/ Muscle Aches	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N	
	NERV	Headache/ Headache	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N	
>55/ C4591001 1027 10271153	INFEC	Urinary tract infection/ Urinary Tract Infection	2	02NOV2020	33/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1027 10271160	GENRL	Pyrexia/ Low grade fever post Covid Vaccination 4#	3	05JAN2021	20/2	1	Yes		NA	R (06JAN2021)	N/N	
>55/ C4591001 1027 10271161	INJ&P	Limb injury/ Left Shoulder Injury	2	NOV2020	35/	2	No	O	NA/TCN	R (14JAN2021)	N/N	
>55/ C4591001	GASTR	Nausea/ Nausea	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1027 10271166	GENRL	Chills/ Chills	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
>55/ C4591001 1027 10271184	NERV	Headache/ Headache#	4	05JAN2021	1/2	2	Yes		NA	R (06JAN2021)	N/N
>55/ C4591001 1027 10271191	INFEC	COVID-19/ COVID-19#	2	12JAN2021	103/33	4	No	O	NA/TC/TCN/W	F (13FEB2021)	Y/N
	RESP	Acute respiratory failure/ Acute Hypoxic Respiratory Failure#	2	12JAN2021	103/33	4	No	O	NA/TC/TCN/W	F (13FEB2021)	Y/N
>55/ C4591001 1027 10271202	GASTR	Nausea/ Nausea#	3	18JAN2021	1/3	2	Yes		NA	R (20JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	3	18JAN2021	1/3	2	Yes		NA	R (20JAN2021)	N/N
	NERV	Headache/ Headache#	3	18JAN2021	1/3	2	Yes		NA	R (20JAN2021)	N/N
>55/ C4591001 1027 10271213	GENRL	Chills/ Chills	2	30OCT2020	2/3	1	Yes		NA	R (01NOV2020)	N/N
		Pain/ Generalized Aches	2	30OCT2020	2/3	1	Yes		NA	R (01NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1028 10281006	INV	Body temperature increased/ increased body temperature	1	03SEP2020	18/1	2	No	O	NA	R (03SEP2020)	N/N
	SKIN	Rash/ rash bilateral ankles	2	15OCT2020	37/62	2	No	O	NA/TC	R (15DEC2020)	N/N
		Rash/ rash bilateral elbows	2	15OCT2020	37/62	2	No	O	NA/TC	R (15DEC2020)	N/N
>55/ C4591001 1028 10281011	GENRL	Injection site pain/ Injection Site Pain, Left Arm	1	19AUG2020	2/3	2	Yes		NA	R (21AUG2020)	N/N
>55/ C4591001 1028 10281012	MUSC	Trigger finger/ RIGHT MIDDLE DIGIT TRIGGER FINGER	2	01OCT2020	16/C	2	No	O	NA	N	N/N
>55/ C4591001 1028 10281014	GENRL	Injection site pain/ sore arm right deltoid injection site	2	08SEP2020	1/2	2	Yes		NA	R (09SEP2020)	N/N
	NERV	Headache/ headache	2	08SEP2020	1/2	2	Yes		NA	R (09SEP2020)	N/N
>55/ C4591001 1028 10281032	GENRL	Injection site pain/ Left Arm Injection Site Pain	1	20AUG2020	1/3	2	Yes		NA	R (22AUG2020)	N/Y
	INJ&P	Joint dislocation/ Left Shoulder Dislocation	2	13SEP2020	3/1	2	No	O	NA	R (13SEP2020)	N/N
	MUSC	Muscle spasms/ Left Arm Muscle Spasms	2	13SEP2020	3/C	2	No	O	NA	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1028 10281034	MUSC	Muscle spasms/ Left Arm Charley Horse	2	15SEP2020	5/1	2	No	O	NA	R (15SEP2020)	N/N	
	INJ&P	Muscle contusion/ Left Bicep Bruise	2	18SEP2020	8/4	2	No	O	NA	R (21SEP2020)	N/N	
	GENRL	Chills/ chills	2	12SEP2020	2/2	2	Yes		NA	R (13SEP2020)	N/N	
>55/ C4591001 1028 10281039	MUSC	Neck pain/ neck pain	2	01OCT2020	21/C	2	Yes		NA/TC	N	N/N	
	GENRL	Injection site pain/ left arm soreness at injection site	1	21AUG2020	1/4	2	Yes		NA	R (24AUG2020)	N/N	
	INJ&P	Fall/ accidental fall	1	10SEP2020	21/1	2	No	O	NA	R (10SEP2020)	N/N	
>55/ C4591001 1028 10281045		Skin abrasion/ abrasion left forearm	1	10SEP2020	21/34	2	No	O	NA	R (13OCT2020)	N/N	
		Skin abrasion/ abrasion right elbow	1	10SEP2020	21/34	2	No	O	NA	R (13OCT2020)	N/N	
		Skin abrasion/ abrasion right side flank	1	10SEP2020	21/34	2	No	O	NA	R (13OCT2020)	N/N	
	GENRL	Injection site pain/ pain at injection site left arm#	3	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N	
>55/ C4591001 1028 10281046	GENRL	Injection site pain/ left deltoid soreness at injection site	2	14SEP2020	1/4	2	Yes		NA	R (17SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1028 10281057	GENRL	Fatigue/ Fatigue	1	26AUG2020	2/2	2	Yes		NA	R (27AUG2020)	N/N
	INJ&P	Wound/ puncture wound	1	30AUG2020	6/1	2	No	O	NA	R (30AUG2020)	N/N
>55/ C4591001 1028 10281073	GENRL	Injection site pain/ LEFT ARM SORENESS AT INJECTION SITE	1	28AUG2020	2/1	2	Yes		NA	R (28AUG2020)	N/N
	GENRL	Injection site pain/ left arm pain at injection site	2	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site rash/ left arm rash at injection site	2	19SEP2020	2/1	2	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1028 10281074	GENRL	Injection site pain/ pain at injection site right arm#	3	08FEB2021	1/3	2	Yes		NA	R (10FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site right arm#	4	01MAR2021	1/C	2	Yes		NA	N	N/Y
>55/ C4591001 1028 10281082	GENRL	Injection site pain/ left arm soreness at injection site	1	31AUG2020	1/8	2	Yes		NA	R (07SEP2020)	N/N
	GENRL	Chills/ Body Chills	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
		Pain/ generalized Body Aches	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ fever	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1028 10281083	MUSC	Intervertebral disc degeneration/ worsening cervical degenerative disc disease	2	05JAN2021	107/2	2	No	O	NA/TCN	R (06JAN2021)	Y/N	
>55/ C4591001 1028 10281092	INV	Body temperature increased/ elevated temp	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N	
>55/ C4591001 1028 10281099	GASTR	Constipation/ constipation	2	14OCT2020	23/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1028 10281108	MUSC	Myalgia/ muscle aches	2	24SEP2020	2/1	2	Yes		NA	R (24SEP2020)	N/N	
>55/ C4591001 1028 10281109	GENRL	Chills/ chills	2	25SEP2020	2/3	2	Yes		NA	R (27SEP2020)	N/N	
		Pyrexia/ fever	2	25SEP2020	2/3	2	Yes		NA	R (27SEP2020)	N/N	
	NERV	Headache/ headache	2	25SEP2020	2/3	2	Yes		NA	R (27SEP2020)	N/N	
>55/ C4591001 1028 10281115	GENRL	Injection site bruising/ Left Arm Injection Site Bruise	1	03SEP2020	1/3	2	Yes		NA/TCN	R (05SEP2020)	N/N	
		Injection site pain/ Left Arm Injection Site Pain	1	03SEP2020	1/3	2	Yes		NA	R (05SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pain/ Generalized Body Aches	1	04SEP2020	2/2	2	Yes		NA	R (05SEP2020)	N/N
	GASTR	Oral pain/ Mouth Pain	1	05SEP2020	3/61	2	No	O	NA/TCN	R (04NOV2020)	N/N
	INJ&P	Tooth fracture/ Broken Tooth, Upper Left	1	05SEP2020	3/17	2	No	O	NA/TC/TCN	R (21SEP2020)	N/N
	GENRL	Injection site bruising/ injection site bruise left arm	2	25SEP2020	2/4	2	Yes		NA	R (28SEP2020)	N/N
		Injection site erythema/ injection site redness left arm	2	25SEP2020	2/4	2	Yes		NA	R (28SEP2020)	N/N
		Injection site pain/ left arm injection site pain	2	25SEP2020	2/4	2	Yes		NA/TC	R (28SEP2020)	N/N
		Injection site reaction/ injection site welt left arm	2	25SEP2020	2/4	2	Yes		NA	R (28SEP2020)	N/N
>55/ C4591001 1028 10281123	GENRL	Chills/ chills#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N
		Fatigue/ fatigue#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N
		Pain/ body aches#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain left arm#	4	29JAN2021	2/3	2	Yes		NA	R (31JAN2021)	N/N
	MUSC	Limb discomfort/ injection arm pressure, left#	4	29JAN2021	2/2	2	Yes		NA	R (30JAN2021)	N/N
>55/ C4591001 1028 10281128	GASTR	Large intestine polyp/ colon polyp, benign	2	13NOV2020	50/1	2	No	O	NA/TCN	R (13NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1028 10281132	NEOPL	Lipoma/ lipoma left inner elbow area	2	11JAN2021	106/C	2	No	O	NA	N	N/N	
>55/ C4591001 1028 10281142	GENRL	Injection site pain/ RIGHT ARM SORENESS AT INJECTION SITE	1	07SEP2020	1/3	2	Yes		NA	R (09SEP2020)	N/N	
		Pain/ BODY ACHES	1	07SEP2020	1/3	2	Yes		NA	R (09SEP2020)	N/N	
	GENRL	Injection site pain/ RIGHT ARM SORENESS AT INJECTION SITE	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N	
		Pain/ BODY ACHES	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N	
>55/ C4591001 1028 10281147	GENRL	Pyrexia/ fever	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N	
	NERV	Headache/ headache	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N	
>55/ C4591001 1028 10281149	GENRL	Injection site bruising/ Bruising at injection site, left side#	3	21DEC2020	1/4	2	Yes		NA	R (24DEC2020)	N/N	
>55/ C4591001 1028 10281151	MUSC	Pain in extremity/ right arm soreness	1	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N	
>55/ C4591001	EYE	Ocular hyperaemia/ bloodshot eyes bilateral	1	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1028 10281157	GENRL	Fatigue/ fatigue	2	29SEP2020	1/4	2	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1028 10281175	GENRL	Pain/ general body aches	1	14SEP2020	1/3	2	Yes		NA	R (16SEP2020)	N/N
	INV	Body temperature increased/ elevated body temperature	2	06OCT2020	2/1	2	Yes		NA	R (06OCT2020)	N/N
>55/ C4591001 1028 10281180	GENRL	Injection site pain/ left arm injection site pain#	4	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/Y
	NERV	Dizziness/ dizziness#	4	13JAN2021	2/1	2	Yes		NA	R (13JAN2021)	N/N
	NERV	Dizziness/ dizziness#	4	22JAN2021	11/C	2	No	O	NA/TC	N	N/N
	PSYCH	Anxiety/ worsening anxiety#	4	22JAN2021	11/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1028 10281193	NERV	Dizziness/ Lightheaded	1	16SEP2020	1/1	2	No	O	NA	R (16SEP2020)	N/Y
	GENRL	Pyrexia/ fever	2	14OCT2020	7/2	2	Yes		NA	R (15OCT2020)	N/N
	GASTR	Nausea/ nausea#	3	11FEB2021	1/2	2	Yes		NA	R (12FEB2021)	N/N
	GENRL	Chills/ chills#	3	11FEB2021	1/2	2	Yes		NA	R (12FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Pain/ body aches#	3	11FEB2021	1/C	2	Yes		NA	N	N/N	
		Pyrexia/ fever#	3	11FEB2021	1/C	2	Yes		NA	N	N/N	
	GASTR	Diarrhoea/ diarrhea#	4	11MAR2021	1/2	2	Yes		NA	R (12MAR2021)	N/N	
		Nausea/ nausea#	4	11MAR2021	1/2	2	Yes		NA	R (12MAR2021)	N/N	
	GENRL	Pain/ generalized body aches#	4	11MAR2021	1/2	2	Yes		NA	R (12MAR2021)	N/N	
	INV	Body temperature increased/ increased body temperature#	4	11MAR2021	1/2	2	Yes		NA	R (12MAR2021)	N/N	
>55/ C4591001 1028 10281199	INJ&P	Epicondylitis/ lateral epicondylitis right elbow	2	20DEC2020	74/C	2	No	O	NA/TC	N	N/N	
		Epicondylitis/ medial epicondylitis right elbow	2	20DEC2020	74/C	2	No	O	NA	N	N/N	
	MUSC	Osteoarthritis/ osteoarthritis right elbow	2	20DEC2020	74/C	2	No	O	NA	N	N/N	
>55/ C4591001 1028 10281201	NEOPL	Bowen's disease/ squamous cell carcinoma in situ right parietal scalp#	3	15JAN2021	11/19	2	No	O	NA/TCN	R (02FEB2021)	N/N	
		Seborrheic keratosis/ seborrheic keratosis#	3	15JAN2021	11/C	2	No	O	NA	N	N/N	
	SKIN	Actinic keratosis/ actinic keratosis#	3	15JAN2021	11/C	2	No	O	NA	N	N/N	
>55/ C4591001	GENRL	Injection site pain/ sore left arm at injection site	2	09OCT2020	1/3	2	Yes		NA	R (11OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1028 10281204	GENRL	Pyrexia/ fever	2	10OCT2020	2/3	2	Yes		NA/TC	R (12OCT2020)	N/N	
>55/ C4591001 1028 10281206	GENRL	Malaise/ general malaise	1	19SEP2020	2/1	2	Yes		NA	R (19SEP2020)	N/N	
	GENRL	Injection site pruritus/ injection site itching left arm	2	09OCT2020	1/7	2	Yes		NA	R (15OCT2020)	N/N	
		Malaise/ general malaise	2	09OCT2020	1/3	2	Yes		NA	R (11OCT2020)	N/N	
>55/ C4591001 1028 10281215	GENRL	Malaise/ general malaise	1	23SEP2020	3/2	2	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Malaise/ general malaise	2	14OCT2020	3/2	2	Yes		NA	R (15OCT2020)	N/N	
>55/ C4591001 1028 10281218	MUSC	Arthralgia/ Right Elbow Pain	2	24OCT2020	12/12	2	No	O	NA	R (04NOV2020)	N/N	
	INFEC	Ear infection/ left ear infection#	3	04FEB2021	18/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1028 10281232	GENRL	Fatigue/ fatigue#	3	30JAN2021	2/2	2	Yes		NA	R (31JAN2021)	N/N	
		Injection site pain/ left deltoid soreness at injection site#	3	30JAN2021	2/2	2	Yes		NA	R (31JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1028 10281234	INFEC	Sinusitis/ sinus infection	2	29OCT2020	14/7	2	No	O	NA/TC	R (04NOV2020)	N/N
>55/ C4591001 1028 10281235	GENRL	Chills/ chills	2	17OCT2020	3/2	2	Yes		NA	R (18OCT2020)	N/N
		Pain/ achiness	2	17OCT2020	3/2	2	Yes		NA	R (18OCT2020)	N/N
	INV	Body temperature increased/ elevated body temperature	2	17OCT2020	3/2	2	Yes		NA	R (18OCT2020)	N/N
>55/ C4591001 1028 10281245	MUSC	Pain in extremity/ bilateral calf pain	2	16NOV2020	22/29	2	No	O	NA	R (14DEC2020)	N/N
>55/ C4591001 1028 10281268	GENRL	Fatigue/ fatigue	1	20OCT2020	1/3	2	Yes		NA	R (22OCT2020)	N/N
	NERV	Headache/ headache	1	20OCT2020	1/1	2	Yes		NA	R (20OCT2020)	N/N
	GASTR	Diarrhoea/ diarrhea	1	21OCT2020	2/2	2	Yes		NA	R (22OCT2020)	N/N
		Retching/ dry heaving	1	21OCT2020	2/2	2	Yes		NA	R (22OCT2020)	N/N
	GENRL	Chills/ chills	1	21OCT2020	2/2	2	Yes		NA	R (22OCT2020)	N/N
		Injection site pain/ left deltoid soreness (injection site)	1	21OCT2020	2/2	2	Yes		NA	R (22OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1028 10281270	SKIN	Hyperhidrosis/ sweating	1	21OCT2020	2/2	2	Yes		NA	R (22OCT2020)	N/N	
	RESP	Rhinorrhoea/ running nose#	3	06FEB2021	20/C	2	No	O	NA	N	N/N	
>55/ C4591001 1028 10281273	NERV	Dizziness/ lightheaded	1	22OCT2020	1/2	2	Yes		NA	R (23OCT2020)	N/Y	
>55/ C4591001 1028 10281277	GENRL	Injection site pain/ pain at injection site left arm	1	23OCT2020	1/4	2	Yes		NA/TC	R (26OCT2020)	N/N	
>55/ C4591001 1028 10281283	GENRL	Injection site erythema/ redness at injection site left arm	1	24OCT2020	2/3	2	Yes		NA	R (26OCT2020)	N/N	
	CARD	Atrial fibrillation/ atrial fibrillation with rapid ventricular response#	4	16FEB2021	13/2	2	No	O	NA/TC	R (17FEB2021)	Y/N	
>55/ C4591001 1028 10281289		Atrial fibrillation/ atrial fibrillation#	4	16FEB2021	13/C	2	No	O	NA	N	N/N	
	RENAL	Acute kidney injury/ acute kidney injury#	4	16FEB2021	13/8	2	No	O	NA	R (23FEB2021)	N/N	
>55/ C4591001 1028 10281289	GENRL	Injection site pain/ soreness of left deltoid injection site#	3	06JAN2021	2/1	2	Yes		NA	R (06JAN2021)	N/N	
>55/ C4591001	HEPAT	Nonalcoholic fatty liver disease/ non-alcoholic fatty liver disease	2	30NOV2020	12/C	2	No	O	NA	N	N/N	



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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1028 10281292	GENRL	Chills/ chills#	3	15JAN2021	2/1	2	Yes		NA	R (15JAN2021)	N/N
		Pain/ body aches#	3	15JAN2021	2/1	2	Yes		NA	R (15JAN2021)	N/N
>55/ C4591001 1028 10281296	GENRL	Injection site pain/ right arm injection site pain	2	19NOV2020	1/3	2	Yes		NA	R (21NOV2020)	N/N
		Injection site swelling/ right arm injection site swelling	2	19NOV2020	1/3	2	Yes		NA	R (21NOV2020)	N/N
>55/ C4591001 1030 10301007	GENRL	Injection site pain/ left arm pain from injection site#	3	23DEC2020	1/3	1	Yes		NA	R (25DEC2020)	N/N
>55/ C4591001 1030 10301052	INFEC	Herpes zoster/ Shingles#	4	22FEB2021	11/9	2	No	O	NA/TC	R (02MAR2021)	N/N
>55/ C4591001 1030 10301059	NERV	Headache/ headaches	2	22OCT2020	21/C	1	No	O	NA	N	N/N
	NEOPL	Lung adenocarcinoma/ adenocarcinoma, right lung	2	02DEC2020	62/C	2	No	O	NA/TCN	RG	Y/N
		Metastases to lymph nodes/ Metastasis to lymph Nodes	2	02DEC2020	62/C	2	No	O	NA/TC	RG	Y/N
>55/ C4591001	RESP	Epistaxis/ nose bleed	2	16NOV2020	49/1	2	No	O	NA/TC	R (16NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1030 10301067	MUSC	Pain in extremity/ ache in left upper arm	1	12OCT2020	22/4	1	Yes		NA	R (15OCT2020)	N/N
>55/ C4591001 1030 10301116	NERV	Headache/ headache	1	12OCT2020	22/2	1	Yes		NA	R (13OCT2020)	N/N
>55/ C4591001 1036 10361002	GENRL	Injection site erythema/ Redness at injection site beginning two days post injection	2	10SEP2020	3/27	1	Yes		NA	R (06OCT2020)	N/N
		Injection site pain/ soreness at the injection site beginning second day post injection	2	10SEP2020	3/27	1	Yes		NA	R (06OCT2020)	N/N
		Injection site swelling/ Swelling at injection site beginning two days post injection	2	10SEP2020	3/27	1	Yes		NA	R (06OCT2020)	N/N
>55/ C4591001 1036 10361003	GENRL	Asthenia/ Weakness#	4	26FEB2021	2/3	2	Yes		NA	R (28FEB2021)	N/N
		Chills/ Chills#	4	26FEB2021	2/3	2	Yes		NA	R (28FEB2021)	N/N
>55/ C4591001 1036 10361028	GENRL	Injection site pain/ muscle soreness at injection site, left deltoid	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
		Injection site swelling/ left deltoid swelling at injection site	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1036 10361031	MUSC	Pain in extremity/ Left arm Pain#	4	23FEB2021	1/3	1	Yes		NA/TC	R (25FEB2021)	N/N
	NERV	Headache/ Headache#	4	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N
>55/ C4591001 1036 10361034	GENRL	Chills/ Chills; for a period of 24 hrs before going away. No OTC meds taken.	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		Pyrexia/ Fever; 101.4 day after 2nd injection. Fever rose to 101.7. Fever gone by next day. No OTC meds taken	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
	NERV	Lethargy/ Lethary; stated after 2nd injection felt run down & tired for 24 hrs. No OTC meds taken.	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C4591001 1036 10361052	GENRL	Fatigue/ Fatigue#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ Pain at injection site#	3	22FEB2021	22/3	2	Yes		NA	R (24FEB2021)	N/N
>55/ C4591001 1036 10361083	GENRL	Injection site pain/ Soreness at injection site#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1036 10361091 >55/ C4591001 1036 10361108 >55/ C4591001 1036 10361116 >55/ C4591001 1036 10361122 >55/ C4591001 1036 10361124	MUSC	Pyrexia/ Fever#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N	
	MUSC	Arthralgia/ Generalized joint pain#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N	
	GENRL	Pyrexia/ fever#	3	22JAN2021	4/6	1	Yes		NA	R (27JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	18FEB2021	2/C	1	Yes		NA	RG	N/N	
	GENRL	Pain/ Body aches	2	29OCT2020	1/1	1	Yes		NA	R (29OCT2020)	N/N	
	NERV	Headache/ Headache	2	29OCT2020	1/1	1	Yes		NA	R (29OCT2020)	N/N	
	MUSC	Muscle spasms/ Lower back muscle spasm*		13OCT2020	-34/9	1	No	O	NA/TC	R (21OCT2020)	N/N	
	MUSC	Arthralgia/ Right shoulder soreness#	4	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N	
	NERV	Headache/ Headache#	4	09FEB2021	2/1	1	Yes		NA/TC	R (09FEB2021)	N/N	
	NERV	Lethargy/ Lethargic#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1036 10361130	GENRL	Injection site pain/ Pain at injection site	1	16OCT2020	1/3	2	Yes		NA/TC	R (18OCT2020)	N/Y
	GENRL	Chills/ Chills	1	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
		Fatigue/ Fatigue	1	17OCT2020	2/2	2	Yes		NA/TC	R (18OCT2020)	N/N
		Pain/ Body Aches	1	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
		Pyrexia/ Fever	1	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
>55/ C4591001 1036 10361139	GASTR	Diarrhoea/ Diarrhea	1	29OCT2020	8/2	1	Yes		NA/TC	R (30OCT2020)	N/N
	GENRL	Chills/ Chills#	4	23FEB2021	2/2	2	Yes		NA	R (24FEB2021)	N/N
		Pain/ Body Aches#	4	23FEB2021	2/2	2	Yes		NA/TC	R (24FEB2021)	N/N
		Pyrexia/ Fever#	4	23FEB2021	2/2	2	Yes		NA/TC	R (24FEB2021)	N/N
>55/ C4591001 1036 10361140	INJ&P	Injury/ Traumatic Injuries#	2	10FEB2021	91/1	4	No	O	NA/W	F (10FEB2021)	Y/N
		Road traffic accident/ Motor Vehicle Accident#	2	10FEB2021	91/1	4	No	CND	NA/W	F (10FEB2021)	Y/N
>55/ C4591001	SKIN	Alopecia/ HAIR LOSS	2	12SEP2020	4/C	1	No	O	NA	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1037 10371004 >55/ C4591001 1037 10371009	GENRL	Fatigue/ FATIGUE	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1037 10371012	MUSC	Myalgia/ MUSCLE ACHES	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1037 10371013	GENRL	Pyrexia/ LOW GRADE FEVER	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1037 10371019	MUSC	Myalgia/ MUSCLE ACHES	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1037 10371013	GASTR	Vomiting/ VOMITING	2	28SEP2020	21/1	2	No	O	NA	R (28SEP2020)	N/N
>55/ C4591001 1037 10371019	GASTR	Diarrhoea/ DIARRHEA	1	21AUG2020	3/3	2	Yes		NA/TC	R (23AUG2020)	N/N
	MUSC	Arthralgia/ BILATERAL SHOULDER PAIN	2	09SEP2020	2/1	2	Yes		NA/TC	R (09SEP2020)	N/N
	NERV	Somnolence/ MORNING SLEEPINESS	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
>55/ C4591001 1037 10371020	GASTR	Constipation/ CONSTIPATION	1	01SEP2020	14/8	1	No	O	NA	R (08SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1037 10371027	GENRL	Fatigue/ FATIGUE	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Pyrexia/ FEVER	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
>55/ C4591001 1037 10371031	SKIN	Rash/ GENERALIZED DIFFUSE RASH	2	24SEP2020	17/C	1	No	O	NA/TCN	N	N/N
>55/ C4591001 1037 10371034	INJ&P	Arthropod bite/ INSECT BITE	1	07SEP2020	19/5	2	No	O	NA/TC	R (11SEP2020)	N/N
>55/ C4591001 1037 10371055	GENRL	Chills/ CHILLS	2	15SEP2020	2/4	1	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C4591001 1037 10371069	INFEC	Hepatitis C/ HEPATITIS C	2	12OCT2020	28/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1037 10371070	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C4591001 1037 10371075	GENRL	Pain/ BODY ACHES	2	15SEP2020	1/1	1	Yes		NA/TC	R (15SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INFEC	Influenza/ MILD FLU SYMPTOMS	2	15SEP2020	1/1	1	Yes		NA/TC	R (15SEP2020)	N/N
>55/ C4591001 1037 10371084	MUSC	Muscle spasms/ GENERALIZED MUSCLE CRAMPS	2	02OCT2020	17/3	1	No	O	NA	R (04OCT2020)	N/N
>55/ C4591001 1037 10371086	MUSC	Pain in extremity/ ACHY LEGS	1	15SEP2020	16/1	1	No	O	NA/TC	R (15SEP2020)	N/N
>55/ C4591001 1037 10371094	GENRL	Fatigue/ FATIGUE	1	31AUG2020	1/2	1	Yes		NA/TC	R (01SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	31AUG2020	1/2	1	Yes		NA/TC	R (01SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
	GENRL	Injection site pain/ LEFT UPPER ARM PAIN AT INJECTION SITE	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C4591001 1037 10371095	GASTR	Nausea/ NAUSEA	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	21SEP2020	1/3	2	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN	2	21SEP2020	1/4	2	Yes		NA	R (24SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1037 10371099	NERV	Headache/ HEADACHE	2	21SEP2020	1/4	3	Yes		NA/TC	R (24SEP2020)	N/N
	MUSC	Muscle spasms/ NECK SPASMS	1	02SEP2020	2/2	1	No	O	NA	R (03SEP2020)	N/N
>55/ C4591001 1037 10371103	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	25SEP2020	3/4	1	Yes		NA	R (28SEP2020)	N/N
	INJ&P	Procedural pain/ POST-OP ABDOMINAL PAIN	2	28SEP2020	8/3	2	No	O	NA/TC	R (30SEP2020)	N/N
>55/ C4591001 1037 10371105	SKIN	Night sweats/ Nocturnal sweats	2	22SEP2020	2/3	2	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1037 10371108	INJ&P	Muscle strain/ LUMBAR SACRUM STRAIN	1	03SEP2020	3/2	1	No	O	NA/TCN	R (04SEP2020)	N/N
>55/ C4591001 1037 10371113	GENRL	Chills/ chills	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C4591001 1037 10371119	GASTR	Diarrhoea/ DIARRHEA	1	03SEP2020	2/18	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ CHILLS	1	03SEP2020	2/18	1	Yes		NA	R (20SEP2020)	N/N
>55/ C4591001 1037 10371122	GENRL	Injection site pain/ LEFT UPPER ARM PAIN AT INJECTION SITE	1	02SEP2020	1/1	1	Yes		NA/TC	R (02SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	23SEP2020	1/1	2	Yes		NA	R (23SEP2020)	N/N
>55/ C4591001 1037 10371135	INFEC	Urinary tract infection/ URINARY TRACK INFECTION	2	25OCT2020	32/4	2	No	O	NA/TC	R (28OCT2020)	N/N
	SKIN	Rash/ GENERALIZED RASH	2	31OCT2020	38/6	1	No	CD	NA	R (05NOV2020)	N/N
>55/ C4591001 1037 10371141	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY#	2	08FEB2021	139/C	1	No	O	NA	N	N/N
>55/ C4591001 1037 10371147	INJ&P	Burns second degree/ SECOND DEGREE SKIN BURNS RIGHT TRUNK	2	03DEC2020	70/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1037 10371158	GENRL	Injection site pain/ PAIN AT INJECTION SITE LEFT DELTOID#	3	19DEC2020	3/38	1	Yes		NA	R (25JAN2021)	N/N
	NERV	Headache/ HEADACHES#	3	19DEC2020	3/10	2	Yes		NA	R (28DEC2020)	N/N
>55/ C4591001	GASTR	Nausea/ Nausea	1	10SEP2020	3/4	2	No	O	NA/TC	R (13SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1037 10371160	GENRL	Fatigue/ Tired (fatigue)	1	10SEP2020	3/4	2	No	O	NA/TC	R (13SEP2020)	N/N
	INFEC	Urinary tract infection/ Urinary tract infection	1	10SEP2020	3/11	2	No	O	NA/TC	R (20SEP2020)	N/N
	NERV	Headache/ Headache	1	10SEP2020	3/4	2	No	O	NA/TC	R (13SEP2020)	N/N
	MUSC	Myalgia/ Leg muscle pain	2	30SEP2020	3/2	2	No	O	NA/TC	R (01OCT2020)	N/N
	INFEC	Skin infection/ SKIN INFECTION Bilateral Arms and Legs	2	03OCT2020	6/11	2	No	O	NA/TC	R (13OCT2020)	N/N
	MUSC	Myalgia/ BILATERAL LEG MUSCLE PAIN	2	09JAN2021	104/4	1	No	O	NA	R (12JAN2021)	N/N
>55/ C4591001 1037 10371167	GENRL	Influenza like illness/ Flu-like Symptoms	2	02OCT2020	2/2	2	Yes		NA/TC	R (03OCT2020)	N/N
>55/ C4591001 1037 10371174	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
>55/ C4591001 1037 10371177	INFEC	Ear infection/ LEFT EAR INFECTION	1	04OCT2020	26/6	2	No	O	NA/TC	R (09OCT2020)	N/N
>55/ C4591001 1037 10371178	SKIN	Lipodystrophy acquired/ LIPODYSTROPHY (Right arm)	2	04NOV2020	35/C	2	No	O	NA	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1037 10371181	MUSC	Myalgia/ Muscle aches	2	01OCT2020	1/2	2	Yes		NA	R (02OCT2020)	N/N
		Pain in extremity/ Left arm pain	2	01OCT2020	1/2	2	Yes		NA/TC	R (02OCT2020)	N/N
>55/ C4591001 1037 10371185	INJ&P	Rib fracture/ RIB FRACTURE	1	13SEP2020	4/12	1	No	O	NA/TC	R (24SEP2020)	N/N
>55/ C4591001 1037 10371195	GENRL	Pyrexia/ FEVER#	3	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
	MUSC	Myalgia/ MYALGIAS#	3	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
>55/ C4591001 1037 10371196	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	26OCT2020	25/29	2	No	O	NA/TC	R (23NOV2020)	N/N
	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	24DEC2020	84/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1037 10371203	GENRL	Chills/ RIGORS STARTED POST VACCINE#	4	08FEB2021	1/2	2	Yes		NA	R (09FEB2021)	N/N
		Pyrexia/ FEVER STARTED POST VACCINE#	4	08FEB2021	1/2	2	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001	GENRL	Chills/ CHILLS	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Investigational Vaccine Dose/ Subject	Action: Outcome (End Date)	SAE/Imm AE (Yes/No)
1037 10371211		Injection site pain/ PAIN AT INJECTION SITE	1	15SEP2020	1/1	1	Yes	NA	R (15SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	1	15SEP2020	1/2	1	Yes	NA/TC	R (16SEP2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTIO SITE	1	22SEP2020	8/1	2	Yes	NA	R (22SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN	1	22SEP2020	8/1	2	Yes	NA/TC	R (22SEP2020)	N/N
	NERV	Lethargy/ LETHARGY	1	22SEP2020	8/1	2	Yes	NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	06OCT2020	2/1	2	Yes	NA	R (06OCT2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN	2	06OCT2020	2/1	2	Yes	NA/TC	R (06OCT2020)	N/N
	NERV	Lethargy/ LETHARGY	2	06OCT2020	2/1	2	Yes	NA	R (06OCT2020)	N/N
>55/ C4591001 1037 10371212	GENRL	Injection site pain/ LEFT DELTOID ARM PAIN AT INJECTION SITE POST INJECTION#	3	18DEC2020	1/3	1	Yes	NA	R (20DEC2020)	N/N
	GENRL	Fatigue/ FATIGUE#	3	19DEC2020	2/2	1	Yes	NA	R (20DEC2020)	N/N
	NERV	Headache/ WORSENING OF HEADACHE#	3	19DEC2020	2/2	1	Yes	NA	R (20DEC2020)	N/N
>55/ C4591001 1037 10371234	GENRL	Chills/ CHILLS	2	08OCT2020	2/2	2	Yes	NA/TC	R (09OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1037 10371239	GENRL	Pain/ GENERALIZED BODY ACHES	2	08OCT2020	2/2	2	Yes		NA/TC	R (09OCT2020)	N/N
		Pyrexia/ LOW GRADE FEVER	2	08OCT2020	2/2	2	Yes		NA/TC	R (09OCT2020)	N/N
		Chills/ CHILLS	2	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
>55/ C4591001 1037 10371252	MUSC	Muscle spasms/ MUSCLE CRAMPS	2	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
	GASTR	Nausea/ Nausea	1	07OCT2020	17/1	1	No	O	NA	R (07OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
Pyrexia/ FEVER		2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N	
MUSC		Myalgia/ MUSCLE ACHES	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C4591001 1037 10371261	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	14OCT2020	1/2	2	Yes		NA/TC	R (15OCT2020)	N/N
	INFEC	Herpes ophthalmic/ HERPES CONJUNCTIVITIS BILATERAL EYES	2	17NOV2020	35/3	2	No	O	NA/TC	R (19NOV2020)	N/N
>55/ C4591001 1037 10371263	GENRL	Chills/ CHILLS	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Fatigue/ FATIGUE	2	13OCT2020	2/2	2	Yes		NA/TC	R (14OCT2020)	N/N
		Pyrexia/ FEVER	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C4591001 1037 10371264	INFEC	Vaginal infection/ VAGINAL INFECTION	1	11OCT2020	20/1	1	No	O	NA/TC	R (11OCT2020)	N/N
>55/ C4591001 1037 10371268	NERV	Dizziness/ DIZZINESS	2	14OCT2020	3/1	1	No	O	NA	R (14OCT2020)	N/N
>55/ C4591001 1037 10371280	GENRL	Chills/ CHILLS#	3	04MAR2021	1/3	1	Yes		NA	R (06MAR2021)	N/N
		Pain/ BODY ACHES#	3	04MAR2021	1/3	1	Yes		NA	R (06MAR2021)	N/N
		Pyrexia/ FEVER#	3	04MAR2021	1/3	1	Yes		NA	R (06MAR2021)	N/N
	NERV	Headache/ HEADACHE#	3	04MAR2021	1/3	1	Yes		NA	R (06MAR2021)	N/N
>55/ C4591001 1037 10371295	GENRL	Pyrexia/ ASYMPTOMATIC LOW GRADE FEVER OF 100.4 F*		25SEP2020	-3/1	1	No	O	NA	R (25SEP2020)	N/N
	GENRL	Pyrexia/ FEVER	2	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N
	INJ&P	Muscle strain/ PULLED MUSCLE IN NECK	2	27OCT2020	9/9	2	No	O	NA/TC	R (04NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1037 10371318	INV	Blood pressure increased/ ELEVATED BLOOD PRESSURE	2	15DEC2020	54/4	3	No	O	NA/TC	R (18DEC2020)	Y/N
>55/ C4591001 1037 10371320	GENRL	Pyrexia/ FEVER	2	27OCT2020	2/1	2	Yes		NA/TC	R (27OCT2020)	N/N
>55/ C4591001 1037 10371334	GASTR	Dental caries/ DENTAL CARIES	1	02NOV2020	22/8	1	No	O	NA	R (09NOV2020)	N/N
>55/ C4591001 1037 10371356	MUSC	Myalgia/ MUSCLE ACHES	2	12NOV2020	1/2	1	Yes		NA/TC	R (13NOV2020)	N/N
>55/ C4591001 1038 10381007	GASTR	Diarrhoea/ Diarrhea	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/N
>55/ C4591001 1038 10381046	GENRL	Injection site pain/ Injection site tenderness	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Fatigue/ fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1038 10381050	RESP	Chronic obstructive pulmonary disease/ COPD exacerbation#	3	07FEB2021	10/2	2	No	O	NA/TC	R (08FEB2021)	Y/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1038 10381064	INV	Blood pressure increased/ Elevated blood pressure#	3	17FEB2021	20/1	1	No	O	NA/TC	R (17FEB2021)	N/N
	GENRL	Chills/ chills#	3	30JAN2021	2/3	1	Yes		NA	R (01FEB2021)	N/N
		Pain/ body aches#	3	30JAN2021	2/3	1	Yes		NA	R (01FEB2021)	N/N
		Pyrexia/ fever#	3	30JAN2021	2/3	1	Yes		NA	R (01FEB2021)	N/N
>55/ C4591001 1038 10381074	NERV	Headache/ headache#	3	30JAN2021	2/3	1	Yes		NA	R (01FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ injection site tenderness	1	23SEP2020	23/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1038 10381101	INV	Body temperature increased/ Increased Body Temperature (100F)	1	23SEP2020	23/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Injection site tenderness	1	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001	NERV	Ischaemic stroke/ Acute Ischemic Stroke	2	04OCT2020	7/3	2	No	O	NA	R (06OCT2020)	Y/N
	GENRL	Injection site pain/ Injection Site Tenderness	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1038 10381108 >55/ C4591001 1038 10381126	GASTR	Diarrhoea/ Diarrhea	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
		Nausea/ Nausea	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Pain/ Body Aches	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
	NERV	Headache/ Headache	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
>55/ C4591001 1038 10381134	GENRL	Injection site pain/ injection site tenderness	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	SURG	Skin neoplasm excision/ basal cell carcinoma removed from L side of nose	1	01OCT2020	11/1	1	No	O	NA	R (01OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	14OCT2020	3/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C4591001 1039 10391005	GENRL	Injection site pain/ left arm injection site pain#	3	18JAN2021	1/5	1	Yes		NA/TC	R (22JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1039 10391006	GENRL	Injection site pain/ injection arm soreness#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1039 10391010	GENRL	Injection site pain/ injection site soreness#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N	
	INJ&P	Contusion/ right arm bruising	1	21AUG2020	1/13	1	Yes		NA	R (02SEP2020)	N/Y	
	GENRL	Injection site pain/ injection site pain	2	09SEP2020	1/3	2	Yes		NA	R (11SEP2020)	N/N	
	GENRL	Pyrexia/ FEVER	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N	
	CARD	Hypertensive heart disease/ hypertensive cardiovascular disease	2	18NOV2020	71/1	4	No	O	NA/W	F (18NOV2020)	Y/N	
	VASC	Arteriosclerosis/ arthrosclerotic cardiovascular disease	2	18NOV2020	71/1	4	No	O	NA/W	F (18NOV2020)	Y/N	
	NEOPL	Skin cancer/ sebaceous carcinoma of skin	2	10DEC2020	92/22	2	No	O	NA/TCN	R (31DEC2020)	Y/N	
	>55/ C4591001 1039 10391012	GASTR	Diarrhoea/ diarrhea	1	22AUG2020	2/3	1	Yes		NA	R (24AUG2020)	N/N
	>55/ C4591001 1039 10391013	INV	Monocyte count increased/ monocyte level elevated	2	30SEP2020	15/49	1	No	O	NA	R (17NOV2020)	N/N
>55/ C4591001 1039 10391015	GENRL	Injection site pain/ Injection Arm Soreness#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection Arm Soreness#	4	09FEB2021	2/5	1	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1039 10391018	GENRL	Injection site pain/ Injection Site Soreness#	4	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
>55/ C4591001 1039 10391019	GASTR	Colitis microscopic/ EXACERBATION OF LYMPHOCYTIC-PLASMACYTIC COLITIS	1	29AUG2020	6/29	2	No	O	NA/TC	R (26SEP2020)	N/N
	GENRL	Injection site pain/ Injection site Arm Soreness#	2	01MAR2021	1/3	1	Yes		NA/TC	R (03MAR2021)	N/N
>55/ C4591001 1039 10391023	GENRL	Chills/ chills#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
		Injection site pain/ left arm injection soreness#	3	20JAN2021	1/2	2	Yes		NA	R (21JAN2021)	N/N
		Pyrexia/ fever#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Chills/ chills#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		Injection site pain/ injection site soreness#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		Pyrexia/ fever#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	MUSC	Myalgia/ muscle aches#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ headache#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1039 10391024	GENRL	Injection site pain/ INJECTION SITE PAIN	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/N
	MUSC	Arthralgia/ INCREASED BILATERAL KNEE PAIN	2	16SEP2020	2/5	1	Yes		NA	R (20SEP2020)	N/N
		Pain in extremity/ RIGHT ARM SORENESS	2	16SEP2020	2/5	1	Yes		NA	R (20SEP2020)	N/N
>55/ C4591001 1039 10391027	EAR	Ear pain/ left ear pain	1	15SEP2020	22/1	1	No	O	NA/TC	R (15SEP2020)	N/N
	RESP	Nasal septum deviation/ Deviated Nasal Septum#	4	24FEB2021	29/C	1	No	O	NA/TC/TCN	RG	N/N
>55/ C4591001 1039 10391031	GENRL	Pain/ generalized aching	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ fatigue	1	28AUG2020	3/2	1	Yes		NA	R (29AUG2020)	N/N
>55/ C4591001 1039 10391032	GENRL	Injection site swelling/ swelling at injection site	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	MUSC	Pain in extremity/ left arm pain	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
>55/ C4591001 1039 10391033	GENRL	Injection site pain/ injection arm soreness#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ injection site pain#	4	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1039 10391034	GENRL	Injection site pain/ Injection Arm Soreness#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1039 10391035	GENRL	Injection site pain/ injection site pain#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
>55/ C4591001 1039 10391038	INJ&P	Fall/ FALL	2	15NOV2020	60/1	3	No	O	NA/TC	R (15NOV2020)	N/N
		Pelvic fracture/ PELVIC FRACTURE	2	15NOV2020	60/24	3	No	O	NA/TC	R (08DEC2020)	Y/N
>55/ C4591001 1039 10391039	BLOOD	Lymphadenopathy/ left axillary lymphadenopathy#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	MUSC	Myalgia/ left pectoral muscle pain#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
>55/ C4591001 1039 10391040	GENRL	Injection site pain/ Injection Site Pain#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ left arm soreness at injection site	1	27AUG2020	1/4	1	Yes		NA	R (30AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1039 10391041 >55/ C4591001 1039 10391043	GENRL	Chills/ chills#	4	18JAN2021	1/4	1	Yes		NA	R (21JAN2021)	N/N
		Fatigue/ fatigue#	4	18JAN2021	1/4	1	Yes		NA	R (21JAN2021)	N/N
	MUSC	Myalgia/ generalized muscle aches#	4	18JAN2021	1/4	1	Yes		NA	R (21JAN2021)	N/N
>55/ C4591001 1039 10391046	GENRL	Chills/ mild chills	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		Fatigue/ fatigue	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ fever	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Muscle spasms/ leg muscle cramping	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		Pain in extremity/ Left upper arm soreness	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	NERV	Headache/ mild headache	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	PSYCH	Insomnia/ difficulty sleeping	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C4591001 1039 10391047	GENRL	Injection site pain/ Injection site, left upper arm pain	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1039 10391049	EYE	Vitreous detachment/ detached Left vitreous	2	07OCT2020	20/1	2	No	O	NA	R (07OCT2020)	N/N	
	GENRL	Fatigue/ fatigue#	3	13JAN2021	2/6	2	Yes		NA	R (18JAN2021)	N/N	
	GENRL	Injection site pain/ injection site soreness#	4	02FEB2021	1/6	1	Yes		NA	R (07FEB2021)	N/Y	
	GASTR	Nausea/ nausea#	4	03FEB2021	2/3	1	Yes		NA	R (05FEB2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	03FEB2021	2/5	2	Yes		NA	R (07FEB2021)	N/N	
	MUSC	Osteoarthritis/ Osteoarthritis Exacerbation#	4	02MAR2021	29/C	3	No	O	NA/TC	RG	N/N	
	>55/ C4591001 1039 10391050	GENRL	Chills/ chills#	4	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
	>55/ C4591001 1039 10391052	MUSC	Pain in extremity/ left upper arm pain	2	15OCT2020	18/2	1	No	O	NA/TC	R (16OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	4	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N	
	MUSC	Myalgia/ generalized muscle aches#	4	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N	
NERV	Headache/ headache#	4	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N		
>55/ C4591001	INV	Body temperature increased/ temperature elevation	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1039 10391055	MUSC	Pain in extremity/ bilateral upper arm pain	2	24SEP2020	4/1	1	No	O	NA	R (24SEP2020)	N/N	
>55/ C4591001 1039 10391056	GENRL	Injection site pain/ Left Arm Injection Site Pain#	3	19JAN2021	1/3	1	Yes		NA	R (21JAN2021)	N/N	
>55/ C4591001 1039 10391060	GENRL	Injection site pain/ INJECTION SITE SORENESS	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N	
1039 10391061	GENRL	Injection site pain/ INJECTION SITE SORENESS	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N	
>55/ C4591001 1039 10391062	GENRL	Injection site pain/ injection site soreness#	3	05JAN2021	1/2	1	Yes		NA/TC	R (06JAN2021)	N/N	
1039 10391062	NERV	Headache/ headache#	3	05JAN2021	1/2	1	Yes		NA/TC	R (06JAN2021)	N/N	
1039 10391062	GENRL	Injection site pain/ injection site soreness#	4	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N	
>55/ C4591001 1039 10391069	GENRL	Pain/ general body aches#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N	
1039 10391069		Pyrexia/ fever 100.4#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1039 10391070	GENRL	Pain/ general bodyache#	4	26JAN2021	2/1	1	Yes		NA/TC	R (26JAN2021)	N/N
		Pyrexia/ 102 fever#	4	26JAN2021	2/1	2	Yes		NA/TC	R (26JAN2021)	N/N
	NERV	Headache/ dull headache#	4	26JAN2021	2/1	1	Yes		NA/TC	R (26JAN2021)	N/N
	GENRL	Injection site pain/ left upper arm injection site soreness	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Injection site pain/ left upper arm injection site soreness	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Neck pain/ worsening acute chronic neck pain	2	16OCT2020	24/6	2	No	O	NA	R (21OCT2020)	N/N
	GENRL	Injection site pain/ injection site soreness#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
>55/ C4591001 1039 10391075	GENRL	Fatigue/ fatigue#	4	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	PSYCH	Panic attack/ panic attack	1	05SEP2020	4/1	1	No	O	NA	R (05SEP2020)	N/N
	INFEC	Conjunctivitis/ conjunctivitis	1	09SEP2020	8/52	2	No	O	NA/TC	R (30OCT2020)	N/N
	NEOPL	Malignant melanoma/ melanoma, left ankle	2	13NOV2020	52/41	3	No	O	NA/TCN	R (23DEC2020)	Y/N
	CARD	Cardiac failure congestive/ exacerbation of congestive heart failure#	3	22JAN2021	17/5	3	No	O	NA/TC	R (26JAN2021)	Y/N
	INFEC	Cellulitis/ cellulitis- left ankle#	3	23JAN2021	18/39	2	No	O	NA/TC	R (02MAR2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1039 10391077	GENRL	Injection site pain/ injection site soreness	1	02SEP2020	1/2	1	Yes		NA/TC	R (03SEP2020)	N/N
	GENRL	Chills/ chills	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		Pain/ body aches	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1039 10391078	SKIN	Pseudofolliculitis/ Pseudofolliculitis Barbae left axilla	1	23SEP2020	22/12	1	No	O	NA	R (04OCT2020)	N/N
>55/ C4591001 1039 10391079	GASTR	Nausea/ nausea	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Chills/ chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Arthralgia/ arthlagias	2	24SEP2020	1/3	1	Yes		NA/TC	R (26SEP2020)	N/N
	NERV	Headache/ headache	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
>55/ C4591001 1039 10391083	GENRL	Injection site pain/ injection site soreness#	4	08JAN2021	1/3	1	Yes		NA/TC	R (10JAN2021)	N/N
>55/ C4591001	GASTR	Nausea/ nausea	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1039 10391089	GENRL	Pain/ generalized aches	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ fever	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1039 10391092	GENRL	Injection site pain/ injection site pain	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
		Pyrexia/ fever	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ injection site soreness	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ fever	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Chills/ chills	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
		Pain/ generalized aching	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1039 10391095	MUSC	Pain in extremity/ right big toe pain	1	13SEP2020	10/7	1	No	O	NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ injection arm soreness#	3	07JAN2021	2/2	1	Yes		NA/TC	R (08JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
	GASTR	Diarrhoea/ diarrhea#	4	29JAN2021	3/1	1	Yes		NA	R (29JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1039 10391100	GENRL	Chills/ chills#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site swelling/ injection site swelling#	4	26JAN2021	2/4	1	Yes		NA	R (29JAN2021)	N/N
>55/ C4591001 1039 10391101	GENRL	Injection site pain/ injection site soreness#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
>55/ C4591001 1039 10391105	GENRL	Injection site nodule/ nodule at injection site#	4	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N
		Injection site pruritus/ injection site pruritus#	4	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N
		Injection site swelling/ injection site swelling#	4	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N
>55/ C4591001 1039 10391107	GENRL	Pain/ generalized aching	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ headache	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Pain/ generalized aching	2	29SEP2020	1/4	1	Yes		NA	R (02OCT2020)	N/N
	NERV	Headache/ headache	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
	INJ&P	Fall/ Fell on left arm while biking	2	13OCT2020	15/14	1	No	CD	NA/TC	R (26OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INJ&P	Skin abrasion/ abrasions left arm (upper arm and forearm)	2	26OCT2020	28/1	1	No	O	NA	R (26OCT2020)	N/N
	SKIN	Dermatitis contact/ contact dermatitis left forearm arm	2	27OCT2020	29/23	1	No	O	NA/TC	R (18NOV2020)	N/N
>55/ C4591001 1039 10391111	GENRL	Fatigue/ fatigue#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
>55/ C4591001 1039 10391122	GENRL	Chills/ chills	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ injection site pain	1	10SEP2020	1/4	1	Yes		NA	R (13SEP2020)	N/N
	MUSC	Myalgia/ myalgias	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ headache	1	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
>55/ C4591001 1039 10391123	GENRL	Chills/ chills	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ myalgias	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Chills/ chills	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Pain/ aches	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1039 10391126	NERV	Pyrexia/ fever	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		Headache/ headache	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Injection arm soreness#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
>55/ C4591001 1039 10391129	GENRL	Injection site pain/ Injection arm soreness#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain	2	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Chills/ chills	2	15OCT2020	3/1	1	Yes		NA	R (15OCT2020)	N/N
>55/ C4591001 1039 10391131	MUSC	Pyrexia/ fever	2	15OCT2020	3/1	1	Yes		NA	R (15OCT2020)	N/N
		Myalgia/ myalgias	2	15OCT2020	3/2	1	Yes		NA/TCN	R (16OCT2020)	N/N
	GENRL	Pain/ generalized aching	1	12SEP2020	2/2	2	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Pain/ generalized aching	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
NERV	Headache/ headache	2	03OCT2020	2/8	1	Yes		NA/TC	R (10OCT2020)	N/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1039 10391138	GENRL	Discomfort/ left body discomfort#	3	19JAN2021	1/1	1	No	O	NA	R (19JAN2021)	N/Y
		Injection site pain/ injection arm soreness#	3	19JAN2021	1/3	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
	SKIN	Dermatitis contact/ contact dermatitis of bilateral lower legs#	3	06FEB2021	19/7	1	No	O	NA/TC	R (12FEB2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1039 10391139	GENRL	Injection site pain/ injection site pain left arm#	3	05JAN2021	1/2	1	Yes		NA/TC	R (06JAN2021)	N/N
	INFEC	Hordeolum/ right upper eyelid stye#	3	14JAN2021	10/36	1	No	O	NA/TC	R (18FEB2021)	N/N
	GENRL	Injection site pain/ injection site soreness#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1039 10391141	GENRL	Injection site pain/ injection site pain	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/Y
>55/ C4591001 1039 10391143	GENRL	Injection site pain/ Injection Site Pain#	2	12JAN2021	98/5	1	Yes		NA/TC	R (16JAN2021)	N/N
	GENRL	Chills/ Chills#	4	08FEB2021	6/2	1	Yes		NA/TC	R (09FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1039 10391148	GENRL	Injection site pain/ Injection Site Soreness#	4	08FEB2021	6/2	1	Yes		NA/TC	R (09FEB2021)	N/N
		Injection site pain/ injection site pain	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Pain in extremity/ bilateral thigh pain	2	16OCT2020	9/59	1	No	O	NA	R (13DEC2020)	N/N
		Plantar fasciitis/ recurrence of plantar fasciitis	2	16OCT2020	9/C	1	No	O	NA	RG	N/N
>55/ C4591001 1039 10391155	NERV	Sciatica/ chronic bilateral sciatica	2	05NOV2020	29/C	1	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ injection site aching	1	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ inject site soreness	2	15OCT2020	1/3	1	Yes		NA/TC	R (17OCT2020)	N/N
	NERV	Headache/ headaches	1	28SEP2020	4/2	1	Yes		NA	R (29SEP2020)	N/N
>55/ C4591001 1039 10391158	GENRL	Injection site pain/ injection arm soreness#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/Y
	GENRL	Chills/ chills#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
		Pyrexia/ fever#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N

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>55/ C4591001 1039 10391163	MUSC	Myalgia/ generalized muscle aches#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N	
	NERV	Headache/ headache#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N	
	GENRL	Injection site pain/ injection site soreness#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N	
	>55/ C4591001 1039 10391173	GENRL	Injection site pain/ injection site pain	1	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	1	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N	
	GASTR	Dyspepsia/ heartburn	2	21OCT2020	1/2	2	Yes		NA/TC	R (22OCT2020)	N/N	
	GENRL	Injection site pain/ injection site pain	2	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N	
	MUSC	Myalgia/ generalized muscle aches	2	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/Y	
	NERV	Headache/ headache	2	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N	
	RESP	Epistaxis/ epistaxis#	2	31JAN2021	103/11	1	No	O	NA/TC	R (10FEB2021)	N/N	
>55/ C4591001 1039 10391174	RENAL	Chronic kidney disease/ chronic kidney disease stage 3b	2	NOV2020	10/C	1	No	O	NA	RG	N/N	
	GENRL	Injection site pain/ Injection site soreness#	3	27JAN2021	22/2	1	Yes		NA	R (28JAN2021)	N/N	

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	GENRL	Chills/ chills#	4	28JAN2021	2/10	1	Yes		NA	R (06FEB2021)	N/N
		Fatigue/ fatigue#	4	28JAN2021	2/C	1	Yes		NA	RG	N/N
	PSYCH	Insomnia/ insomnia exacerbation#	4	28JAN2021	2/10	2	No	O	NA/TC	R (06FEB2021)	N/N
>55/ C4591001 1039 10391184	GENRL	Injection site bruising/ injection site bruising	2	29OCT2020	1/7	1	Yes		NA	R (04NOV2020)	N/Y
	INJ&P	Muscle strain/ muscle strain, upper back	2	30OCT2020	2/3	1	No	O	NA/TC	R (01NOV2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	31OCT2020	3/4	1	Yes		NA	R (03NOV2020)	N/N
	GENRL	Injection site pain/ injection site soreness#	3	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	11FEB2021	1/5	1	Yes		NA	R (15FEB2021)	N/N
>55/ C4591001 1039 10391189	GENRL	Injection site pain/ injection site pain	1	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/N
>55/ C4591001 1039 10391192	GENRL	Injection site pain/ injection site soreness	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
	MUSC	Myalgia/ muscle ache, left arm	1	16OCT2020	1/1	1	Yes		NA/TC	R (16OCT2020)	N/N

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	GENRL	Chills/ chills	2	06NOV2020	1/1	1	Yes		NA	R (06NOV2020)	N/N
		Injection site pain/ injection site pain	2	06NOV2020	1/1	1	Yes		NA	R (06NOV2020)	N/Y
	NERV	Headache/ headache	2	06NOV2020	1/1	1	Yes		NA/TC	R (06NOV2020)	N/N
>55/ C4591001 1039 10391193	GENRL	Chills/ chills	2	04NOV2020	1/42	1	Yes		NA	R (15DEC2020)	N/N
	GENRL	Injection site pain/ Injection Arm Soreness#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ Injection Arm Soreness#	4	03FEB2021	1/1	1	Yes		NA/TC	R (03FEB2021)	N/N
>55/ C4591001 1039 10391202	GASTR	Inguinal hernia/ right inguinal hernia	1	02NOV2020	15/44	2	No	O	NA/TC	R (15DEC2020)	N/N
>55/ C4591001 1039 10391211	GENRL	Injection site pain/ inject site pain#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Chills/ chills#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ headache#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1039 10391213	GENRL	Injection site pain/ Injection site pain#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N

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	GENRL	Injection site pain/ Injection site pain#	4	28JAN2021	1/5	1	Yes		NA	R (01FEB2021)	N/N
>55/ C4591001 1039 10391217	GENRL	Fatigue/ fatigue	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
		Injection site pain/ injection site pain	1	22OCT2020	1/2	2	Yes		NA/TC	R (23OCT2020)	N/N
>55/ C4591001 1039 10391227	GENRL	Fatigue/ fatigue	2	17NOV2020	2/2	1	Yes		NA	R (18NOV2020)	N/N
		Pain/ generalized aches	2	17NOV2020	2/2	1	Yes		NA/TC	R (18NOV2020)	N/N
	NERV	Headache/ headache	2	17NOV2020	2/5	1	Yes		NA/TC	R (21NOV2020)	N/N
>55/ C4591001 1039 10391229	MUSC	Arthralgia/ bilateral knee pain	2	30NOV2020	15/2	1	No	O	NA	R (01DEC2020)	N/N
	INJ&P	Ligament sprain/ left sprained ankle#	4	07FEB2021	4/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1042 10421018	SKIN	Urticaria/ HIVES (Back and Inner thighs)	1	02AUG2020	3/6	1	Yes		NA/TC	R (07AUG2020)	N/N
>55/ C4591001 1042 10421023	NEOPL	Lung adenocarcinoma/ Adenocarcinoma of the lung	2	15JAN2021	145/C	3	No	O	NA	N	Y/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1042 10421066	GENRL	Chills/ Chills#	4	05MAR2021	1/2	1	Yes		NA	R (06MAR2021)	N/N	
		Pyrexia/ Fever#	4	05MAR2021	1/2	1	Yes		NA	R (06MAR2021)	N/N	
>55/ C4591001 1042 10421091	GENRL	Chest pain/ Chest Pain Right Side (Intermittent)#	2	16FEB2021	169/C	2	No	O	NA/TC	N	N/N	
	MUSC	Arthralgia/ Right Shoulder Pain#	2	16FEB2021	169/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1042 10421113	MUSC	Arthritis/ Worsening Arthritis	2	01DEC2020	83/1	2	No	O	NA	R (01DEC2020)	N/N	
>55/ C4591001 1042 10421127	INJ&P	Arthropod sting/ wasp sting	2	14SEP2020	6/1	1	No	O	NA/TC	R (14SEP2020)	N/N	
	NEOPL	Skin papilloma/ Veruca under left eye	2	13OCT2020	35/C	1	No	O	NA	N	N/N	
	INJ&P	Rib fracture/ Fractured Rib (Left Side)#	2	25FEB2021	170/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1042 10421141	GENRL	Injection site pain/ Pain at injection site#	3	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N	
	GENRL	Injection site pain/ Pain at Injection site#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1042 10421154	VASC	Hypertension/ Hypertension#	2	08MAR2021	174/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1042 10421160	GASTR	Diarrhoea/ Diarrhea	1	28AUG2020	3/1	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ Chills	2	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
>55/ C4591001 1042 10421166	INJ&P	Brain contusion/ Left frontal lobe contusion	1	03SEP2020	9/30	1	No	O	NA	R (02OCT2020)	N/N
		Fall/ FALL	1	03SEP2020	9/1	1	No	O	NA/TC	R (03SEP2020)	N/N
		Pelvic fracture/ Closed Fracture of Rt Interior Pubic Ramus	1	03SEP2020	9/30	2	No	O	NA	R (02OCT2020)	N/N
		Rib fracture/ Closed Fracture of Four Ribs	1	03SEP2020	9/30	2	No	O	NA	R (02OCT2020)	N/N
		Scapula fracture/ Closed Displaced Fracture of body Right Scapula	1	03SEP2020	9/48	2	No	O	NA	R (20OCT2020)	N/N
	MUSC	Arthralgia/ Acute Pain hip right side	1	03SEP2020	9/30	1	No	O	NA/TC	R (02OCT2020)	N/N
		Arthralgia/ Right Shoulder Pain	1	03SEP2020	9/48	1	No	O	NA/TC	R (20OCT2020)	N/N
		Mobility decreased/ Decreased Mobility	1	03SEP2020	9/48	1	No	O	NA	R (20OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Muscle spasms/ Muscle Spasm	1	03SEP2020	9/30	2	No	O	NA	R (02OCT2020)	N/N	
	NERV	Subarachnoid haemorrhage/ SUBARACHNOID HEMORRAGE	1	03SEP2020	9/6	3	No	O	NA/TC	R (08SEP2020)	Y/N	
>55/ C4591001 1042 10421171	BLOOD	Iron deficiency anaemia/ iron deficient anemia worsening	2	07OCT2020	17/C	3	No	O	NA	N	N/N	
>55/ C4591001 1042 10421191	GASTR	Glossodynia/ Tongue Sensitivity	1	09SEP2020	8/C	2	Yes		NA	N	N/N	
>55/ C4591001 1042 10421202	GENRL	Pyrexia/ Fever	2	29SEP2020	2/1	2	Yes		NA/TC	R (29SEP2020)	N/N	
>55/ C4591001 1042 10421208	RESP	Oropharyngeal pain/ Sore Throat	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N	
		Rhinorrhoea/ Nasal Discharge	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N	
>55/ C4591001 1042 10421212	GENRL	Fatigue/ Fatigue	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N	
	RESP	Cough/ New or Increased Cough	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N	
>55/ C4591001	GENRL	Chills/ Chills	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1042 10421215		Fatigue/ Fatigue	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N	
		Pyrexia/ Low Grade Fever	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N	
>55/ C4591001 1042 10421223	GENRL	Pyrexia/ Fever of 101.3#	3	24FEB2021	2/2	1	Yes		NA	R (25FEB2021)	N/N	
>55/ C4591001 1042 10421224	INFEC	Conjunctivitis/ Right Conjunctivitis	2	07OCT2020	9/11	1	No	O	NA/TC	R (17OCT2020)	N/N	
>55/ C4591001 1044 10441003	INFEC	Acute sinusitis/ Acute Sinusitis	2	13OCT2020	20/11	1	No	O	NA/TC	R (23OCT2020)	N/N	
>55/ C4591001 1044 10441005	IMMUN	Allergy to animal/ pet allergy	2	DEC2020	91/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1044 10441008	MUSC	Back pain/ low back pain	2	11SEP2020	7/1	1	No	O	NA	R (11SEP2020)	N/N	
>55/ C4591001 1044 10441010	INFEC	Fungal skin infection/ Worsening of skin fungal infection (both legs)#	2	02FEB2021	150/C	2	No	O	NA/TC	RG	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1044 10441012	INJ&P	Ligament sprain/ Right elbow sprain#	4	17FEB2021	8/C	1	No	O	NA	RG	N/N
>55/ C4591001 1044 10441013	INFEC	Urinary tract infection/ UTI	1	03SEP2020	16/6	1	No	O	NA/TC	R (08SEP2020)	N/N
>55/ C4591001 1044 10441014	INV	Blood pressure increased/ Elevated Blood Pressure	1	08SEP2020	21/1	2	No	O	NA/TC	R (08SEP2020)	N/N
>55/ C4591001 1044 10441016	RESP	Upper-airway cough syndrome/ post nasal drip	2	08OCT2020	31/C	1	No	O	NA	RG	N/N
>55/ C4591001 1044 10441017	MUSC	Myalgia/ generalized Myalgia	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
>55/ C4591001 1044 10441025	GENRL	Fatigue/ fatigue	2	15SEP2020	2/2	2	Yes		NA/TC	R (16SEP2020)	N/N
	NERV	Headache/ headache	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	SKIN	Alopecia/ hair loss#	2	FEB2021	141/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001	RESP	Sinus congestion/ sinus congestion	2	18DEC2020	94/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1044 10441046 >55/ C4591001 1044 10441049	METAB	Hyperlipidaemia/ Worsening of hyperlipidemia#	2	FEB2021	140/C	2	No	O	NA/TC	RG	N/N	
	VASC	Hypertension/ Worsening of hypertension#	2	FEB2021	140/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1044 10441062	GENRL	Chills/ chills	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
		Injection site pain/ Injection site pain	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
>55/ C4591001 1044 10441066	GENRL	Injection site haematoma/ injection site hematoma	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N	
>55/ C4591001 1044 10441067	GENRL	Pyrexia/ fever	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N	
>55/ C4591001 1044 10441070	VASC	Hypertension/ hypertension	2	NOV2020	41/C	1	No	O	NA/TC	RG	N/N	
	INFEC	Diverticulitis/ Diverticulitis	2	02JAN2021	103/5	2	No	O	NA/TC	R (06JAN2021)	N/N	
>55/ C4591001	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1044 10441073		Pyrexia/ fever	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N	
	MUSC	Myalgia/ generalized Myalgia	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N	
>55/ C4591001 1044 10441074	EYE	Blepharitis/ Blepharitis (Left eye)#	4	27FEB2021	11/12	2	No	O	NA/TC	R (10MAR2021)	N/N	
>55/ C4591001 1044 10441078	GENRL	Injection site haematoma/ INJECTION SITE HEMATOMA	1	04SEP2020	1/4	1	Yes		NA	R (07SEP2020)	N/Y	
>55/ C4591001 1044 10441080	INJ&P	Ligament sprain/ left ankle sprain	1	17SEP2020	14/24	1	No	O	NA/TC	R (10OCT2020)	N/N	
>55/ C4591001 1044 10441082	GENRL	Fatigue/ fatigue	2	02OCT2020	10/2	1	No	O	NA	R (03OCT2020)	N/N	
	MUSC	Myalgia/ myalgia	2	02OCT2020	10/2	1	No	O	NA/TC	R (03OCT2020)	N/N	
>55/ C4591001 1044 10441090	GASTR	Constipation/ constipation	1	09SEP2020	4/6	1	No	O	NA/TC	R (14SEP2020)	N/N	
	INFEC	Cystitis/ Bladder Infection	1	24SEP2020	19/9	1	No	O	NA/TC	R (02OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1044 10441091	MUSC	Tendonitis/ Worsening of Achilles Tendinitis (Right Foot)	2	JAN2021	96/C	2	No	O	NA/TC	RG	N/N	
	INFEC	Urinary tract infection/ Urinary Tract Infection#	3	22FEB2021	19/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1044 10441092	MUSC	Fibromyalgia/ Worsening of Fibromyalgia	1	08SEP2020	1/C	1	No	O	NA	RG	N/N	
	MUSC	Tendonitis/ Patellar tendinitis, left knee	2	05OCT2020	8/C	1	No	O	NA	RG	N/N	
>55/ C4591001 1044 10441093	INJ&P	Muscle injury/ Muscle Sprain (Right Leg)	1	23SEP2020	16/C	1	No	O	NA/TC	RG	N/N	
	INJ&P	Overdose/ Heroin Overdose	2	23OCT2020	26/2	4	No	O	NA/TC	R (24OCT2020)	Y/N	
	METAB	Hypokalaemia/ Hypokalemia	2	23OCT2020	26/2	2	No	O	NA/TC	R (24OCT2020)	N/N	
		Hypomagnesaemia/ Hypomagnesemia	2	23OCT2020	26/2	2	No	O	NA/TC	R (24OCT2020)	N/N	
>55/ C4591001 1044 10441100	SKIN	Necrobiosis lipoidica diabetorum/ Necrobiosis Lipoidica Diabetorum#	2	04MAR2021	157/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1044 10441104	GASTR	Diarrhoea/ Diarrhea	1	20SEP2020	11/1	1	Yes		NA	R (20SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1044 10441106	INV	Low density lipoprotein increased/ elevated ldl	2	09OCT2020	4/C	1	No	O	NA	RG	N/N	
>55/ C4591001 1044 10441108	METAB	Type 2 diabetes mellitus/ Worsening of Diabetes Type 2	2	01OCT2020	3/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1044 10441110	INFEC	Urinary tract infection/ Urinary Tract Infection	2	01OCT2020	2/10	1	No	O	NA/TC	R (10OCT2020)	N/N	
>55/ C4591001 1044 10441111	NERV	Cerebrovascular accident/ stroke#	3	01MAR2021	14/2	2	No	O	NA/TC	R (02MAR2021)	Y/N	
>55/ C4591001 1044 10441116	MUSC	Arthralgia/ Worsening of Shoulder Pain (Left)	1	23SEP2020	10/9	2	No	O	NA/TC	R (01OCT2020)	N/N	
>55/ C4591001 1044 10441120	GENRL	Chills/ chills	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N	
		Injection site pain/ injection site pain	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N	
		Pyrexia/ fever	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1044 10441128	GENRL	Fatigue/ fatigue	2	14OCT2020	2/4	1	Yes		NA	R (17OCT2020)	N/N
>55/ C4591001 1044 10441131	GASTR	Diarrhoea/ Diarrhea	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	15OCT2020	2/5	1	Yes		NA	R (19OCT2020)	N/N
	NERV	Headache/ Headache	2	15OCT2020	2/4	1	Yes		NA/TC	R (18OCT2020)	N/N
	SKIN	Rash/ Rash (hands & feet)	2	16OCT2020	3/4	1	No	O	NA	R (19OCT2020)	N/N
	GENRL	Chest discomfort/ Pressure in Chest	2	18OCT2020	5/1	2	No	O	NA	R (18OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	19OCT2020	6/2	1	No	O	NA	R (20OCT2020)	N/N
>55/ C4591001 1044 10441134	GENRL	Injection site pain/ injection site pain	2	14OCT2020	1/6	1	Yes		NA	R (19OCT2020)	N/N
	NERV	Headache/ headache	2	14OCT2020	1/2	1	Yes		NA/TC	R (15OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
	VASC	Hypertension/ Worsening of Hypertension#	3	02FEB2021	13/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001	GENRL	Fatigue/ fatigue	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1044 10441135		Injection site pain/ injection site pain	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N	
	GENRL	Pyrexia/ fever	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N	
>55/ C4591001 1044 10441138	VASC	Hypertension/ Hypertension	2	06NOV2020	25/C	1	No	O	NA/TC	RG	N/N	
	RESP	Dyspnoea/ shortness of breath#	2	01MAR2021	140/2	1	No	O	NA	R (02MAR2021)	N/N	
>55/ C4591001 1044 10441145	GENRL	Chills/ chills	2	14OCT2020	1/2	1	Yes		NA/TC	R (15OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N	
	NERV	Headache/ headache	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N	
>55/ C4591001 1044 10441147	GENRL	Chills/ chills#	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N	
		Fatigue/ fatigue#	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N	
		Pyrexia/ Fever#	4	11FEB2021	2/2	2	Yes		NA/TC	R (12FEB2021)	N/N	
	MUSC	Myalgia/ Generalized Myalgia#	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1044 10441149	GENRL	Chills/ chills	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
		Fatigue/ Fatigue	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	16OCT2020	2/3	1	Yes		NA	R (18OCT2020)	N/N
		Pyrexia/ Fever	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N
>55/ C4591001 1044 10441150	INFEC	Cystitis/ bladder infection	1	30SEP2020	6/12	1	No	O	NA/TC	R (11OCT2020)	N/N
	NERV	Dizziness/ dizzines	2	15OCT2020	1/1	1	Yes		NA	R (15OCT2020)	N/N
>55/ C4591001 1044 10441169	MUSC	Myalgia/ muscle aches	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
	NERV	Headache/ headache	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	26OCT2020	1/2	1	Yes		NA/TC	R (27OCT2020)	N/N
>55/ C4591001 1044 10441172	GENRL	Chills/ chills#	4	10FEB2021	2/1	1	Yes		NA/TC	R (10FEB2021)	N/N
		Fatigue/ fatigue#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1044 10441184	GENRL	Chills/ chills	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
		Injection site pain/ injection site pain	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
	MUSC	Myalgia/ myalgia	1	18OCT2020	3/3	1	Yes		NA	R (20OCT2020)	N/N
	NERV	Headache/ headache	1	18OCT2020	3/2	1	Yes		NA	R (19OCT2020)	N/N
>55/ C4591001 1044 10441194	GENRL	Injection site pain/ injection site pain	1	18OCT2020	1/2	1	Yes		NA	R (19OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N
	INJ&P	Skin laceration/ laceration right hand#	3	06FEB2021	2/C	1	No	O	NA/TCN	RG	N/N
	GENRL	Fatigue/ Severe Fatigue#	3	07FEB2021	3/1	4	No	O	NA/TC	R (07FEB2021)	Y/N
	NERV	Balance disorder/ Unsteadiness on feet#	3	07FEB2021	3/C	1	No	O	NA	RG	N/N
	GASTR	Dry mouth/ dry mouth#	3	08FEB2021	4/C	1	No	O	NA	RG	N/N
	GENRL	Fatigue/ fatigue#	3	08FEB2021	4/C	2	No	O	NA	RG	N/N
	GENRL	Injection site erythema/ injection site Erythema#	4	26FEB2021	1/2	1	Yes		NA	R (27FEB2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ injection site pain	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1044 10441205 >55/ C4591001 1044 10441208	INV	Intraocular pressure increased/ increased ophthalmic intra ocular pressure	1	10NOV2020	21/4	1	Yes		NA/TC	R (13NOV2020)	N/N
>55/ C4591001 1044 10441209	INFEC	Vulvovaginal mycotic infection/ Vaginal yeast infection	1	22OCT2020	2/4	1	No	O	NA/TC	R (25OCT2020)	N/N
>55/ C4591001 1044 10441216	GENRL	Fatigue/ fatigue#	3	23DEC2020	1/3	2	Yes		NA	R (25DEC2020)	N/N
>55/ C4591001 1044 10441220	MUSC	Myalgia/ Myalgia#	3	23DEC2020	1/3	2	Yes		NA	R (25DEC2020)	N/N
>55/ C4591001 1044 10441220	EAR	Ear pain/ Right earache	1	30OCT2020	8/8	1	No	O	NA	R (06NOV2020)	N/N
>55/ C4591001 1046 10461009	GASTR	Hiatus hernia/ Hiatal Hernia	2	13DEC2020	104/6	3	No	O	NA/TCN	R (18DEC2020)	Y/N
>55/ C4591001 1046 10461022	METAB	Type 2 diabetes mellitus/ Worsening of Diabetes Mellitus Type 2#	2	19FEB2021	170/C	1	No	O	NA/TC	N	N/N
>55/ C4591001	GENRL	Injection site pain/ Sore Left Arm at Injection Site#	4	27JAN2021	1/4	2	Yes		NA	R (30JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1046 10461041	NERV	Headache/ Headache#	4	27JAN2021	1/4	1	Yes		NA	R (30JAN2021)	N/N	
>55/ C4591001 1046 10461059	GASTR	Diarrhoea/ Diarrhea	2	22SEP2020	14/2	2	No	O	NA	R (23SEP2020)	N/N	
>55/ C4591001 1046 10461083	GENRL	Injection site pain/ Sore Left Arm at Injection Site#	4	09FEB2021	1/1	1	Yes		NA	R (09FEB2021)	N/N	
		Pyrexia/ Low Grade Fever#	4	09FEB2021	1/1	1	Yes		NA	R (09FEB2021)	N/N	
>55/ C4591001 1046 10461085	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/4	1	Yes		NA	R (21FEB2021)	N/N	
		Injection site pain/ PAIN LEFT ARM AT INJECTION SITE#	4	18FEB2021	2/4	1	Yes		NA	R (21FEB2021)	N/N	
	NERV	Headache/ Headache#	4	18FEB2021	2/4	1	Yes		NA	R (21FEB2021)	N/N	
>55/ C4591001 1046 10461095	GENRL	Fatigue/ Fatigue#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N	
		Pyrexia/ Fever#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N	
>55/ C4591001	GENRL	Fatigue/ Fatigue	2	06OCT2020	18/4	1	No	O	NA	R (09OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1046 10461138		Pyrexia/ Fever	2	06OCT2020	18/4	1	No	O	NA	R (09OCT2020)	N/N	
	INFECTION	Sinusitis/ Sinus Infection	2	06OCT2020	18/4	1	No	O	NA	R (09OCT2020)	N/N	
	RESP	Sinus congestion/ SINUS CONGESTION	2	06OCT2020	18/4	1	No	O	NA	R (09OCT2020)	N/N	
>55/ C4591001 1046 10461165	GENRL	Injection site pain/ Sore Left Arm at Injection Site#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N	
	INV	Blood cholesterol increased/ High Cholesterol#	4	23FEB2021	13/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1046 10461187	GENRL	Injection site pain/ Left Arm Soreness at Injection Site#	3	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N	
>55/ C4591001 1046 10461230	GENRL	Pyrexia/ Low Grade Fever#	4	29JAN2021	2/3	2	Yes		NA	R (31JAN2021)	N/N	
	MUSC	Myalgia/ Muscle Aches#	4	29JAN2021	2/3	1	Yes		NA	R (31JAN2021)	N/N	
>55/ C4591001 1046 10461244	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N	
>55/ C4591001	MUSC	Arthralgia/ Left Shoulder Pain	1	01OCT2020	22/C	2	No	O	NA/TC	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1046 10461245 >55/ C4591001 1046 10461259	NERV	Dizziness/ Dizziness	1	16SEP2020	3/2	1	No	O	NA	R (17SEP2020)	N/N	
>55/ C4591001 1046 10461260	GENRL	Injection site pain/ Sore Left Arm at Injection Site#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N	
>55/ C4591001 1046 10461283	GENRL	Pain/ Body Aches#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	
>55/ C4591001 1047 10471012	NERV	Pyrexia/ Fever# Syncope/ Syncope episodes	3 2	08FEB2021 19JAN2021	1/2 134/34	1 2	Yes No		NA O	R (09FEB2021) R (21FEB2021)	N/N Y/N	
>55/ C4591001 1047 10471016	MUSC	Myalgia/ muscle pain#	4	22FEB2021	1/2	2	Yes		NA	R (23FEB2021)	N/N	
>55/ C4591001 1047 10471022	GENRL	Fatigue/ fatigue#	4	25FEB2021	1/2	1	Yes		NA	R (26FEB2021)	N/N	
	MUSC	Myalgia/ sore muscles#	4	25FEB2021	1/2	1	Yes		NA	R (26FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1047 10471023	GASTR	Nausea/ nausea#	4	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N
>55/ C4591001 1047 10471043	GENRL	Fatigue/ fatigue#	3	22JAN2021	3/5	2	Yes		NA	R (26JAN2021)	N/N
	NERV	Headache/ headache#	3	22JAN2021	3/5	1	Yes		NA	R (26JAN2021)	N/N
>55/ C4591001 1047 10471060	GENRL	Injection site discolouration/ Discoloration at injection site*		26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
		Injection site pain/ Soreness at injection site*		26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/N
		Pain/ Bodyaches*		26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
	NERV	Headache/ Headache*		26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Pain/ Bodyaches	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C4591001 1047 10471063	GASTR	Abdominal pain upper/ Stomach Cramps	1	09SEP2020	14/4	1	No	O	NA	R (12SEP2020)	N/N
		Diarrhoea/ Diarrhea	1	09SEP2020	14/4	1	No	O	NA	R (12SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Diarrhoea/ Diarrhea	2	16SEP2020	2/4	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Pain/ Body Aches	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ Fever 100.8	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1047 10471073	GENRL	Fatigue/ fatigue while walking#	3	19DEC2020	2/1	2	Yes		NA	R (19DEC2020)	N/N
>55/ C4591001 1047 10471090	GENRL	Injection site pain/ Pain at injection site	1	01SEP2020	2/1	2	Yes		NA	R (01SEP2020)	N/N
	GENRL	Chills/ Chills	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
		Pain/ Bodyaches	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
>55/ C4591001 1047 10471092	GENRL	Chills/ chills	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ soreness at injection site.	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	INV	Body temperature increased/ increased body temperature 100.1	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ injection site soreness	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1047 10471097	GENRL	Chills/ Chills	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N	
		Pyrexia/ Fever 102	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N	
>55/ C4591001 1047 10471099	GENRL	Chills/ chills	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
	MUSC	Myalgia/ muscle aches	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
>55/ C4591001 1047 10471101	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
>55/ C4591001 1047 10471102	GENRL	Chills/ chills#	3	17FEB2021	22/2	1	Yes		NA	R (18FEB2021)	N/N	
		Pain/ body aches#	3	17FEB2021	22/2	1	Yes		NA	R (18FEB2021)	N/N	
		Pyrexia/ fever (100.5)#	3	17FEB2021	22/2	1	Yes		NA	R (18FEB2021)	N/N	
	NERV	Headache/ headache#	3	17FEB2021	22/2	1	Yes		NA	R (18FEB2021)	N/N	
>55/ C4591001 1047 10471103	GENRL	Chills/ chills#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1047 10471110	NERV	Pain/ body aches#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
		Pyrexia/ fever (101.0)#	4	17FEB2021	1/2	2	Yes		NA	R (18FEB2021)	N/N
		Headache/ headaches#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
>55/ C4591001 1047 10471114	GENRL	Chills/ Chills	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GASTR	Diarrhoea/ diarrhea	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
	INJ&P	Nausea/ nausea	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
		Vomiting/ vomiting	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
NERV	Cervical vertebral fracture/ Cervical spine fracture	2	18OCT2020	26/C	2	No	O	NA/TCN	N	N/N	
	Fall/ Accidental Fall	2	18OCT2020	26/1	1	No	O	NA	R (18OCT2020)	N/N	
	Cerebrovascular accident/ multi focal Cerebral Vascular Accidents	2	18OCT2020	26/C	3	No	O	NA	RG	Y/N	
GASTR	Dysphagia/ Dysphagia	2	28OCT2020	36/C	2	No	O	NA/TCN	N	N/N	
>55/ C4591001	MUSC	Pain in extremity/ bilateral hand pain	1	04SEP2020	2/C	2	No	O	NA	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1047 10471123 >55/ C4591001 1047 10471130	NERV	Headache/ headache	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
	RESP	Paranasal sinus discomfort/ Sinus Pressure	2	25SEP2020	3/3	1	Yes		NA	R (27SEP2020)	N/N
>55/ C4591001 1047 10471132	RESP	Productive cough/ Wet cough	1	06SEP2020	3/5	1	No	O	NA	R (10SEP2020)	N/N
	SKIN	Rash/ Rash left upper leg	1	19SEP2020	16/4	1	No	O	NA	R (22SEP2020)	N/N
	GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Fatigue/ Fatigue	1	23SEP2020	20/2	1	Yes		NA	R (24SEP2020)	N/N
		Pain/ Body Aches	2	23SEP2020	1/8	1	Yes		NA	R (30SEP2020)	N/N
	NERV	Headache/ Headaches	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	SKIN	Night sweats/ Night Sweats	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1047 10471136	GENRL	Pyrexia/ Temp 101.8	2	26SEP2020	2/1	2	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ headache	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1047 10471139	GASTR	Diarrhoea/ Diarrhea	2	26SEP2020	3/1	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1047 10471169	SKIN	Acne/ facial acne	2	01DEC2020	63/C	1	No	O	NA	N	N/N
>55/ C4591001 1047 10471170	GENRL	Injection site pain/ injection site Left deltoid Soreness*		09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1047 10471175	GENRL	Fatigue/ Fatigue	2	01OCT2020	1/4	1	Yes		NA	R (04OCT2020)	N/N
	NERV	Headache/ headache#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
>55/ C4591001 1047 10471183	GENRL	Injection site pain/ Soreness at injection site Left Deltoid	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
>55/ C4591001 1047 10471184	GASTR	Diarrhoea/ Diarrhea	1	02OCT2020	22/2	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Syncope/ Vagal Response/fainted	2	02OCT2020	1/1	2	Yes		NA	R (02OCT2020)	N/Y
	MUSC	Pain in extremity/ sore left arm#	3	18DEC2020	1/2	2	Yes		NA	R (19DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache#	3	19DEC2020	2/2	2	Yes		NA	R (20DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
		Injection site pain/ sore injection site#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
>55/ C4591001 1047 10471185	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
		Pain/ Bodyaches	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
>55/ C4591001 1047 10471191	NERV	Headache/ Headache	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Therapeutic response unexpected/ improved vision unexpected effect	2	01OCT2020	1/C	1	No	O	NA	N	N/N
	GASTR	Nausea/ nausea#	4	22FEB2021	1/3	2	Yes		NA	R (24FEB2021)	N/N
	GENRL	Chills/ chills#	4	22FEB2021	1/2	2	Yes		NA	R (23FEB2021)	N/N
		Fatigue/ fatigue#	4	22FEB2021	1/2	2	Yes		NA	R (23FEB2021)	N/N
	NERV	Headache/ headache#	4	22FEB2021	1/2	2	Yes		NA	R (23FEB2021)	N/N
>55/ C4591001 1047 10471194	INJ&P	Fall/ Fall	2	06NOV2020	19/1	2	No	O	NA	R (06NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1047 10471206		Upper limb fracture/ Fractured Left Elbow	2	06NOV2020	19/40	2	No	O	NA	R (15DEC2020)	N/N
	RESP	Chronic obstructive pulmonary disease/ Dyspnea with exacerbation of COPD#	2	04FEB2021	109/4	3	No	O	NA/TC	R (07FEB2021)	Y/N
	NERV	Headache/ Headache	1	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
	GASTR	Diarrhoea/ diarrhea	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/Y
		Nausea/ nausea	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/Y
	GENRL	Chills/ chills	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/Y
>55/ C4591001 1047 10471208	MUSC	Injection site pain/ injection site soreness	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/Y
		Arthralgia/ JOINT PAIN (ELBOW)	2	30OCT2020	23/C	2	No	O	NA	N	N/N
>55/ C4591001 1047 10471209		Arthralgia/ joint pain (hand)	2	30OCT2020	23/C	2	No	O	NA	N	N/N
	INFEC	Furuncle/ boil left thigh	2	09NOV2020	34/	2	No	O	NA/TC	RS	N/N
>55/ C4591001		Skin bacterial infection/ Strep skin infection	2	09NOV2020	34/	2	No	O	NA/TC	R	N/N
	GENRL	Pyrexia/ Fever#	4	12MAR2021	2/1	1	Yes		NA	R (12MAR2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day*/ Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1047 10471215	GENRL	Fatigue/ Fatigue*		15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
>55/ C4591001 1047 10471216	GASTR	Constipation/ Constipation	2	02NOV2020	26/31	2	No	O	NA	R (02DEC2020)	N/N
>55/ C4591001 1047 10471224	INFEC	Vulvovaginal mycotic infection/ yeast infection vaginal infection	2	04NOV2020	28/15	2	No	O	NA	R (18NOV2020)	N/N
>55/ C4591001 1047 10471247	MUSC	Arthralgia/ left shoulder pain	2	31DEC2020	81/C	2	No	O	NA	N	N/N
>55/ C4591001 1047 10471249	GASTR	Exostosis/ left shoulder bone spur Nausea/ Nausea	1	23SEP2020	3/1	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Pain in extremity/ Bilateral Leg Pain	1	23SEP2020	3/5	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
		Injection site pain/ injection site soreness#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
>55/ C4591001	GASTR	Nausea/ nausea	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1047 10471250	GENRL	Pyrexia/ low grade fever 100.7	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
>55/ C4591001 1047 10471252	CARD	Acute coronary syndrome/ acute coronary syndrome	1	25SEP2020	5/3	2	No	O	NA/TC/TCN	R (27SEP2020)	Y/N
		Bundle branch block left/ left bundle branch block	1	25SEP2020	5/3	2	No	O	NA/TC/TCN	R (27SEP2020)	N/N
>55/ C4591001 1047 10471268	GENRL	Chills/ Chills	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ Right Arm Soreness at injection site	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Musculoskeletal stiffness/ Stiff Neck	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	NERV	Headache/ Headache	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Muscle spasms/ Muscle Spasms Bilateral Legs	1	05OCT2020	14/1	2	No	O	NA	R (05OCT2020)	N/N
>55/ C4591001 1047 10471274	GENRL	Fatigue/ fatigue	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
		Pyrexia/ fever 100.8	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
>55/ C4591001	INJ&P	Contusion/ Stone Bruise right Foot	1	01OCT2020	9/63	1	No	O	NA	R (02DEC2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1047 10471276	GASTR	Nausea/ intermittent nausea	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
	NERV	Headache/ headache	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
>55/ C4591001 1047 10471290	GASTR	Abdominal hernia/ Abdominal hernia	2	07DEC2020	56/8	3	No	O	NA/TCN	R (14DEC2020)	Y/N
		Intestinal strangulation/ Small bowel strangulation	2	07DEC2020	56/8	3	No	O	NA/TCN	R (14DEC2020)	Y/N
	HEPAT	Cholelithiasis/ Cholelithiasis	2	07DEC2020	56/37	2	No	O	NA/TCN	R (12JAN2021)	N/N
	GASTR	Gastrointestinal haemorrhage/ possible GI Bleed#	2	22FEB2021	133/1	1	No	O	NA/TC	R (22FEB2021)	N/N
	INFEC	Post procedural infection/ Intra abdominal infection post cholecystectomy#	2	22FEB2021	133/C	3	No	O	NA/TC	N	Y/N
>55/ C4591001 1048 10481003	VASC	Hypotension/ HYPOTENSIVE	2	18SEP2020	15/137	1	No	O	NA/TC	R (01FEB2021)	N/N
	METAB	Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2	24NOV2020	82/C	1	No	O	NA/TC	RG	N/N
	GASTR	Toothache/ Tooth pain#	3	20FEB2021	20/C	1	No	O	NA	RG	N/N
>55/ C4591001	HEPAT	Biliary dyskinesia/ biliary dyskinesia	2	06SEP2020	3/61	2	No	O	NA	R (05NOV2020)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1048 10481006 >55/ C4591001 1048 10481007	EYE	Glaucoma/ GLAUCOMA LEFT EYE	2	06OCT2020	29/C	2	No	O	NA/TC	N	N/N
	INJ&P	Procedural pain/ POST OP PAIN SECONDARY TO RIGHT HIP REPLACEMENT.	2	14OCT2020	37/8	1	No	O	NA/TC	R (21OCT2020)	N/N
>55/ C4591001 1048 10481008	NEOPL	Skin papilloma/ Right thumb Verruca vulgaries#	2	02FEB2021	148/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1048 10481012	INJ&P	Procedural pain/ Post-operative pain, right shoulder#	3	02FEB2021	12/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1048 10481015	GENRL	Pain/ BODY ACHES	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Dizziness/ LIGHTHEADEDNESS	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		Headache/ HEADACHE	2	10SEP2020	1/8	2	Yes		NA/TC	R (17SEP2020)	N/N
	RESP	Rhinorrhoea/ RHINORRHEA	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	RESP	Rhinorrhoea/ RHINORRHEA	2	15SEP2020	6/1	1	Yes		NA	R (15SEP2020)	N/N
	SKIN	Rash/ Rash on back	2	30NOV2020	82/1	1	No	O	NA	R (30NOV2020)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1048 10481016	GASTR	Nausea/ nausea	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1048 10481028	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	26AUG2020	2/5	1	Yes		NA	R (30AUG2020)	N/N
>55/ C4591001 1048 10481033	INFEC	Tooth infection/ MOLAR #31 INFECTION	1	29AUG2020	5/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1048 10481034	GENRL	Injection site pain/ Pain at injection site#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	VASC	Hypertension/ Hypertension#	3	27JAN2021	9/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1048 10481038	GENRL	Injection site pain/ Left arm pain at injection site#	3	26JAN2021	1/3	1	Yes		NA/TC	R (28JAN2021)	N/N
>55/ C4591001 1048 10481041	GENRL	Injection site irritation/ SKIN IRRITATION AT INJECTION SITE	2	18SEP2020	2/5	1	Yes		NA	R (22SEP2020)	N/N
		Pain/ BODY ACHES	2	18SEP2020	2/2	2	Yes		NA/TC	R (19SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1048 10481042	GASTR	Diarrhoea/ diarrhea	1	02SEP2020	7/1	1	Yes		NA	R (02SEP2020)	N/N
>55/ C4591001 1048 10481043	INJ&P	Fall/ fell when walking on a dirt parking log	2	03NOV2020	48/1	2	No	O	NA	RS (03NOV2020)	N/N
		Meniscus injury/ partially torn Right meniscus.	2	03NOV2020	48/48	2	No	O	NA/TC/TCN	R (20DEC2020)	N/N
	INJ&P	Procedural pain/ Post op right knee pain	2	18DEC2020	93/28	2	No	O	NA/TC	R (14JAN2021)	N/N
	GENRL	Injection site pain/ Arm pain at injection site#	4	18JAN2021	1/C	1	Yes		NA	RG	N/N
	GENRL	Fatigue/ fatigue#	4	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	19JAN2021	2/1	1	Yes		NA/TC	R (19JAN2021)	N/N
>55/ C4591001 1048 10481049	INFEC	Herpes zoster/ SHINGLES	1	16SEP2020	20/16	2	No	O	NA/TC	R (01OCT2020)	N/N
	NERV	Post herpetic neuralgia/ POST HERPATIC NEURALGIA	1	17SEP2020	21/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1048 10481051	GENRL	Fatigue/ Fatigue	2	19SEP2020	3/6	1	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ headache	2	19SEP2020	3/5	1	No	O	NA/TC	R (23SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1048 10481058	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
>55/ C4591001 1048 10481060	GASTR	Nausea/ Nausea	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Pain/ Body Aches	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N
>55/ C4591001 1048 10481066	NERV	Dizziness/ dizziness	1	20SEP2020	20/2	1	No	O	NA	R (21SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	03FEB2021	2/1	1	Yes		NA/TC	R (03FEB2021)	N/N
>55/ C4591001 1048 10481067	GENRL	Influenza like illness/ flu like symptoms	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C4591001 1048 10481068	GENRL	Injection site pain/ Right arm pain at injection site#	3	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N
>55/ C4591001 1048 10481074	GENRL	Fatigue/ fatigue#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	NERV	Headache/ headache#	3	23JAN2021	2/1	1	Yes		NA/TC	R (23JAN2021)	N/N	
>55/ C4591001 1048 10481084	GENRL	Pain/ BODY ACHES	2	30SEP2020	9/2	2	Yes		NA/TC	R (01OCT2020)	N/N	
>55/ C4591001 1048 10481087	VASC	Hypertension/ worsening of hypertension	2	07OCT2020	13/C	1	No	O	NA	N	N/N	
	GASTR	Gastric polyps/ Benign gastric polyp	2	09OCT2020	15/15	1	No	O	NA/TCN	R (23OCT2020)	N/N	
>55/ C4591001 1048 10481090	VASC	Hypertension/ WORSENING OF HYPERTENSION	1	16SEP2020	13/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1048 10481096	GENRL	Malaise/ general malaise	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
	NERV	Headache/ HEADACHE	1	08SEP2020	1/8	2	Yes		NA/TC	R (15SEP2020)	N/N	
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	09SEP2020	2/8	1	Yes		NA	R (16SEP2020)	N/N	
	GENRL	Injection site pain/ PAIN AT INJECTION	2	01OCT2020	2/6	1	Yes		NA	R (06OCT2020)	N/N	
	NERV	Headache/ HEADACHE	2	01OCT2020	2/21	2	Yes		NA	R (21OCT2020)	N/N	
>55/ C4591001	GENRL	Fatigue/ FATIGUE	1	11SEP2020	3/2	1	Yes		NA	R (12SEP2020)	N/N	

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1048 10481104	EAR	Hypoacusis/ decreased hearing right ear	2	30NOV2020	62/53	2	No	O	NA	R (21JAN2021)	N/N
>55/ C4591001 1048 10481105	GENRL	Fatigue/ FATIGUE	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	30SEP2020	1/33	1	Yes		NA	R (01NOV2020)	N/N
	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1048 10481117	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
>55/ C4591001 1048 10481121	GENRL	Injection site pain/ RIGHT ARM PAIN AT INJECTION SITE	1	10SEP2020	1/3	2	Yes		NA	R (12SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	11SEP2020	2/3	2	Yes		NA	R (13SEP2020)	N/N
	INV	Body temperature increased/ INCREASED TEMPERATURE 99.4 F	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ RIGHT ARM PAIN AT INJECTION SITE	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N

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>55/ C4591001 1048 10481122	MUSC	Back pain/ back pain	2	26OCT2020	28/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1048 10481123	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N	
>55/ C4591001 1048 10481124	INJ&P	Procedural pain/ MOUTH PAIN SECONDARY TO TOOTH EXTRACTION	2	18OCT2020	19/3	1	No	O	NA/TC	R (20OCT2020)	N/N	
>55/ C4591001 1048 10481129	GENRL	Fatigue/ FATIGUE	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N	
>55/ C4591001 1052 10521098	GENRL	Chills/ chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
		Injection site pain/ pain at injection site	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
		Pyrexia/ low grade fever	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N	
>55/ C4591001 1054 10541021	MUSC	Arthralgia/ worsening of right hip pain	1	24AUG2020	4/C	2	No	O	NA/TC/TCN	N	N/N	
	GASTR	Abdominal discomfort/ abdominal discomfort	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N	



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>55/ C4591001 1054 10541045	GENRL	Diarrhoea/ diarrhea	2	11SEP2020	2/1	2	Yes		NA	R (11SEP2020)	N/N	
		Nausea/ nausea	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N	
		Fatigue/ general tiredness	2	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N	
		Pyrexia/ fever	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N	
	MUSC	Myalgia/ muscle aches	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N	
	GASTR	Gastrointestinal disorder/ colonic lesion	2	13OCT2020	30/1	1	No	O	NA	R (13OCT2020)	N/N	
	>55/ C4591001 1054 10541056	GENRL	Large intestine polyp/ colonic polyp	2	13OCT2020	30/1	1	No	O	NA	R (13OCT2020)	N/N
		GENRL	Injection site pain/ L shoulder soreness site injection#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
		GENRL	Fatigue/ fatigue#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
	>55/ C4591001 1054 10541059	GENRL	Pyrexia/ fever, 100.9 degrees Fahrenheit#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
Injection site pain/ injection site soreness			1	26AUG2020	1/2	1	Yes		NA/TC	R (27AUG2020)	N/N	
		Pyrexia/ low grade fever of 99.4 degF	1	26AUG2020	1/2	1	Yes		NA/TC	R (27AUG2020)	N/N	

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>55/ C4591001 1054 10541062	GENRL	Chills/ chills	2	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1054 10541063	GENRL	Injection site pain/ site injection pain	1	27AUG2020	1/2	1	Yes		NA/TC	R (28AUG2020)	N/N
	NERV	Headache/ headache	1	27AUG2020	1/2	1	Yes		NA/TC	R (28AUG2020)	N/N
	GASTR	Nausea/ nausea	2	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Chills/ chills	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		Pain/ body aches	2	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N
		Pyrexia/ subjective fever	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ headache	2	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N
>55/ C4591001 1054 10541075	NERV	Dizziness/ intermittent dizziness	1	10SEP2020	14/2	2	No	O	NA	R (11SEP2020)	N/N
>55/ C4591001 1054 10541077	MUSC	Myalgia/ myalgia - generalized	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N

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>55/ C4591001 1054 10541093	NERV	Headache/ headache	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Chills/ chills	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
		Pyrexia/ fever (99.6 degree F), subjective	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
	MUSC	Myalgia/ muscle soreness	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	1	02SEP2020	2/2	1	Yes		NA/TC	R (03SEP2020)	N/N
	NERV	Headache/ headache	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	03SEP2020	3/1	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
		Injection site pain/ pain at injection site L arm	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
		Pain/ body aches	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1054 10541095	NERV	Headache/ headache	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ pain L arm injection site	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/Y
	GENRL	Injection site pain/ L arm soreness at injection site#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1054 10541103	GENRL	Chills/ chills#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N	
		Injection site pain/ L arm injection site soreness#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/Y	
	NERV	Headache/ headache#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N	
	GENRL	Injection site pain/ muscle soreness at injection site	1	03SEP2020	2/1	1	Yes		NA/TC	R (03SEP2020)	N/N	
	NERV	Headache/ headache	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N	
	GENRL	Injection site pain/ muscle soreness R arm injection site	2	23SEP2020	1/3	1	Yes		NA/TC	R (25SEP2020)	N/N	
	NERV	Headache/ headache	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N	
	NERV	Lethargy/ lethargy	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N	
	>55/ C4591001 1054 10541112	NERV	Dyskinesia/ LUE - mild involuntary movement of muscle	1	03SEP2020	1/1	1	Yes		NA	R (03SEP2020)	N/Y
		GASTR	Nausea/ nausea	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N	
	INJ&P	Arthropod sting/ bee sting	1	19SEP2020	17/9	1	No	O	NA/TC	R (27SEP2020)	N/N	
	VASC	Hot flush/ hot flash	1	21SEP2020	19/1	1	No	O	NA	R (21SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Toothache/ toothache L lower tooth	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Sluggishness/ sluggish	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
	NERV	Dizziness/ lightheadedness	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
		Headache/ headache	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Asthenia/ generalized weakness	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	VASC	Hot flush/ hot flashes	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Muscle twitching/ intermittent migratory muscle twitches	2	26SEP2020	3/112	1	Yes		NA	R (15JAN2021)	N/N
	VASC	Hot flush/ hot flashes	2	26SEP2020	3/1	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1054 10541116	GENRL	Injection site pain/ soreness L arm injection site	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ soreness at L arm injection site	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1054 10541128	GENRL	Injection site pain/ L arm soreness at the injection site#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1054 10541129	GENRL	Injection site pain/ injection site pain L arm#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
		Pain/ generalized body aches#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
	NERV	Headache/ headache#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
	SKIN	Hyperhidrosis/ generalized perspiration#	4	19FEB2021	3/1	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site, L arm	1	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/Y
	GENRL	Fatigue/ fatigue	1	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
	EYE	Vision blurred/ blurred vision	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Chills/ chills	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ injection site soreness	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Pyrexia/ fever	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Myalgia/ diffuse muscle aches	2	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ injection site soreness	2	30SEP2020	2/4	2	Yes		NA	R (03OCT2020)	N/N
	MUSC	Myalgia/ diffuse muscle aches	2	30SEP2020	2/4	2	Yes		NA/TC	R (03OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headaches	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	PSYCH	Insomnia/ insomnia	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
		Paranoia/ paranoia	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
>55/ C4591001 1054 10541134	GENRL	Injection site pain/ injection site muscle ache	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
>55/ C4591001 1054 10541136	INV	Blood pressure increased/ elevated blood pressure	1	09SEP2020	1/2	1	No	O	NA	R (10SEP2020)	N/N
	NERV	Dizziness/ lightheadedness	1	09SEP2020	1/1	1	No	O	NA	R (09SEP2020)	N/Y
	GENRL	Injection site pain/ L arm soreness site injection#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	GASTR	Diarrhoea/ diarrhea#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
>55/ C4591001 1054 10541143	GENRL	Injection site pain/ L arm site injection pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
		Injection site pain/ L arm site injection soreness#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Pain/ generalized body aches#	4	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
	GASTR	Nausea/ nausea#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1054 10541149	GENRL	Fatigue/ fatigue#	4	10FEB2021	2/2	2	Yes		NA	R (11FEB2021)	N/N
		Pyrexia/ fever#	4	10FEB2021	2/1	1	Yes		NA/TC	R (10FEB2021)	N/N
	CARD	Atrial fibrillation/ atrial fibrillation#	4	12FEB2021	4/1	2	No	O	NA	R (12FEB2021)	N/N
	GASTR	Dyspepsia/ intermittent heartburn	1	30SEP2020	20/C	1	No	O	NA/TC	N	N/N
	GASTR	Tongue discolouration/ black discoloration of tongue	2	05OCT2020	4/26	1	No	CD	NA	R (30OCT2020)	N/N
>55/ C4591001 1054 10541151	GENRL	Injection site pain/ soreness L arm - site injection#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Chills/ chills#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site	1	15SEP2020	2/3	1	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Injection site pain/ soreness L arm injection site	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
	GENRL	Chills/ chills	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
		Injection site pain/ soreness L arm injection site	2	06OCT2020	2/4	2	Yes		NA/TC	R (09OCT2020)	N/N
		Injection site swelling/ swelling L arm injection site	2	06OCT2020	2/12	1	Yes		NA	R (17OCT2020)	N/N
	Pain/ body aches	2	06OCT2020	2/2	2	Yes		NA/TC	R (07OCT2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Pyrexia/ fever	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N	
	NERV	Headache/ headache	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N	
			2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N	
>55/ C4591001 1054 10541163	NERV	Dizziness/ lightheadedness	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/Y	
>55/ C4591001 1054 10541164	GENRL	Injection site pain/ muscle pain L arm injection site	1	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N	
>55/ C4591001 1054 10541166	GENRL	Injection site pain/ L arm soreness site injection#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N	
>55/ C4591001 1054 10541167	GENRL	Injection site pain/ soreness at R arm injection site	1	17SEP2020	1/5	1	Yes		NA	R (21SEP2020)	N/N	
		Injection site swelling/ swelling at R arm injection site	1	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N	
	GENRL	Chills/ chills	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N	
		Injection site pain/ pain at injection site	2	08OCT2020	1/6	1	Yes		NA/TC	R (13OCT2020)	N/N	
		Pyrexia/ fever - 101 degrees Fahrenheit	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	SKIN	Hyperhidrosis/ diaphoresis (mild)	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
>55/ C4591001 1054 10541168	INJ&P	Lumbar vertebral fracture/ closed fracture, transverse process of lumbar vertebra	2	03DEC2020	57/C	3	No	O	NA/TC/TCN	RG	Y/N
>55/ C4591001 1054 10541169	GASTR	Nausea/ nausea	1	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/Y
	GENRL	Injection site pain/ injection site pain	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ burning at L arm injection site	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/Y
		Non-cardiac chest pain/ L chest discomfort (noncardiac)	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/Y
	EYE	Conjunctival haemorrhage/ subconjunctival hemorrhage L eye	2	15JAN2021	100/C	1	No	O	NA	RG	N/N
>55/ C4591001 1054 10541173	CARD	Aortic valve incompetence/ acute aortic insufficiency	2	28OCT2020	20/49	4	No	O	NA/TC/TCN	R (15DEC2020)	Y/N
	INFEC	Subacute endocarditis/ subacute bacterial endocarditis	2	28OCT2020	20/49	4	No	O	NA/TC/TCN	R (15DEC2020)	Y/N
	MUSC	Myalgia/ pain L hamstring muscles	2	28OCT2020	20/C	2	No	O	NA/TC	N	N/N
	NERV	Subarachnoid haemorrhage/ subarachnoid hemorrhage	2	05NOV2020	28/1	3	No	O	NA/TC/TCN	R (05NOV2020)	Y/N
	CARD	Atrial fibrillation/ intermittent atrial fibrillation	2	06NOV2020	29/C	2	No	O	NA/TC	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1054 10541186	GASTR	Nausea/ nausea	1	23SEP2020	1/1	1	Yes		P	R (23SEP2020)	N/Y
	NERV	Dizziness/ lightheadedness	1	23SEP2020	1/1	1	Yes		P	R (23SEP2020)	N/Y
>55/ C4591001 1054 10541187	GASTR	Abdominal pain upper/ intermittent upper abdominal pain	2	15OCT2020	2/3	1	Yes		NA	R (17OCT2020)	N/N
		Nausea/ nausea	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Chills/ chills	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
		Fatigue/ tiredness	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
		Pyrexia/ fever	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
	MUSC	Myalgia/ muscle aches	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
	NERV	Headache/ headache	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
>55/ C4591001 1054 10541205	GENRL	Injection site pain/ L arm soreness injection site#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
	NERV	Headache/ headache#	4	24FEB2021	2/1	1	Yes		NA/TC	R (24FEB2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ L arm site injection pain	1	28OCT2020	1/3	1	Yes		NA/TC	R (30OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1054 10541210	GENRL	Fatigue/ fatigue	1	29OCT2020	2/3	1	Yes		NA	R (31OCT2020)	N/N
	MUSC	Limb discomfort/ L arm heaviness	1	29OCT2020	2/3	1	Yes		NA	R (31OCT2020)	N/N
	GENRL	Fatigue/ tiredness	2	16NOV2020	1/4	1	Yes		NA	R (19NOV2020)	N/N
	GENRL	Injection site pain/ soreness of injection site L arm	2	17NOV2020	2/4	1	Yes		NA	R (20NOV2020)	N/N
>55/ C4591001 1054 10541211	GENRL	Injection site pain/ L arm site injection pain	1	28OCT2020	1/3	1	Yes		NA	R (30OCT2020)	N/N
	GENRL	Injection site pain/ injection site soreness L arm	2	16NOV2020	1/3	1	Yes		NA	R (18NOV2020)	N/N
	GENRL	Fatigue/ tiredness	2	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N
>55/ C4591001 1054 10541213†	NERV	Headache/ headache#	3	03FEB2021	1/1	1	Yes		NA/TC	R (03FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	04FEB2021	2/4	1	Yes		NA	R (07FEB2021)	N/N
>55/ C4591001 1055 10551004	GENRL	Injection site pain/ injection site soreness#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1055 10551006	INFEC	Urinary tract infection/ Urinary Tract Infection	2	01SEP2020	7/6	1	No	O	NA/TC	R (06SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/3	2	Yes		NA/TC	R (24DEC2020)	N/Y	
	GENRL	Chills/ chills#	4	11JAN2021	1/1	1	Yes		NA	R (11JAN2021)	N/N	
		Injection site pain/ injection site pain#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N	
	BLOOD	Lymphadenopathy/ lymph node swelling#	4	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N	
>55/ C4591001 1055 10551008	GENRL	Injection site pain/ injection site pain#	3	21JAN2021	1/3	2	Yes		NA	R (23JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N	
>55/ C4591001 1055 10551009	GENRL	Injection site pain/ injection site pain#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N	
	GENRL	Fatigue/ fatigue#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N	
	MUSC	Myalgia/ myalgias#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N	
	NERV	Headache/ headache#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1055 10551011	EAR	Vertigo positional/ Worsening of recurrent benign positional vertigo	2	07SEP2020	8/36	3	No	O	NA/TC	R (12OCT2020)	N/N
>55/ C4591001 1055 10551015	GENRL	Chills/ Chills#	4	12FEB2021	1/2	2	Yes		NA	R (13FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	13FEB2021	2/4	2	Yes		NA/TC	R (16FEB2021)	N/N
>55/ C4591001 1055 10551018	EYE	Retinal detachment/ Detached retina	2	10SEP2020	11/8	3	No	O	NA/TC/TCN	R (17SEP2020)	N/N
	MUSC	Myalgia/ Myalgias#	3	11FEB2021	2/3	1	Yes		NA/TC	R (13FEB2021)	N/N
	GENRL	Chills/ Chills#	4	05MAR2021	1/5	2	Yes		NA/TC	R (09MAR2021)	N/N
		Pyrexia/ Fever#	4	05MAR2021	1/2	1	Yes		NA/TC	R (06MAR2021)	N/N
	GASTR	Nausea/ Nausea#	4	06MAR2021	2/4	1	Yes		NA	R (09MAR2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	06MAR2021	2/4	2	Yes		NA	R (09MAR2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	06MAR2021	2/4	2	Yes		NA/TC	R (09MAR2021)	N/N
	GENRL	Injection site erythema/ Erythema at Injection Site#	4	08MAR2021	4/4	3	Yes		NA	R (11MAR2021)	N/N
		Injection site pruritus/ Pruritus at Injection Site#	4	08MAR2021	4/4	1	Yes		NA	R (11MAR2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1055 10551024	NEOPL	Basal cell carcinoma/ Basal cell cancer	1	11AUG2020	1/81	2	No	O	NA	R (30OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	11JAN2021	1/3	2	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	11JAN2021	1/3	2	Yes		NA	R (13JAN2021)	N/N
	NERV	Headache/ Headache#	4	11JAN2021	1/3	2	Yes		NA/TC	R (13JAN2021)	N/N
>55/ C4591001 1055 10551027	NEOPL	Melanocytic naevus/ atypical nevus#	2	15JAN2021	136/1	1	No	O	NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	3	26JAN2021	1/4	2	Yes		NA/TC	R (29JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection site soreness#	4	16FEB2021	1/5	1	Yes		NA	R (20FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
>55/ C4591001 1055 10551030	GENRL	Injection site pain/ injection site pain#	4	15JAN2021	3/8	1	Yes		NA/TC	R (22JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1055 10551035	GENRL	Injection site pain/ injection site pain#	3	19JAN2021	1/3	2	Yes		NA	R (21JAN2021)	N/N
	GENRL	Chills/ chills#	3	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/2	2	Yes		NA/TC	R (11FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	10FEB2021	2/3	2	Yes		NA/TC	R (12FEB2021)	N/N
		Pyrexia/ Fever#	4	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
>55/ C4591001 1055 10551036	GENRL	Injection site pain/ injection site pain#	3	26JAN2021	1/3	1	Yes		NA/TC	R (28JAN2021)	N/N
>55/ C4591001 1055 10551039	GASTR	Hypoaesthesia oral/ Tongue numbness	1	13AUG2020	1/1	1	Yes		NA/TC	R (13AUG2020)	N/N
	RESP	Asthma/ Asthma exacerbation	1	19AUG2020	7/35	2	No	O	NA/TC	R (22SEP2020)	N/N
	SKIN	Perioral dermatitis/ Perioral Dermatitis	1	01NOV2020	81/C	1	No	O	NA/TC	N	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	19FEB2021	1/4	2	Yes		NA/TC	R (22FEB2021)	N/N
	GENRL	Injection site erythema/ Erythema at Injection Site#	3	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	3	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1055 10551047	GENRL	Injection site pain/ Injection site pain#	3	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
>55/ C4591001 1055 10551048	METAB	Hyperlipidaemia/ hyperlipidemia	2	12JAN2021	112/C	1	No	O	NA/TC	N	N/N
	GENRL	Injection site pain/ injection site pain#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
	NERV	Headache/ headache#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
		Pyrexia/ Fever#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1055 10551052	GENRL	Injection site pain/ Injection site tenderness	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
>55/ C4591001 1055 10551053	GENRL	Injection site pain/ injection site soreness#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	4	09FEB2021	1/3	2	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1055 10551055	NERV	Headache/ Headache#	4	09FEB2021	1/2	2	Yes		NA/TC	R (10FEB2021)	N/N
	IMMUN	Seasonal allergy/ Seasonal Allergies	2	29SEP2020	22/C	1	No	O	NA/TC	N	N/N
	GASTR	Nausea/ nausea#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ injection site soreness#	3	14JAN2021	1/3	1	Yes		NA	R (16JAN2021)	N/N
>55/ C4591001 1055 10551059	GASTR	Nausea/ Nausea#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	17AUG2020	1/4	1	Yes		NA	R (20AUG2020)	N/N
	GASTR	Nausea/ Nausea	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pruritus/ Injection site itching	2	10SEP2020	2/15	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1055 10551060	GENRL	Injection site pain/ Injection site pain	1	18AUG2020	1/4	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1055 10551062	GENRL	Injection site pain/ injection site pain#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
>55/ C4591001 1055 10551064	GENRL	Injection site pain/ Left arm injection site pain	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	NEOPL	Malignant melanoma/ Melanoma	2	30NOV2020	83/1	2	No	O	NA/TCN	R (30NOV2020)	N/N
>55/ C4591001 1055 10551065	GENRL	Injection site pain/ injection site pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	NERV	Headache/ Headache#	4	04FEB2021	1/2	2	Yes		NA	R (05FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	05FEB2021	2/1	2	Yes		NA/TC	R (05FEB2021)	N/N
>55/ C4591001 1055 10551066	GENRL	Injection site pain/ injection site pain#	3	19JAN2021	1/3	1	Yes		NA/TC	R (21JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	18AUG2020	1/3	1	Yes		NA	R (20AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1055 10551068	GENRL	Chills/ Chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
		Fatigue/ Fatigue	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
	MUSC	Myalgia/ Myalgias	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
>55/ C4591001 1055 10551069	GENRL	Fatigue/ fatigue#	3	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N	
	GENRL	Injection site swelling/ Injection site swelling#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N	
>55/ C4591001 1055 10551081	GASTR	Diarrhoea/ Diarrhea	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	13JAN2021	2/3	2	Yes		NA	R (15JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N	
>55/ C4591001 1055 10551083	GENRL	Fatigue/ Fatigue	2	11SEP2020	2/4	2	Yes		NA	R (14SEP2020)	N/N	
		Pyrexia/ Fever	2	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1055 10551088	MUSC	Myalgia/ Myalgias	2	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N
	NERV	Headache/ Headache	2	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N
	RENAL	Bladder spasm/ Bladder spasm	2	11SEP2020	2/1	2	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	14JAN2021	1/4	1	Yes		NA	R (17JAN2021)	N/N
	GENRL	Pyrexia/ fever#	3	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Chills/ Chills#	4	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1055 10551091	NERV	Headache/ Headache#	4	05FEB2021	2/2	2	Yes		NA	R (06FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	24AUG2020	1/4	2	Yes		NA	R (27AUG2020)	N/N
	EAR	Vertigo/ Vertigo	1	26AUG2020	3/5	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	14SEP2020	1/4	1	Yes		NA	R (17SEP2020)	N/N
	EAR	Vertigo/ Vertigo	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1055 10551093	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	25AUG2020	2/1	2	Yes		NA/TC	R (25AUG2020)	N/N
	MUSC	Myalgia/ Myalgia	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
>55/ C4591001 1055 10551094	MUSC	Arthralgia/ Arthralgia generalized	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ Headache	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ injection site soreness#	3	22JAN2021	2/2	1	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	11FEB2021	1/3	1	Yes		NA/TC	R (13FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Left Axillary Adenopathy#	4	12FEB2021	2/4	1	Yes		NA	R (15FEB2021)	N/N
	NERV	Headache/ Headache#	4	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N
>55/ C4591001 1055 10551095	GENRL	Pyrexia/ Fever	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ Headache	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ injection site pain#	3	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1055 10551096	GENRL	Injection site pain/ Injection site pain	1	25AUG2020	2/5	2	Yes		NA	R (29AUG2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	15SEP2020	2/3	1	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	17SEP2020	4/2	1	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001 1055 10551098	GENRL	Injection site pain/ Injection Site Pain#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1055 10551100	GENRL	Injection site pain/ Injection Site Pain	1	25AUG2020	2/5	1	Yes		NA	R (29AUG2020)	N/N
>55/ C4591001 1055 10551101	GENRL	Injection site pain/ injection site pain#	3	07JAN2021	2/4	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	08JAN2021	3/3	1	Yes		NA	R (10JAN2021)	N/N
		Injection site erythema/ injection site erythema#	3	08JAN2021	3/3	1	Yes		NA	R (10JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1055 10551102	GENRL	Fatigue/ Fatigue#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
		Injection site bruising/ Injection site bruising#	4	27JAN2021	1/24	1	Yes		NA	R (19FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	28JAN2021	2/1	2	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	26AUG2020	2/2	2	Yes		NA/TC	R (27AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	16SEP2020	2/1	2	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	16SEP2020	2/2	1	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	26AUG2020	2/4	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
MUSC	Myalgia/ Myalgias	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N	
NERV	Headache/ Headache	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1055 10551108	GENRL	Injection site pain/ Injection site pain#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1055 10551109	GENRL	Injection site pain/ injection site pain#	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
	METAB	Decreased appetite/ Decreased Appetite#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1055 10551110	PSYCH	Nightmare/ Nightmares	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
	GASTR	Nausea/ Nausea	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
	GASTR	Nausea/ Nausea	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	PSYCH	Insomnia/ Insomnia	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1055 10551112	GENRL	Chills/ Chills	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/N
		Injection site pain/ Injection site pain	1	25AUG2020	1/5	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N
	NERV	Headache/ headache#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
		Pyrexia/ Fever#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
>55/ C4591001 1055 10551113	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
	GENRL	Chills/ Chills	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N
		Pyrexia/ Fever	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N
>55/ C4591001	GASTR	Nausea/ Nausea	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1055 10551114	GASTR	Nausea/ Nausea	2	18SEP2020	3/1	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	05FEB2021	2/2	1	Yes		NA/TC	R (06FEB2021)	N/N
>55/ C4591001 1055 10551119	GENRL	Injection site pain/ Injection site pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Chills/ Chills	1	27AUG2020	2/1	1	Yes		NA/TC	R (27AUG2020)	N/N
		Fatigue/ Fatigue	1	27AUG2020	2/1	2	Yes		NA	R (27AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	16SEP2020	1/6	2	Yes		NA	R (21SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	17SEP2020	2/1	2	Yes		NA	R (17SEP2020)	N/N
	GENRL	Chills/ Chills	2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N
		Fatigue/ Fatigue	2	17SEP2020	2/1	2	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1055 10551120	GENRL	Injection site pain/ injection site soreness#	3	13JAN2021	1/1	1	Yes		NA	R (13JAN2021)	N/N
	SKIN	Hyperhidrosis/ Diaphoresis#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001	MUSC	Arthritis/ Arthritis of hands	2	28SEP2020	12/C	1	No	O	NA	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1055 10551122	GENRL	Injection site pain/ injection site pain#	3	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	26JAN2021	2/3	2	Yes		NA	R (28JAN2021)	N/N
		Pyrexia/ fever#	4	26JAN2021	2/1	1	Yes		NA/TC	R (26JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	4	26JAN2021	2/1	2	Yes		NA/TC	R (26JAN2021)	N/N
>55/ C4591001 1055 10551123	GENRL	Injection site pain/ injection site pain#	3	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
		Pyrexia/ fever#	3	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Injection site pain/ Injection site soreness#	4	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Pyrexia/ Low grade fever#	4	05FEB2021	2/1	1	Yes		NA/TC	R (05FEB2021)	N/N
>55/ C4591001 1055 10551124	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
>55/ C4591001 1055 10551126	GENRL	Injection site pain/ Injection Site Pain	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1055 10551127	GENRL	Injection site pain/ Injection Site Pain	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
>55/ C4591001 1055 10551130	GENRL	Injection site pain/ injection site pain#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Mental impairment/ mental fogginess#	3	13JAN2021	1/1	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Chills/ Chills#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	4	03FEB2021	1/4	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1055 10551132	GENRL	Injection site pain/ Left arm injection site tenderness	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	16SEP2020	2/2	1	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C4591001 1055 10551137	GENRL	Fatigue/ Fatigue	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
>55/ C4591001 1055 10551140	GENRL	Fatigue/ Fatigue	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1055 10551141	GENRL	Injection site pain/ Injection site pain	1	28AUG2020	1/8	1	Yes		NA	R (04SEP2020)	N/N
		Injection site pruritus/ Injection site itching	1	28AUG2020	1/8	1	Yes		NA	R (04SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	16SEP2020	1/6	2	Yes		NA	R (21SEP2020)	N/N
		Injection site swelling/ Injection Site Swelling	2	16SEP2020	1/6	2	Yes		NA	R (21SEP2020)	N/N
	GENRL	Fatigue/ fatigue#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Injection site pain/ injection site soreness#	3	20JAN2021	1/4	1	Yes		NA	R (23JAN2021)	N/N
		Fatigue/ Fatigue#	4	10FEB2021	1/1	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	4	10FEB2021	1/1	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
	NERV	Headache/ Headache	1	31AUG2020	1/2	1	Yes		NA/TC	R (01SEP2020)	N/N
GENRL	Injection site pain/ Injection Site Pain	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N	
GASTR	Nausea/ Nausea	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
MUSC	Myalgia/ Myalgia	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1055 10551148	GENRL	Fatigue/ Fatigue	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	04JAN2021	1/4	1	Yes		NA	R (07JAN2021)	N/N	
	GENRL	Injection site pain/ injection site pain#	4	25JAN2021	1/4	1	Yes		NA	R (28JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	26JAN2021	2/2	2	Yes		NA	R (27JAN2021)	N/N	
>55/ C4591001 1055 10551149	GENRL	Injection site pain/ injection site pain#	3	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N	
	NERV	Headache/ headache#	3	14JAN2021	2/2	2	Yes		NA	R (15JAN2021)	N/N	
	GENRL	Injection site pain/ Injection Site Pain#	4	03FEB2021	1/4	1	Yes		NA	R (06FEB2021)	N/N	
>55/ C4591001 1055 10551150	GENRL	Injection site pain/ Injection site pain	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N	
>55/ C4591001 1055 10551153	GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/4	1	Yes		NA	R (03SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1055 10551154	INFEC	Appendicitis perforated/ Perforated appendicitis	1	31AUG2020	1/17	3	No	O	NA/TC/TCN	R (16SEP2020)	Y/N
	GENRL	Fatigue/ Fatigue	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ injection site soreness#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Chills/ Chills#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1055 10551155	GENRL	Pyrexia/ Fever#	4	13FEB2021	2/1	1	Yes		NA/TC	R (13FEB2021)	N/N
	ENDO	Hypothyroidism/ Hypothyroid#	4	02MAR2021	19/C	1	No	O	NA/TC	N	N/N
	GASTR	Food poisoning/ Food poisoning	1	20SEP2020	21/2	1	No	O	NA	R (21SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1055 10551156	GENRL	Injection site pain/ injection site pain#	4	07JAN2021	2/5	2	Yes		NA	R (11JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1055 10551158	GENRL	Injection site pain/ Left injection site pain	1	01SEP2020	1/6	1	Yes		NA/TC	R (06SEP2020)	N/N
	GENRL	Injection site erythema/ Left injection site erythema	1	02SEP2020	2/5	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	22SEP2020	1/15	2	Yes		NA/TC	R (06OCT2020)	N/N
>55/ C4591001 1055 10551159	GENRL	Injection site pain/ Pain at injection site left arm	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	24SEP2020	3/3	1	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
			Pyrexia/ Fever#	4	10FEB2021	1/2	1	Yes		NA/TC	R (11FEB2021)
>55/ C4591001 1055 10551160	GENRL	Injection site pain/ injection site pain#	3	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
			Injection site pain/ Injection Site Pain#	4	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	NERV	Headache/ Headache#	4	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
>55/ C4591001 1055 10551166	GENRL	Injection site pain/ injection site soreness#	3	15JAN2021	2/2	1	Yes		NA/TC	R (16JAN2021)	N/N
		Pain/ body aches#	3	15JAN2021	2/1	1	Yes		NA/TC	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	05FEB2021	2/2	1	Yes		NA/TC	R (06FEB2021)	N/N
>55/ C4591001 1055 10551167	GENRL	Injection site pain/ Injection Site Pain	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1055 10551170	GENRL	Fatigue/ Fatigue	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	REPRO	Prostatitis/ Prostatitis	2	19OCT2020	27/10	2	No	O	NA/TC	R (28OCT2020)	N/N
>55/ C4591001 1055 10551172	GENRL	Injection site pain/ injection site pain#	3	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site erythema/ injection site erythema#	3	06JAN2021	2/4	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Chills/ Chills#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
	NERV	Headache/ Headache#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	27JAN2021	2/1	2	Yes		NA/TC	R (27JAN2021)	N/N
>55/ C4591001 1055 10551178	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	2/3	1	Yes		NA	R (06SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	05SEP2020	3/1	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Chills/ Chills	1	05SEP2020	3/1	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	23SEP2020	1/2	1	Yes		NA/TCN	R (24SEP2020)	N/N
	GENRL	Chills/ Chills	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1055 10551182	SKIN	Skin lesion/ skin lesion of scalp	1	25SEP2020	23/53	1	No	O	NA/TCN	RS (16NOV2020)	N/N
	NEOPL	Malignant melanoma/ Melanoma	2	16NOV2020	53/C	2	No	O	NA/TC/TCN	N	Y/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INFEC	Latent tuberculosis/ Latent Tuberculosis Infection#	2	17FEB2021	146/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1055 10551183	GENRL	Injection site pain/ injection site pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1055 10551187	GENRL	Injection site pain/ injection site pain#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001 1055 10551188	GENRL	Injection site pain/ injection site pain#	3	04JAN2021	1/5	2	Yes		NA	R (08JAN2021)	N/N
		Pyrexia/ low grade fever#	3	04JAN2021	1/2	1	Yes		NA/TC	R (05JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	3	04JAN2021	1/2	2	Yes		NA/TC	R (05JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Chills/ chills#	4	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
		Pyrexia/ fever#	4	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	4	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	04SEP2020	1/3	2	Yes		NA/TC	R (06SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1055 10551189	GENRL	Injection site pain/ Injection site pain	2	26SEP2020	2/2	2	Yes		NA/TC	R (27SEP2020)	N/N
>55/ C4591001 1055 10551191	GENRL	Injection site pain/ Injection site pain#	3	08JAN2021	2/3	1	Yes		NA/TC	R (10JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	3	08JAN2021	2/3	1	Yes		NA/TC	R (10JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
	NERV	Headache/ Headache#	4	28JAN2021	1/3	2	Yes		NA	R (30JAN2021)	N/N
>55/ C4591001 1055 10551192	GASTR	Nausea/ Nausea	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	24SEP2020	1/4	2	Yes		NA/TC	R (27SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	25SEP2020	2/3	2	Yes		NA/TC	R (27SEP2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	04SEP2020	1/3	2	Yes		NA	R (06SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1055 10551194	GENRL	Injection site pain/ Injection Site Pain	2	23SEP2020	1/4	2	Yes		NA	R (26SEP2020)	N/N
	CARD	Tachycardia/ Tachycardia	2	24SEP2020	2/1	2	Yes		NA/TC	R (24SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Chills/ Chills	2	24SEP2020	2/1	3	Yes		NA	R (24SEP2020)	N/N
		Malaise/ Malaise	2	24SEP2020	2/3	3	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1055 10551196	GENRL	Injection site pain/ injection site pain#	3	17DEC2020	1/5	1	Yes		NA/TC	R (21DEC2020)	N/Y
>55/ C4591001 1055 10551197	GENRL	Injection site pain/ Injection site pain	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	INJ&P	Corneal abrasion/ Corneal abrasion	1	24SEP2020	17/6	2	No	O	NA/TC/TCN	R (29SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	29SEP2020	1/45	2	Yes		NA	R (12NOV2020)	N/N
>55/ C4591001 1055 10551199	GENRL	Fatigue/ fatigue#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1055 10551201	GENRL	Injection site pain/ injection site pain#	3	21DEC2020	1/5	1	Yes	NA/TC	R (25DEC2020)	N/N	
		Fatigue/ fatigue#	4	12JAN2021	1/2	1	Yes	NA	R (13JAN2021)	N/N	
		Injection site pain/ injection site pain#	4	12JAN2021	1/5	2	Yes	NA/TC	R (16JAN2021)	N/N	
	GENRL	Injection site bruising/ bruising at injection site#	4	15JAN2021	4/7	2	Yes	NA	R (21JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue	1	11SEP2020	1/2	1	Yes	NA	R (12SEP2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/3	1	Yes	NA	R (13SEP2020)	N/N	
		Chills/ Chills	2	30SEP2020	1/2	2	Yes	NA	R (01OCT2020)	N/N	
		Pyrexia/ Fever	2	30SEP2020	1/2	1	Yes	NA	R (01OCT2020)	N/N	
		MUSC	Myalgia/ Generalized myalgias	1	11SEP2020	3/1	1	Yes	NA	R (11SEP2020)	N/N
	GENRL	NERV	Headache/ Headache	1	11SEP2020	3/1	1	Yes	NA	R (11SEP2020)	N/N
MUSC		Myalgia/ Myalgias	2	04OCT2020	5/3	1	Yes	NA	R (06OCT2020)	N/N	
NERV		Headache/ Headache	2	04OCT2020	5/3	1	Yes	NA	R (06OCT2020)	N/N	
>55/ C4591001	GENRL	Injection site pain/ injection site pain#	4	07JAN2021	1/3	1	Yes	NA	R (09JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1055 10551209 >55/ C4591001 1055 10551210	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/2	2	Yes		NA	R (18DEC2020)	N/N
>55/ C4591001 1055 10551212	GENRL	Injection site pain/ Pain at injection site	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Malaise/ Malaise	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/6	1	Yes		NA/TC	R (06OCT2020)	N/N
>55/ C4591001 1055 10551213	GENRL	Injection site pain/ injection site pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	4	12JAN2021	1/4	1	Yes		NA	R (15JAN2021)	N/N
		Injection site pain/ injection site pain#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	NERV	Headache/ headache#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
>55/ C4591001 1055 10551214	GENRL	Injection site pain/ Injection site pain	1	13SEP2020	4/3	1	Yes		NA	R (15SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
	NERV	Headache/ Headache	2	01OCT2020	2/1	2	Yes		NA/TC	R (01OCT2020)	N/N
	BLOOD	Iron deficiency anaemia/ Iron deficiency anemia	2	18OCT2020	19/	2	No	O	NA/TC	R	N/N
>55/ C4591001 1055 10551216	GENRL	Injection site pain/ injection site pain#	3	14JAN2021	1/2	2	Yes		NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	4	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1055 10551217	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N
>55/ C4591001 1055 10551218	GENRL	Fatigue/ Fatigue	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/15	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1055 10551227	GENRL	Injection site pain/ injection site pain#	3	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ injection site pain#	4	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	4	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N
>55/ C4591001 1055 10551236	GENRL	Injection site pain/ Injection site pain	1	15SEP2020	1/5	2	Yes		NA/TC	R (19SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	05OCT2020	1/3	2	Yes		NA	R (07OCT2020)	N/N
		Injection site pain/ Injection site pain	2	05OCT2020	1/5	2	Yes		NA/TC	R (09OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	05OCT2020	1/3	2	Yes		NA/TC	R (07OCT2020)	N/N
	SKIN	Night sweats/ Night sweats	2	07OCT2020	3/1	2	Yes		NA	R (07OCT2020)	N/N
>55/ C4591001 1055 10551248	GASTR	Diarrhoea/ Diarrhea	2	28NOV2020	5/1	1	Yes		NA	R (28NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ injection site pain#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1056 10561030	GENRL	Pyrexia/ FEVER	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
>55/ C4591001 1056 10561037	GENRL	Chills/ CHILLS#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN#	4	16FEB2021	2/C	1	Yes		NA	RG	N/N
>55/ C4591001 1056 10561040	GENRL	Pyrexia/ FEVER	2	29OCT2020	46/4	1	No	O	NA	R (01NOV2020)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	2	29OCT2020	46/4	1	No	O	NA	R (01NOV2020)	N/N
	NERV	Headache/ HEADACHE	2	29OCT2020	46/4	1	No	O	NA	R (01NOV2020)	N/N
>55/ C4591001 1056 10561064	GENRL	Injection site pain/ PAIN IN INJECTION SITE	1	30AUG2020	4/4	1	Yes		NA	R (02SEP2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ PAIN AT INJECTION SITE LEFT	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine Subject	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1056 10561083 >55/ C4591001 1056 10561086	GENRL	Injection site pain/ TENDERNESS AT INJECTION SITE	1	30AUG2020	2/5	1	Yes	NA	NA	R (03SEP2020)	N/N
>55/ C4591001 1056 10561120	EAR	Tinnitus/ HEARS A NOISE IN HIS RIGHT EAR									/N
>55/ C4591001 1056 10561148	GENRL	Chills/ CHILLS#	4	09FEB2021	2/2	1	Yes	NA	NA	R (10FEB2021)	N/N
		Injection site pain/ INJECTION SITE PAIN LEFT#	4	09FEB2021	2/2	1	Yes	NA	NA	R (10FEB2021)	N/N
		Pyrexia/ FEVER#	4	09FEB2021	2/2	1	Yes	NA	NA	R (10FEB2021)	N/N
>55/ C4591001 1056 10561180	GENRL	Injection site pain/ LEFT ARM INJECTION SITE MUSCLE PAIN	2	28SEP2020	1/4	1	Yes	NA	NA	R (01OCT2020)	N/N
>55/ C4591001 1056 10561257	GENRL	Injection site pain/ INJECTION SITE PAIN	2	05OCT2020	1/2	1	Yes	NA	NA	R (06OCT2020)	N/N
>55/ C4591001 1056 10561302	GENRL	Injection site pain/ PAIN AT INJECTION SITE LEFT#	3	21JAN2021	2/1	1	Yes	NA	NA	R (21JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1056 10561324	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN#	3	21JAN2021	2/1	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Pyrexia/ FEVER	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
>55/ C4591001 1056 10561339	GENRL	Pyrexia/ FEVER#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1056 10561362	INFEC	Rhinitis/ RHINITIS	1	07OCT2020	9/4	1	No	O	NA	R (10OCT2020)	N/N
>55/ C4591001 1056 10561382	SKIN	Pruritus/ PRURITUS AT FOREARMS BACK AND ABDOMEN WITHOUT RASH#	3	23JAN2021	2/5	1	No	O	NA/TC	R (27JAN2021)	N/N
>55/ C4591001 1056 10561416	EAR	Vertigo/ VERTIGO	1	07OCT2020	2/6	1	No	O	NA	R (12OCT2020)	N/N
>55/ C4591001 1056 10561449	GENRL	Chills/ CHILLS	2	26OCT2020	1/6	1	Yes		NA	R (31OCT2020)	N/N
	PSYCH	Anxiety/ ACUTE ANXIETY ATTACK	2	09NOV2020	15/1	1	No	O	NA	R (09NOV2020)	N/N
	GASTR	Stomatitis/ ORAL STOMATITIS	1	11OCT2020	4/4	1	No	O	NA	R (14OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1056 10561454	GASTR	Diarrhoea/ DIARRHEA	2	28OCT2020	1/9	1	Yes		NA	R (05NOV2020)	N/N
	NERV	Headache/ HEADACHE	2	28OCT2020	1/9	1	Yes		NA	R (05NOV2020)	N/N
>55/ C4591001 1056 10561461	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN#	3	19JAN2021	1/4	1	Yes		NA	R (22JAN2021)	N/N
	GASTR	Diarrhoea/ DIARRHEA#	4	08FEB2021	1/1	1	Yes		NA	R (08FEB2021)	N/N
		Vomiting/ VOMIT#	4	08FEB2021	1/1	1	Yes		NA	R (08FEB2021)	N/N
	GENRL	Pyrexia/ FEVER#	4	08FEB2021	1/1	1	Yes		NA	R (08FEB2021)	N/N
>55/ C4591001 1056 10561557	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE LEFT	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N
>55/ C4591001 1056 10561597	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
>55/ C4591001 1056 10561605	GENRL	Pyrexia/ FEVER	2	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N
>55/ C4591001	REPRO	Testicular pain/ RIGHT TESTICULAR PAIN	1	30OCT2020	4/C	1	No	O	NA	RG	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1056 10561616 >55/ C4591001 1057 10571004	GENRL	Chills/ Chills	2	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
		Injection site pain/ Injection Site Soreness	2	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
		Pain/ Body Aches	2	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
		Pyrexia/ Fever	2	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
	SKIN	Rash/ RASH ON TRUNK	2	29SEP2020	30/33	1	Yes		NA	R (31OCT2020)	N/N
>55/ C4591001 1057 10571020	GENRL	Fatigue/ FATIGUE#	4	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
>55/ C4591001 1057 10571052	INFEC	Pneumonia/ PNEUMONIA	2	20SEP2020	12/15	2	No	O	NA/TC	R (04OCT2020)	Y/N
>55/ C4591001 1057 10571063	INJ&P	Chest injury/ Bruised ribs	2	10NOV2020	62/C	2	No	O	NA/TC	N	N/N
		Road traffic accident/ MOTOR VEHICLE ACCIDENT	2	10NOV2020	62/1	2	No	O	NA	R (10NOV2020)	N/N
>55/ C4591001	GENRL	Chills/ CHILLS#	4	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1057 10571066	MUSC	Pain in extremity/ LEFT ARM SORENESS#	4	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N	
>55/ C4591001 1057 10571107	GASTR	Diarrhoea/ DIARRHEA	2	17SEP2020	3/2	1	Yes		NA	R (18SEP2020)	N/N	
>55/ C4591001 1057 10571126	GENRL	Injection site pain/ INJECTION SITE PAIN LEFT ARM#	4	25JAN2021	1/5	1	Yes		NA	R (29JAN2021)	N/N	
>55/ C4591001 1057 10571133	GENRL	Injection site pain/ INJECTION SITE PAIN LEFT ARM#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N	
>55/ C4591001 1057 10571143	SKIN	Skin mass/ ENLARGEMENT OF SUBCUTANEOUS MASS OVER RIGHT SHOULDER BLADE	2	01OCT2020	11/C	1	No	O	NA	N	N/N	
>55/ C4591001 1057 10571150	NEOPL	Lipoma/ LIPOMA RIGHT SIDE OF NECK#	2	10FEB2021	142/C	1	No	O	NA	N	N/N	
>55/ C4591001 1057 10571150	GENRL	Chills/ CHILLS	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N	
		Fatigue/ FATIGUE	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N	
		Injection site pain/ PAIN AT INJECTION SITE	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N	



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>55/ C4591001 1057 10571167	GENRL	Injection site pain/ LEFT ARM SORENESS AT INJECTION SITE#	3	06JAN2021	3/2	1	Yes		NA	R (07JAN2021)	N/N
		Pyrexia/ FEVER#	3	06JAN2021	3/1	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Chills/ CHILLS#	4	26JAN2021	2/6	1	Yes		NA/TC	R (31JAN2021)	N/N
		Fatigue/ FATIGUE#	4	26JAN2021	2/6	1	Yes		NA	R (31JAN2021)	N/N
		Pyrexia/ FEVER#	4	26JAN2021	2/4	1	Yes		NA	R (29JAN2021)	N/N
>55/ C4591001 1057 10571178	MUSC	Pain in extremity/ LEFT ARM PAIN	2	29SEP2020	1/3	2	Yes		NA	R (01OCT2020)	N/N
>55/ C4591001 1057 10571181	GENRL	Pyrexia/ Fever	1	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1057 10571183	GENRL	Fatigue/ FATIGUE#	3	26JAN2021	22/2	1	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ HEADACHE#	3	26JAN2021	22/2	1	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001 1057 10571190	GASTR	Diarrhoea/ LOOSE STOOLS	1	16SEP2020	2/4	1	Yes		NA	R (19SEP2020)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Sluggishness/ SLUGGISHNESS	1	16SEP2020	2/4	1	Yes		NA	R (19SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	1	16SEP2020	2/4	1	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1057 10571290	GENRL	Chills/ Chills	2	29OCT2020	2/3	1	Yes		NA	R (31OCT2020)	N/N
>55/ C4591001 1057 10571306	GENRL	Injection site pain/ Soreness at injection site on left arm	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C4591001 1057 10571327	INFEC	Peritonsillar abscess/ LEFT PERITONSILLAR ABSCESS	1	22OCT2020	7/33	3	No	O	NA/TC/TCN	R (23NOV2020)	Y/N
>55/ C4591001 1057 10571346	GENRL	Chills/ CHILLS	2	09NOV2020	1/6	1	Yes		NA	R (14NOV2020)	N/N
		Fatigue/ FATIGUE	2	09NOV2020	1/6	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ HEADACHE	2	09NOV2020	1/6	1	Yes		NA	R (14NOV2020)	N/N
>55/ C4591001 1066 10661005	RESP	Cough/ dry cough due to air quality	1	30AUG2020	20/2	1	No	O	NA	R (31AUG2020)	N/N
>55/ C4591001	INFEC	Urinary tract infection/ UTI#	3	13FEB2021	19/C	2	No	O	NA/TC	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1066 10661006												
>55/ C4591001 1066 10661007	GENRL	Fatigue/ Fatigue	1	11AUG2020	1/23	1	Yes		NA	R (02SEP2020)	N/N	
>55/ C4591001 1066 10661009	GENRL	Fatigue/ fatigue	1	12AUG2020	1/3	1	Yes		NA	R (14AUG2020)	N/N	
		Injection site pain/ injection site pain	1	12AUG2020	1/4	1	Yes		NA	R (15AUG2020)	N/N	
	GENRL	Injection site erythema/ injection site redness	1	13AUG2020	2/2	1	Yes		NA	R (14AUG2020)	N/N	
>55/ C4591001 1066 10661011	GENRL	Injection site pain/ pain at injection site#	3	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N	
>55/ C4591001 1066 10661012	GENRL	Injection site pain/ Injection site pain	1	13AUG2020	2/2	1	Yes		NA	R (14AUG2020)	N/N	
	GASTR	Diarrhoea/ diarrhea	1	16AUG2020	5/2	1	Yes		NA	R (17AUG2020)	N/N	
	GENRL	Fatigue/ fatigue	1	16AUG2020	5/2	1	Yes		NA	R (17AUG2020)	N/N	
	NERV	Headache/ headache	1	18AUG2020	7/2	1	Yes		NA	R (19AUG2020)	N/N	
>55/ C4591001	GENRL	Injection site pain/ pain at injection site#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1066 10661013	GENRL	Injection site pain/ pain at injection site#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1066 10661014	GENRL	Fatigue/ Fatigue#	4	26JAN2021	1/3	2	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1066 10661016	NERV	Headache/ headache#	4	26JAN2021	1/3	2	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1066 10661017	GENRL	Injection site pain/ injection site pain	1	13AUG2020	2/2	1	Yes		NA	R (14AUG2020)	N/N
>55/ C4591001 1066 10661018	GENRL	Fatigue/ Fatigue#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
>55/ C4591001 1066 10661019	GENRL	Injection site pain/ Left arm pain at injection site#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
>55/ C4591001 1066 10661020	GENRL	Chills/ Chills#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
>55/ C4591001 1066 10661021	NERV	Migraine/ migraine	2	06OCT2020	28/2	2	No	O	NA/TC	R (07OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1066 10661047	GENRL	Fatigue/ Fatigue#	3	03MAR2021	2/8	1	Yes		NA	R (10MAR2021)	N/N
		Pain/ body aches#	3	03MAR2021	2/8	1	Yes		NA	R (10MAR2021)	N/N
>55/ C4591001 1066 10661051	GENRL	Injection site pain/ injection site pain	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
>55/ C4591001 1066 10661052	GENRL	Fatigue/ fatigue#	3	22JAN2021	2/3	1	Yes		NA	R (24JAN2021)	N/N
		Injection site pain/ pain at injection site#	3	22JAN2021	2/3	1	Yes		NA	R (24JAN2021)	N/N
		Fatigue/ fatigue#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1066 10661055	GENRL	Injection site pain/ pain at injection site#	4	12FEB2021	2/3	1	Yes		NA	R (14FEB2021)	N/N
	GASTR	Abdominal distension/ bloating	2	26NOV2020	79/2	1	No	O	NA	R (27NOV2020)	N/N
	GENRL	Dyspepsia/ indigestion	2	26NOV2020	79/2	1	No	O	NA	R (27NOV2020)	N/N
		Fatigue/ fatigue#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
		Injection site pain/ pain at injection site#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1066 10661066	NERV	Dizziness/ dizziness	1	22AUG2020	3/2	1	Yes		NA	R (23AUG2020)	N/N	
	RESP	Epistaxis/ epistaxis	1	22AUG2020	3/2	1	Yes		NA	R (23AUG2020)	N/N	
	GASTR	Vomiting/ vomiting	1	23AUG2020	4/2	1	Yes		NA	R (24AUG2020)	N/N	
	GENRL	Fatigue/ fatigue	1	23AUG2020	4/2	1	Yes		NA	R (24AUG2020)	N/N	
	INFEC	Ear infection/ ear infection	1	22SEP2020	34/6	1	No	O	NA/TC	R (27SEP2020)	N/N	
	GENRL	Pain/ body aches#	3	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N	
>55/ C4591001 1066 10661070	GENRL	Oedema peripheral/ bilateral lower extremity edema	2	25NOV2020	77/C	1	No	O	NA	N	N/N	
>55/ C4591001 1066 10661074	GENRL	Fatigue/ fatigue	1	21AUG2020	2/7	1	Yes		NA	R (27AUG2020)	N/N	
		Pain/ body aches	1	21AUG2020	2/7	1	Yes		NA	R (27AUG2020)	N/N	
	NERV	Headache/ headache	1	21AUG2020	2/7	1	Yes		NA	R (27AUG2020)	N/N	
>55/ C4591001 1066 10661076	GENRL	Injection site pain/ soreness at injection site#	3	23JAN2021	2/3	1	Yes		NA	R (25JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	INFEC	Tooth infection/ infected tooth#	3	05FEB2021	15/6	1	No	O	NA	R (10FEB2021)	N/N	
>55/ C4591001 1066 10661080	NERV	Dizziness/ dizziness	2	24SEP2020	16/2	1	No	O	NA	R (25SEP2020)	N/N	
>55/ C4591001 1066 10661091	GENRL	Gait disturbance/ unsteady gait	1	27AUG2020	3/2	2	Yes		NA	R (28AUG2020)	N/N	
	NERV	Dizziness/ dizziness	1	27AUG2020	3/2	1	Yes		NA	R (28AUG2020)	N/N	
		Mental impairment/ mental fogginess	1	27AUG2020	3/2	2	Yes		NA	R (28AUG2020)	N/N	
		Nystagmus/ 30 to 45 seconds of nystagmus	1	27AUG2020	3/1	2	Yes		NA	R (27AUG2020)	N/N	
	NERV	Dizziness/ dizziness	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N	
	GENRL	Fatigue/ fatigue#	3	17DEC2020	1/4	1	Yes		NA	R (20DEC2020)	N/N	
		Injection site pain/ pain at injection site#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N	
>55/ C4591001 1066 10661103	GENRL	Chills/ chills#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N	
		Pain/ body aches#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N	
		Pyrexia/ fever#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1066 10661109	GENRL	Injection site pain/ injection site pain	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
>55/ C4591001 1066 10661114	MUSC	Bursitis/ bursitis left knee	1	03SEP2020	9/7	1	No	O	NA/TC	R (09SEP2020)	N/N
>55/ C4591001 1066 10661128	MUSC	Arthralgia/ right shoulder pain	1	01SEP2020	6/C	1	No	O	NA	N	N/N
	NERV	Headache/ intermittent headaches	1	01SEP2020	6/C	1	No	O	NA	N	N/N
>55/ C4591001 1066 10661134	INFEC	Localised infection/ infected right index finger	2	10OCT2020	24/11	1	No	O	NA/TC	R (20OCT2020)	N/N
	INV	Mean cell volume decreased/ low MCV value on CBC	2	14OCT2020	28/C	1	No	O	NA	N	N/N
>55/ C4591001 1066 10661150	GENRL	Injection site pain/ pain at injection site#	3	19DEC2020	2/3	1	Yes		NA	R (21DEC2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
>55/ C4591001 1066 10661153	GENRL	Pain/ body aches	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Pyrexia/ fever	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N	
>55/ C4591001 1066 10661171	INJ&P	Upper limb fracture/ fractured right arm#	3	16FEB2021	21/C	2	No	O	NA	N	N/N	
>55/ C4591001 1066 10661175	GENRL	Chills/ chills	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N	
		Pain/ body aches	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
>55/ C4591001 1066 10661176	GENRL	Fatigue/ Fatigue#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N	
>55/ C4591001 1066 10661207	GENRL	Injection site pain/ soreness at injection site#	4	12JAN2021	2/6	1	Yes		NA	R (17JAN2021)	N/N	
>55/ C4591001 1066 10661213	GENRL	Chills/ chills#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N	
		Fatigue/ fatigue#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N	
		Pain/ body aches#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1066 10661222	GENRL	Fatigue/ fatigue#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
		Injection site pain/ pain at injection site#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1066 10661227	GENRL	Injection site pain/ pain at injection site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
>55/ C4591001 1066 10661228	GENRL	Injection site pain/ tenderness at injection site#	3	19JAN2021	1/3	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
		Injection site pain/ pain at injection site#	4	10FEB2021	2/3	1	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1066 10661231	GENRL	Injection site erythema/ redness at injection site	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
>55/ C4591001 1066 10661234	GENRL	Chills/ chills	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		Fatigue/ fatigue	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1066 10661240	GENRL	Pain/ body aches	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C4591001 1066 10661244	GENRL	Injection site pain/ pain at injection site#	3	12FEB2021	2/3	1	Yes		NA	R (14FEB2021)	N/N
>55/ C4591001 1066 10661255	GENRL	Pyrexia/ fever	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N
		Pain/ body aches	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
>55/ C4591001 1066 10661266	GENRL	Injection site pain/ pain at injection site#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Chills/ chills#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
		Pain/ body aches#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1066 10661292	GENRL	Pain/ body aches	2	15OCT2020	2/4	1	Yes		NA	R (18OCT2020)	N/N
>55/ C4591001	SKIN	Hyperhidrosis/ sweating	1	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine Subject	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1066 10661298	GENRL	Injection site pain/ pain at injection site	1	01OCT2020	2/3	1	Yes	NA		R (03OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	23OCT2020	1/3	1	Yes	NA		R (25OCT2020)	N/N
>55/ C4591001 1066 10661303	GENRL	Pain/ body aches	2	16OCT2020	1/3	1	Yes	NA		R (18OCT2020)	N/N
		Pyrexia/ fever	2	16OCT2020	1/2	1	Yes	NA		R (17OCT2020)	N/N
	NERV	Headache/ headache	2	17OCT2020	2/2	1	Yes	NA		R (18OCT2020)	N/N
>55/ C4591001 1066 10661304	GENRL	Pain/ body aches#	3	27JAN2021	2/2	1	Yes	NA		R (28JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	16FEB2021	2/3	1	Yes	NA		R (18FEB2021)	N/N
	MUSC	Arthralgia/ joint pain#	4	16FEB2021	2/2	1	Yes	NA		R (17FEB2021)	N/N
	NERV	Headache/ headache#	4	16FEB2021	2/2	1	Yes	NA		R (17FEB2021)	N/N
>55/ C4591001 1066 10661313	GENRL	Injection site pain/ soreness at injection site#	3	28JAN2021	2/3	1	Yes	NA		R (30JAN2021)	N/N
	NERV	Headache/ headache#	3	28JAN2021	2/2	1	Yes	NA		R (29JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1066 10661314	GENRL	Chills/ Chills#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
>55/ C4591001 1066 10661318	GENRL	Pain/ body aches	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
		Pyrexia/ fever	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
>55/ C4591001 1066 10661327	GASTR	Diarrhoea/ diarrhea	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N
		Vomiting/ vomiting	2	02NOV2020	1/1	1	Yes		NA	R (02NOV2020)	N/N
	GENRL	Chills/ chills	2	02NOV2020	1/1	1	Yes		NA	R (02NOV2020)	N/N
		Fatigue/ fatigue	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/N
		Pain/ body aches	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/N
>55/ C4591001 1066 10661328	GENRL	Chills/ chills	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N
>55/ C4591001 1066 10661334	GENRL	Fatigue/ fatigue	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Pyrexia/ fever	2	05NOV2020	2/1	1	Yes		NA/TC	R (05NOV2020)	N/N
	NERV	Headache/ headache	2	05NOV2020	2/3	1	Yes		NA	R (07NOV2020)	N/N
	SKIN	Hyperhidrosis/ sweating	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
>55/ C4591001 1066 10661350	CARD	Myocardial infarction/ myocardial infarction	1	03NOV2020	16/1	4	No	O	P/W	F (03NOV2020)	Y/N
>55/ C4591001 1066 10661351	GENRL	Injection site pain/ pain at injection site	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	10NOV2020	2/3	1	Yes		NA	R (12NOV2020)	N/N
>55/ C4591001 1066 10661352	MUSC	Pain in jaw/ jaw pain	2	23DEC2020	45/2	1	No	O	NA	R (24DEC2020)	N/N
>55/ C4591001 1066 10661353	GENRL	Chills/ chills	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
		Injection site pain/ pain at injection site	1	19OCT2020	1/3	1	Yes		NA	R (21OCT2020)	N/N
>55/ C4591001 1066 10661354	GENRL	Injection site pain/ pain at injection site	1	20OCT2020	1/4	1	Yes		NA	R (23OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Malaise/ malaise	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
>55/ C4591001 1066 10661357	GENRL	Fatigue/ fatigue	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N
		Pain/ body aches	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N
>55/ C4591001 1066 10661362	GENRL	Pain/ body aches#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
		Pyrexia/ Fever#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1066 10661374	GENRL	Injection site pain/ pain at injection site	2	13NOV2020	2/4	1	Yes		NA	R (16NOV2020)	N/N
>55/ C4591001 1066 10661376	GENRL	Pain/ body aches	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N
		Pyrexia/ fever	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N
	NERV	Headache/ headache	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N
>55/ C4591001 1066 10661383	GENRL	Injection site pain/ pain at injection site	1	24OCT2020	2/4	1	Yes		NA	R (27OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1066 10661384	GENRL	Injection site pain/ pain at injection site	2	13NOV2020	1/5	1	Yes		NA	R (17NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	17NOV2020	2/2	1	Yes		NA	R (18NOV2020)	N/N
>55/ C4591001 1068 10681004		Injection site swelling/ swelling at injection site	2	17NOV2020	2/3	1	Yes		NA	R (19NOV2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	19AUG2020	1/4	1	Yes		NA/TC/TCN	R (22AUG2020)	N/N
		Pyrexia/ Fever	1	19AUG2020	1/2	1	Yes		NA/TC/TCN	R (20AUG2020)	N/N
	NERV	Headache/ Headache	1	19AUG2020	1/4	1	Yes		NA/TC/TCN	R (22AUG2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	09SEP2020	1/6	1	Yes		NA/TC	R (14SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	10SEP2020	2/3	1	Yes		NA/TC/TCN	R (12SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
	NERV	Headache/ Headache	2	10SEP2020	2/3	1	Yes		NA/TC	R (12SEP2020)	N/N
>55/ C4591001 1068 10681008	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/2	1	Yes		NA/TC	R (20AUG2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Generalized Muscle Aches	1	20AUG2020	2/1	1	Yes		NA/TC/TCN	R (20AUG2020)	N/N
	GENRL	Chills/ Chills	2	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N
		Injection site pain/ Injection site pain	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ Fever	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ Headache	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1068 10681009	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/2	1	Yes		NA/TC	R (20AUG2020)	N/N
	MUSC	Myalgia/ Muscle Aches	1	20AUG2020	2/1	1	Yes		NA/TC	R (20AUG2020)	N/N
>55/ C4591001 1068 10681014	GENRL	Feeling abnormal/ brain fog#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
		Injection site pain/ injection site pain#	4	18FEB2021	1/4	1	Yes		NA	R (21FEB2021)	N/N
	NERV	Headache/ headache#	4	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
>55/ C4591001 1068 10681015	GENRL	Feeling abnormal/ brain fog#	3	29JAN2021	1/4	1	Yes		NA	R (01FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1068 10681019	NERV	Headache/ headache#	3	29JAN2021	1/4	1	Yes		NA	R (01FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Chills/ Chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1068 10681020		Pyrexia/ Fever	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	NERV	Headache/ Headache	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	1	23AUG2020	3/5	1	Yes		NA/TC	R (27AUG2020)	N/N
>55/ C4591001 1068 10681023	GENRL	Injection site pain/ Pain at injection site	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N
>55/ C4591001 1068 10681030	SKIN	Rash/ Rash on legs	1	24AUG2020	4/2	1	Yes		NA	R (25AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	SKIN	Rash/ Rash on arms and trunk	2	13SEP2020	3/3	1	Yes		NA	R (15SEP2020)	N/N
	MUSC	Myalgia/ generalized muscle pain	1	24AUG2020	1/4	1	Yes		NA	R (27AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1068 10681032	MUSC	Myalgia/ muscle aches#	4	26FEB2021	1/2	1	Yes		NA	R (27FEB2021)	N/N
>55/ C4591001 1068 10681033	SKIN	Skin induration/ Firm swelling induration on left arm	1	29AUG2020	6/C	1	Yes		NA	RG	N/N
>55/ C4591001 1068 10681040	GENRL	Chills/ chills#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
>55/ C4591001 1068 10681041	GENRL	Fatigue/ Fatigue	1	26AUG2020	1/3	2	Yes		NA	R (28AUG2020)	N/N
		Injection site pain/ Injection site pain	1	26AUG2020	1/3	2	Yes		NA	R (28AUG2020)	N/N
	NERV	Headache/ Headache	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
	RESP	Asthma/ Asthma exacerbation	1	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/N
	MUSC	Arthralgia/ Joint pain	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N
	NERV	Headache/ Headache	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Chills/ Chills	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Fatigue/ Fatigue	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Pyrexia/ Fever	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Arthralgia/ Joint Aches	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
		Myalgia/ Muscle Aches	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
>55/ C4591001 1068 10681045	INJ&P	Respiratory fume inhalation disorder/ cough from wildfire smoke per provider and air quality index	1	13SEP2020	19/6	1	No	O	NA	R (18SEP2020)	N/N
>55/ C4591001 1068 10681050	GENRL	Injection site pain/ Injection site pain, left arm	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
		Pyrexia/ Fever	1	27AUG2020	1/4	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Chills/ Chills	2	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ Fever	2	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1068 10681055	GENRL	Injection site pain/ injection site pain#	3	18DEC2020	1/2	1	Yes		NA/TC	R (19DEC2020)	N/N
>55/ C4591001 1068 10681056	GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Diarrhoea/ Diarrhea	1	29AUG2020	3/1	1	No	O	NA	R (29AUG2020)	N/N
	GENRL	Chills/ Chills	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001 1068 10681057	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	1/5	1	Yes		NA/TC/TCN	R (31AUG2020)	N/N
>55/ C4591001 1068 10681059	GENRL	Injection site erythema/ Redness at injection site (2 inch diameter)	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
		Injection site pain/ Injection Site Pain	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
>55/ C4591001 1068 10681062	INV	Glomerular filtration rate decreased/ Decreased GFR	1	03SEP2020	7/C	1	No	O	NA	N	N/N
>55/ C4591001 1068 10681063	GASTR	Nausea/ nausea#	4	26FEB2021	1/1	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	26FEB2021	1/3	2	Yes		NA	R (28FEB2021)	N/N
		Injection site pain/ injection site pain#	4	26FEB2021	1/3	1	Yes		NA	R (28FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	26FEB2021	1/2	1	Yes		NA	R (27FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache#	4	26FEB2021	1/3	2	Yes		NA	R (28FEB2021)	N/N
	PSYCH	Restlessness/ restlessness#	4	26FEB2021	1/2	2	Yes		NA	R (27FEB2021)	N/N
	GENRL	Chills/ chills#	4	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
		Pyrexia/ fever (101.5F)#	4	27FEB2021	2/1	1	Yes		NA	R (27FEB2021)	N/N
>55/ C4591001 1068 10681075	ENDO	Hypothyroidism/ hypothyroidism	2	09OCT2020	19/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1068 10681078	GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/6	1	Yes		NA	R (05SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain Left Back	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Chills/ Chills	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
>55/ C4591001 1068 10681079	MUSC	Myalgia/ Muscle aches	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	INFEC	Meningitis bacterial/ Suspected bacterial meningitis#	2	06FEB2021	139/15	3	No	O	NA/TC	R (20FEB2021)	Y/N
>55/ C4591001	GENRL	Fatigue/ Fatigue	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1068 10681082	NERV	Headache/ Head Ache	1	31AUG2020	1/2	1	Yes		NA/TC/TCN	R (01SEP2020)	N/Y
	MUSC	Arthralgia/ Left shoulder pain	1	01SEP2020	2/1	1	No	O	NA/TC/TCN	R (01SEP2020)	N/N
		Neck pain/ Left neck pain	1	01SEP2020	2/7	1	No	O	NA/TC/TCN	R (07SEP2020)	N/N
>55/ C4591001 1068 10681084	GENRL	Injection site pain/ Pain at injection site	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	NERV	Headache/ Headache	1	01SEP2020	1/3	1	Yes		NA/TC	R (03SEP2020)	N/N
>55/ C4591001 1068 10681088	GENRL	Injection site pain/ Pain at injection site	1	02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N
>55/ C4591001 1068 10681090	GENRL	Injection site pain/ Pain at the injection site	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
	NERV	Headache/ Headache	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C4591001	INJ&P	Fall/ Fall	2	20JAN2021	120/1	2	No	O	NA/TCN	R (20JAN2021)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1068 10681091		Hip fracture/ Left Hip Fracture	2	20JAN2021	120/C	4	No	O	NA/TCN	RG	Y/N
	NERV	Syncope/ Syncope Episode	2	22JAN2021	122/1	1	No	O	NA	R (22JAN2021)	N/N
	VASC	Orthostatic hypotension/ orthostatic hypotension	2	22JAN2021	122/1	1	No	O	NA	R (22JAN2021)	N/N
>55/ C4591001 1068 10681092	RENAL	Nephrolithiasis/ nephrolithiasis	1	04SEP2020	3/1	2	No	O	NA/TC	R (04SEP2020)	N/N
>55/ C4591001 1068 10681093	GENRL	Injection site pain/ pain at the injection site#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
>55/ C4591001 1068 10681094	GENRL	Injection site pain/ pain at the injection site#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	NERV	Headache/ headache#	3	21DEC2020	1/2	1	Yes		NA/TC	R (22DEC2020)	N/N
	METAB	Hyperglycaemia/ hyperglycemia#	3	22DEC2020	2/1	1	Yes		NA/TC/TCN	R (22DEC2020)	N/N
	NERV	Headache/ headache#	4	13JAN2021	2/1	1	Yes		NA/TC	R (13JAN2021)	N/N
>55/ C4591001 1068 10681095	GENRL	Injection site pain/ Pain at the injection site	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/Y



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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Vessel puncture site bruise/ Bruising of arm from blood draw	1	03SEP2020	2/8	1	No	O	NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ Fever	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1068 10681096	GASTR	Nausea/ Nausea	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Myalgia/ Mynlgia	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1068 10681101	GENRL	Chills/ chills	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		Injection site pain/ Injection Site Soreness	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1068 10681104	GASTR	Diarrhoea/ Diarrhea	2	25SEP2020	1/7	1	Yes		NA	R (01OCT2020)	N/N
		Nausea/ Nausea	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Chills/ Chills	2	25SEP2020	1/5	1	Yes		NA	R (29SEP2020)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1068 10681105	MUSC	Fatigue/ Fatigue	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		Myalgia/ Muscle Aches	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ Headache	2	28SEP2020	4/22	1	Yes		NA/TC	R (19OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	04FEB2021	1/4	1	Yes		NA	R (07FEB2021)	N/N
>55/ C4591001 1068 10681111	NERV	Headache/ headache#	3	04FEB2021	1/4	1	Yes		NA	R (07FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Swollen Cervical Lymph Nodes bilateral	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
	RESP	Rhinorrhoea/ Rhinorrhea	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
>55/ C4591001 1068 10681118		Sneezing/ Sneezing	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
	GENRL	Chills/ Chills	1	10SEP2020	1/5	1	Yes		NA	R (14SEP2020)	N/N
	NERV	Headache/ Headache	1	10SEP2020	1/5	1	Yes		NA/TC	R (14SEP2020)	N/N
	NERV	Headache/ Mild Headache	2	30SEP2020	1/3	1	Yes		NA/TC	R (02OCT2020)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1068 10681120	NERV	Headache/ headache#	4	13MAR2021	2/1	2	Yes		NA	R (13MAR2021)	N/N
>55/ C4591001 1068 10681122	GENRL	Fatigue/ Fatigue	1	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	25SEP2020	1/3	1	Yes		NA/TC	R (27SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	1	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
>55/ C4591001 1071 10711023	CARD	Coronary artery disease/ WORSENING coronary artery disease	1	23AUG2020	12/9	2	No	O	P/TCN/W	R (31AUG2020)	Y/N
>55/ C4591001 1071 10711031	NERV	Headache/ HEADACHE#	4	11FEB2021	1/31	1	Yes		NA	R (13MAR2021)	N/N
>55/ C4591001 1071 10711033	GENRL	Fatigue/ FATIGUE	1	18AUG2020	6/15	2	No	O	NA	R (01SEP2020)	N/N
>55/ C4591001 1071 10711035	GENRL	Injection site bruising/ SMALL BRUISE AT INJECTION SITE	1	13AUG2020	1/2	1	Yes		NA	R (14AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1071 10711051	MUSC	Limb discomfort/ LEG DISCOMFORT	2	09SEP2020	9/3	1	No	O	NA	R (11SEP2020)	N/N
	NERV	Tremor/ LEFT ARM TREMOR	1	30AUG2020	14/1	1	No	O	NA	R (30AUG2020)	N/N
>55/ C4591001 1071 10711052	GENRL	Fatigue/ FATIGUE#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
>55/ C4591001 1071 10711052	GENRL	Injection site pain/ INJECTION SITE PAIN	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
>55/ C4591001 1071 10711053	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
>55/ C4591001 1071 10711060	GENRL	Injection site swelling/ SWELLING AT INJECTION SITE	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
>55/ C4591001 1071 10711067	MUSC	Musculoskeletal stiffness/ MUSCLE STIFFNESS	1	07SEP2020	20/3	1	No	O	NA	R (09SEP2020)	N/N
	GENRL	Chills/ CHILLS#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ HEADACHE#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1071 10711068	MUSC	Pain in extremity/ SORE ARM#	4	11FEB2021	1/4	1	Yes		NA	R (14FEB2021)	N/N
>55/ C4591001 1071 10711069	GENRL	Injection site pain/ INJECTION SITE PAIN	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
>55/ C4591001 1071 10711070	GENRL	Injection site pain/ INJECTION SITE PAIN	1	20AUG2020	1/3	2	Yes		NA	R (22AUG2020)	N/N
>55/ C4591001 1071 10711071	RESP	Rhinorrhoea/ INTERMITTENT RUNNY NOSE	1	20AUG2020	1/21	1	No	O	NA	R (09SEP2020)	N/N
>55/ C4591001 1071 10711076	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
>55/ C4591001 1071 10711077	GENRL	Injection site bruising/ INJECTION SITE BRUISING	1	22AUG2020	2/26	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
	GENRL	Pyrexia/ FEVER#	4	16JAN2021	1/3	1	Yes		NA	R (18JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ CHILLS#	4	17JAN2021	2/1	1	Yes		NA	R (17JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	17JAN2021	2/1	1	Yes		NA	R (17JAN2021)	N/N
>55/ C4591001 1071 10711078	MUSC	Arthralgia/ JOINT PAIN IN KNEES	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
>55/ C4591001 1071 10711084	GENRL	Fatigue/ FATIGUE	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		Injection site erythema/ REDNESS AT INJECTION SITE	2	14SEP2020	1/12	2	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1071 10711088	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
	INFEC	Injection site abscess/ ABSCCESS AROUND INJECTION SITE LEFT ARM	2	21SEP2020	7/24	2	Yes		NA	R (14OCT2020)	N/N
>55/ C4591001 1071 10711091	GENRL	Fatigue/ FATIGUE#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Injection site bruising/ BRUISING AT INJECTION SITE#	4	10MAR2021	29/C	1	Yes		NA	N	N/N
>55/ C4591001	RESP	Nasal congestion/ LEFT NOSTRIL CONGESTION#	4	18FEB2021	1/C	1	No	O	NA	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1071 10711101	MUSC	Arthralgia/ BILATERAL SHOULDER PAIN#	4	20FEB2021	3/C	1	Yes		NA	N	N/N	
>55/ C4591001 1071 10711112	GASTR	Diarrhoea/ DIARRHEA	1	13SEP2020	17/1	1	No	O	NA	R (13SEP2020)	N/N	
>55/ C4591001 1071 10711120	MUSC	Pain in extremity/ SORE ARM#	4	12FEB2021	2/4	1	No	O	NA	R (15FEB2021)	N/N	
>55/ C4591001 1071 10711120	INJ&P	Arthropod bite/ INSECT BITES	1	16SEP2020	15/15	1	No	O	NA	R (30SEP2020)	N/N	
>55/ C4591001 1071 10711121	GENRL	Pyrexia/ FEVER	1	18SEP2020	17/2	1	No	O	NA	R (19SEP2020)	N/N	
>55/ C4591001 1071 10711121	GENRL	Chills/ CHILLS	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
>55/ C4591001 1071 10711122	MUSC	Pain in extremity/ SORE LEFT ARM#	4	21FEB2021	2/2	1	Yes		NA	R (22FEB2021)	N/N	
>55/ C4591001 1071 10711126	RESP	Nasal congestion/ NASAL CONGESTION	1	21SEP2020	19/2	1	No	O	NA	R (22SEP2020)	N/N	
		Wheezing/ WHEEZING	1	21SEP2020	19/2	1	No	O	NA	R (22SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1071 10711134	GASTR	Vomiting/ VOMITING	2	10OCT2020	16/1	1	No	O	NA	R (10OCT2020)	N/N
>55/ C4591001 1071 10711139	GASTR	Nausea/ NAUSEA	1	19SEP2020	12/2	1	No	O	NA	R (20SEP2020)	N/N
	RESP	Cough/ COUGH	1	19SEP2020	12/2	1	No	O	NA	R (20SEP2020)	N/N
>55/ C4591001 1071 10711144	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Injection site swelling/ SWELLING AT INJECTION SITE	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
>55/ C4591001 1071 10711165	GENRL	Fatigue/ FATIGUE#	3	30JAN2021	1/2	1	Yes		NA	R (31JAN2021)	N/N
>55/ C4591001 1071 10711169	INJ&P	Alcohol poisoning/ ACUTE ALCOHOL INTOXICATION	1	02OCT2020	18/14	2	No	O	P/W	R (15OCT2020)	Y/N
>55/ C4591001 1071 10711172	PSYCH	Confusional state/ MENTAL CONFUSION#	4	27FEB2021	8/1	1	No	O	NA	R (27FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	VASC	Hypertension/ HYPERTENSION#	4	27FEB2021	8/2	3	No	O	NA/TC	RS (28FEB2021)	Y/N
	VASC	Hypertension/ HYPERTENSION#	4	28FEB2021	9/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1071 10711178	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
		Pyrexia/ FEVER	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
	GENRL	Injection site swelling/ SWELLING ST INJECTION SITE	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
>55/ C4591001 1071 10711179	GENRL	Chills/ CHILLS#	4	17JAN2021	2/1	1	Yes		NA	R (17JAN2021)	N/N
>55/ C4591001 1071 10711180	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
>55/ C4591001	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1071 10711181		Injection site pain/ PAIN AT THE INJECTION SITE	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N	
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N	
>55/ C4591001 1071 10711190	MUSC	Myalgia/ MUSCLE ACHE#	3	02FEB2021	4/8	1	Yes		NA	R (09FEB2021)	N/N	
>55/ C4591001 1071 10711207	GENRL	Pyrexia/ LOW GRADE FEVER	1	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N	
>55/ C4591001 1071 10711240	GENRL	Injection site pain/ SORENESS AT INJECTION SITE#	3	15FEB2021	2/2	1	Yes		NA	R (16FEB2021)	N/N	
>55/ C4591001 1072 10721005	GASTR	Tongue pruritus/ Sides of tongue itching	2	08SEP2020	1/1	1	Yes		NA/TC	R (08SEP2020)	N/Y	
>55/ C4591001 1072 10721007	NERV	Transient ischaemic attack/ Transient Ischaemic Attack	1	04SEP2020	19/6	2	No	O	NA/TC/TCN	R (09SEP2020)	Y/N	
>55/ C4591001 1072 10721014	INJ&P	Burn oral cavity/ Burn in mouth	1	06SEP2020	19/6	1	No	O	NA/TC	R (11SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1072 10721018	NERV	Dizziness/ DIZZINESS	2	06OCT2020	28/2	1	No	O	NA	R (07OCT2020)	N/N
>55/ C4591001 1072 10721038	VASC	Hypertension/ HYPERTENSION#	2	02FEB2021	140/C	1	No	CND	NA/TC/TCN	N	N/N
>55/ C4591001 1072 10721064	EAR	Vertigo/ vertigo	1	31AUG2020	4/1	1	No	CD	NA	R (31AUG2020)	N/N
	CARD	Myocardial infarction/ myocardial infarction#	3	06MAR2021	16/4	3	No	O	NA/TC/TCN	RS (09MAR2021)	Y/N
>55/ C4591001 1077 10771006	INJ&P	Fall/ FALL	1	27AUG2020	18/1	2	No	O	NA	R (27AUG2020)	N/N
		Rib fracture/ TWO FRACTURED RIBS	1	27AUG2020	18/75	2	No	O	NA/TC	R (09NOV2020)	N/N
>55/ C4591001 1077 10771012	METAB	Hyperlipidaemia/ HYPERLIPIDEMIA#	2	28JAN2021	151/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1077 10771039	PSYCH	Anxiety/ WORSENING ANXIETY	1	20AUG2020	9/C	1	No	O	NA/TC	N	N/N
>55/ C4591001	INFEC	Acute sinusitis/ ACUTE SINUSITIS	2	25SEP2020	18/14	2	No	O	NA/TC	R (08OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1077 10771047	GENRL	Fatigue/ FATIGUE	1	21AUG2020	5/2	2	Yes		NA	R (22AUG2020)	N/N
>55/ C4591001 1077 10771048	NERV	Headache/ HEADACHE	1	21AUG2020	5/3	1	Yes		NA	R (23AUG2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N
		Injection site erythema/ REDNESS AT INJECTION SITE- LEFT ARM	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
		Injection site swelling/ SWELLING AT INJECTION SITE- LEFT ARM	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1077 10771049	NERV	Facial paralysis/ BELL'S PALSY, RIGHT SIDE	2	25OCT2020	48/30	2	No	O	NA/TC	R (23NOV2020)	N/N
>55/ C4591001 1077 10771056	VASC	Hypertension/ WORSENING HYPERTENSION#	3	17FEB2021	22/C	1	No	O	NA	N	N/N
>55/ C4591001 1077 10771059	GENRL	Fatigue/ FATIGUE	1	22AUG2020	5/2	2	Yes		NA	R (23AUG2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	23AUG2020	6/2	1	Yes		NA	R (24AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1077 10771064	INJ&P	Skin abrasion/ RIGHT FOREARM ABRASIONS	2	16SEP2020	8/3	1	No	O	NA/TC	R (18SEP2020)	N/N
>55/ C4591001 1077 10771065	NERV	Dizziness/ ACUTE DIZZINESS	2	10JAN2021	124/6	1	No	O	NA/TCN	R (15JAN2021)	N/N
>55/ C4591001 1077 10771088	GENRL	Injection site pain/ PAIN AT INJECTION SITE- LEFT ARM	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
	METAB	Hyperlipidaemia/ HYPERLIPIDEMIA	2	08DEC2020	86/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1077 10771090	NERV	Neuralgia/ ACUTE DIFFUSE NEURALGIA	2	17OCT2020	34/67	1	No	O	NA	R (22DEC2020)	N/N
>55/ C4591001 1077 10771095	GENRL	Injection site swelling/ SWELLING AT INJECTION SITE- RIGHT ARM	1	26AUG2020	3/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	28AUG2020	5/2	2	Yes		NA	R (29AUG2020)	N/N
	NERV	Headache/ HEADACHE	1	28AUG2020	5/2	1	Yes		NA	R (29AUG2020)	N/N
>55/ C4591001 1077 10771099	VASC	Hot flush/ INTERMITTENT HOT FLASHES	1	25AUG2020	1/119	1	No	O	NA	R (21DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	INJ&P	Concussion/ CONCUSSION	2	31JAN2021	139/C	2	No	O	NA	N	N/N	
>55/ C4591001 1077 10771106	EYE	Dry eye/ WORSENING CHRONIC DRY EYE#	2	05FEB2021	144/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1077 10771111	INJ&P	Wound/ PUNCTURE WOUNDS, BILATERAL HANDS	1	25AUG2020	1/11	2	No	O	NA/TC	R (04SEP2020)	N/N	
>55/ C4591001 1077 10771112	RENAL	Nephrolithiasis/ KIDNEY STONES, RIGHT KIDNEY	2	18OCT2020	33/15	1	No	O	NA/TC	R (01NOV2020)	N/N	
>55/ C4591001 1077 10771115	GENRL	Injection site pain/ PAIN AT INJECTION SITE- LEFT ARM	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N	
>55/ C4591001 1077 10771121	GENRL	Injection site pain/ PAIN AT INJECTION SITE- LEFT ARM	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N	
	VASC	Hypertension/ HYPERTENSION#	4	10FEB2021	23/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1077 10771164	INJ&P	Animal bite/ DOG BITE	1	16SEP2020	15/1	1	No	O	NA/TC	R (16SEP2020)	N/N	
		Skin abrasion/ RIGHT FOREARM ABRASIONS	1	16SEP2020	15/3	1	No	O	NA/TC	R (18SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	INJ&P	Fall/ FALL	2	25NOV2020	66/1	1	No	O	NA	R (25NOV2020)	N/N	
		Ligament rupture/ THREE TORN LIGAMENTS IN LEFT ANKLE	2	25NOV2020	66/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1077 10771168	INJ&P	Contusion/ CONTUSION ON LEFT SIDE OF FACE#	2	12MAR2021	173/C	2	No	O	NA	RG	N/N	
		Fall/ FALL#	2	12MAR2021	173/1	2	No	O	NA	R (12MAR2021)	N/N	
>55/ C4591001 1077 10771179	MUSC	Muscle spasms/ WORSENING BACK SPASMS	2	07OCT2020	16/C	1	No	O	NA	N	N/N	
>55/ C4591001 1077 10771180	IMMUN	Seasonal allergy/ WORSENING SEASONAL ALLERGIES	2	29SEP2020	8/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1077 10771187	INFEC	Conjunctivitis/ CONJUNCTIVITIS#	3	18JAN2021	1/C	1	No	O	NA	RG	N/N	
>55/ C4591001 1077 10771191	SKIN	Dermatitis contact/ POISON IVY RASH	2	22OCT2020	30/15	1	No	O	NA/TC	R (05NOV2020)	N/N	
>55/ C4591001 1077 10771194	GASTR	Aphthous ulcer/ RECURRENT ORAL APTHAE	1	12SEP2020	9/C	1	No	O	NA/TC	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1077 10771223		Stomatitis/ ORAL MUCOSITIS	1	12SEP2020	9/C	1	No	O	NA/TC	N	N/N	
	INFEC	Cellulitis/ CELLULITIS RIGHT 5TH FINGER	2	08OCT2020	14/12	1	No	O	NA/TC	R (19OCT2020)	N/N	
	CARD	Acute myocardial infarction/ ST ELEVATION MYOCARDIAL INFARCTION (STEMI)	2	28JAN2021	126/3	4	No	O	NA/TC	R (30JAN2021)	Y/N	
		Coronary artery disease/ CORONARY ARTERY DISEASE	2	28JAN2021	126/C	2	No	O	NA/TC	N	N/N	
	GENRL	Chest pain/ ACUTE CHEST PAIN	2	01FEB2021	130/2	1	No	O	NA/TC	R (02FEB2021)	N/N	
	EAR	Vertigo/ VERTIGO	2	01OCT2020	2/34	1	Yes		NA/TC	R (03NOV2020)	N/N	
	MUSC	Spinal osteoarthritis/ WORSENING OSTEOARTHRITIS, NECK	2	10OCT2020	11/32	2	No	O	NA/TC	R (10NOV2020)	N/N	
	RENAL	Nephrolithiasis/ BILATERAL KIDNEY STONES	2	29NOV2020	59/C	2	No	O	NA/TCN	N	Y/N	
	INFEC	Labyrinthitis/ LABYRINTHITIS	2	23NOV2020	15/15	1	No	O	NA/TC	R (07DEC2020)	N/N	
	PSYCH	Depression/ DEPRESSION	2	NOV2020	1/C	1	No	O	NA/TC	N	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1079 10791020	INJ&P	Fall/ Fall (patient tripped over shoe and hit the ground)*		31JUL2020	1/1	1	No	O	NA	R (31JUL2020)	N/N
>55/ C4591001 1079 10791044	MUSC	Osteoarthritis/ Worsening of Osteoarthritis Bilateral Knee	2	05OCT2020	42/64	2	No	O	NA/TC/TCN	R (07DEC2020)	Y/N
>55/ C4591001 1079 10791076	NEOPL	Uterine cancer/ Uterine Cancer#	2	25JAN2021	151/C	4	No	O	NA/TC/TCN	RG	Y/N
>55/ C4591001 1079 10791078	INFEC	Skin bacterial infection/ BACTERIAL SKIN INFECTION RIGHT BREAST	1	17AUG2020	11/12	1	No	O	NA/TC/TCN	R (28AUG2020)	N/N
>55/ C4591001 1079 10791103	NERV	Carpal tunnel syndrome/ Worsening Carpal Tunnel Syndrome on right hand	2	01JAN2021	123/70	2	No	O	NA	R (11MAR2021)	N/N
>55/ C4591001 1079 10791111	RESP	Chronic obstructive pulmonary disease/ COPD Exacerbation	1	19AUG2020	8/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1079 10791128	NERV	Headache/ Headache	1	19AUG2020	7/3	1	Yes		NA	R (21AUG2020)	N/N
>55/ C4591001 1079 10791158	VASC	Hypertension/ Worsening Hypertension	2	28DEC2020	61/32	2	No	CD	NA/TC	R (28JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1079 10791183	INV	Blood cholesterol increased/ Elevated Cholesterol#	3	06MAR2021	10/C	2	No	O	NA/TC	N	N/N	
	NERV	Cerebrovascular accident/ Cerebrovascular event#	3	06MAR2021	10/C	1	No	O	NA/TC	RG	Y/N	
	VASC	Hypertension/ Hypertension#	3	06MAR2021	10/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1079 10791228	EYE	Retinal artery occlusion/ Central Retinal Artery Occlusion	2	29SEP2020	1/C	1	No	O	NA	N	Y/N	
>55/ C4591001 1079 10791246	NERV	Aphasia/ Expressive Aphasia	2	22OCT2020	28/5	2	No	O	NA	R (26OCT2020)	N/N	
		Cerebrovascular accident/ CVA	2	22OCT2020	28/5	2	No	O	NA	R (26OCT2020)	Y/N	
>55/ C4591001 1079 10791264	MUSC	Back pain/ Worsening of Low Back Pain	1	27SEP2020	19/5	2	No	O	NA/TC	R (01OCT2020)	N/N	
>55/ C4591001 1080 10801006	GASTR	Nausea/ Nausea	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y	
	GENRL	Injection site erythema/ Redness at injection site	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y	
		Injection site swelling/ Swelling at injection site	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1080 10801008	GASTR	Diarrhoea/ Intermittent Diarrhea	1	12AUG2020	3/8	1	No	O	NA	R (19AUG2020)	N/N
	GENRL	Chills/ Chills	1	13AUG2020	4/2	1	No	O	NA	R (14AUG2020)	N/N
	MUSC	Back pain/ Lower Back Pain	1	14AUG2020	5/4	1	No	O	NA	R (17AUG2020)	N/N
	NERV	Headache/ Headache	2	08SEP2020	9/21	1	Yes		NA	R (28SEP2020)	N/N
	GENRL	Drug withdrawal syndrome/ Withdraw from valium#	4	08MAR2021	21/C	3	No	CD	NA/TC/TCN	N	Y/N
	GASTR	Nausea/ Nausea	2	31AUG2020	1/6	1	Yes		NA	R (05SEP2020)	N/N
	NERV	Vomiting/ Vomiting	2	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
		Dizziness/ Light Headed	2	31AUG2020	1/1	1	No	O	NA	R (31AUG2020)	N/Y
		Headache/ Headaches worsening	2	31AUG2020	1/3	3	Yes		NA	R (02SEP2020)	N/N
		Chills/ Chills	2	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N
GENRL	Pyrexia/ Fever of 101.7	2	01SEP2020	2/1	2	Yes		NA	R (01SEP2020)	N/N	
	Rash/ Worsening of skin rash (leg)	2	21DEC2020	113/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1080 10801012	INFEC	Tooth abscess/ Tooth Abscess	2	20OCT2020	50/1	2	No	O	NA	R (20OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1080 10801013	MUSC	Osteoarthritis/ Osteoarthritis of the knee	2	26OCT2020	56/1	3	No	O	NA/TC/TCN	R (26OCT2020)	Y/N	
	GASTR	Colitis ischaemic/ Ischemic colitis	2	31OCT2020	61/C	3	No	O	NA/TC/TCN	RG	Y/N	
		Constipation/ Constipation	2	31OCT2020	61/C	3	No	O	NA/TC/TCN	RG	Y/N	
		Large intestine perforation/ Perforated Colon	2	31OCT2020	61/C	3	No	O	NA/TC/TCN	RG	Y/N	
	INFEC	Parotitis/ Acute parotitis	2	08NOV2020	69/C	2	No	O	NA/TC/TCN	N	N/N	
	RENAL	Polyuria/ Diuresis	2	09NOV2020	70/C	2	No	O	NA/TC/TCN	N	N/N	
	CARD	Atrial fibrillation/ Atrial Fibrillation	2	11NOV2020	72/C	2	No	O	NA	N	N/N	
SKIN	Alopecia/ Unusual hair loss#	4	26FEB2021	23/C	2	No	O	NA	N	N/N		
>55/ C4591001 1080 10801016	GENRL	Pain/ bodyaches#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N	
	NERV	Pyrexia/ fever#	4	19FEB2021	2/2	2	Yes		NA/TC	R (20FEB2021)	N/N	
		Headache/ headaches#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N	
>55/ C4591001 1080 10801021	GENRL	Injection site pain/ pain at injection site#	3	19JAN2021	1/1	1	Yes		NA	R (19JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1080 10801030	INFEC	Kidney infection/ Kidney infection	1	24AUG2020	12/16	1	No	O	NA	R (08SEP2020)	N/N	
>55/ C4591001 1080 10801035	NEOPL	Breast cancer in situ/ Stage 0 Breast Cancer Right Breast	2	30OCT2020	57/35	3	No	O	NA/TCN	R (03DEC2020)	Y/N	
	GENRL	Fatigue/ Fatigue	2	07JAN2021	126/C	1	No	O	NA	RG	N/N	
>55/ C4591001 1080 10801046	GENRL	Injection site pain/ pain at injection site#	3	21JAN2021	1/1	1	Yes		NA	R (21JAN2021)	N/N	
	MUSC	Arthralgia/ increased left knee pain#	3	07FEB2021	18/C	1	No	O	NA	N	N/N	
>55/ C4591001 1080 10801052	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N	
>55/ C4591001 1080 10801062	GASTR	Dental caries/ Cavities in tooth 7 and 8	1	2020	1/	2	No	O	NA/TCN	R (28JAN2021)	N/N	
>55/ C4591001 1080 10801063	RESP	Nasal septum deviation/ Deviated septum	2	OCT2020	22/	2	No	O	NA/TCN	R (27JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1080 10801064	EAR	Vertigo/ Vertigo	1	19AUG2020	1/27	3	No	O	NA/TC	R (14SEP2020)	N/Y	
>55/ C4591001 1080 10801066	INJ&P	Ear injury/ Cut in Right Ear	2	26SEP2020	17/7	2	No	O	NA	R (02OCT2020)	N/N	
>55/ C4591001 1080 10801071	GENRL	Chills/ CHILLS	1	21AUG2020	2/2	2	Yes		NA	R (22AUG2020)	N/N	
		Injection site pain/ PAIN AT INJECTION SIGHT	1	21AUG2020	2/2	2	Yes		NA	R (22AUG2020)	N/N	
	NERV	Lethargy/ LETHARGY	1	21AUG2020	2/2	2	Yes		NA	R (22AUG2020)	N/N	
	GENRL	Chills/ Chills	2	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N	
		Injection site erythema/ Redness at injection site	2	10SEP2020	1/4	2	Yes		NA	R (13SEP2020)	N/N	
		Injection site pain/ Pain at injection site	2	10SEP2020	1/4	2	Yes		NA	R (13SEP2020)	N/N	
		Pyrexia/ Fever	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N	
	MUSC	Myalgia/ Muscle Aches	2	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N	
>55/ C4591001 1080 10801076	VASC	Hypertension/ worsening of hypertension#	2	13JAN2021	125/C	2	No	O	NA/TC	N	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1080 10801083	GENRL	Injection site pain/ injection site pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ Headache	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
>55/ C4591001 1080 10801086	SKIN	Pain of skin/ Sore Skin, Whole Body	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
	NERV	Dizziness/ Lightheadedness	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
>55/ C4591001 1080 10801091	GASTR	Diarrhoea/ Sporadic Diarrhea	2	17SEP2020	4/3	2	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ sore arm injection site pain#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
		Pyrexia/ fever#	4	23FEB2021	1/2	2	Yes		NA/TC	R (24FEB2021)	N/N
>55/ C4591001 1080 10801094	PSYCH	Mental fatigue/ cognitive fatigue#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1080 10801103	NERV	Pain in extremity/ Sore L arm	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
		Headache/ headache	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
		Chills/ Chills#	4	10MAR2021	2/1	2	Yes		NA	R (10MAR2021)	N/N
>55/ C4591001 1080 10801106	GENRL	Pyrexia/ Fever#	4	10MAR2021	2/1	2	Yes		NA	R (10MAR2021)	N/N
		Injection site pain/ pain at injection site#	3	21JAN2021	1/1	1	Yes		NA	R (21JAN2021)	N/N
>55/ C4591001 1080 10801112	CARD	Atrial fibrillation/ Atrial fibrillation#	3	29JAN2021	9/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1080 10801112	MUSC	Pain in extremity/ sore arm#	3	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
>55/ C4591001 1080 10801118	GASTR	Oesophagitis/ Esophagus inflammation	2	OCT2020	14/C	1	No	O	NA	N	N/N
>55/ C4591001 1080 10801121	MUSC	Back pain/ Lower backpain	1	30AUG2020	3/15	2	No	O	NA/TC	R (13SEP2020)	N/N
>55/ C4591001	METAB	Hyperlipidaemia/ hyperlipidemia	2	JAN2021	103/C	2	No	O	NA	N	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1080 10801125	GENRL	Injection site pain/ Injection site pain-left arm#	3	26FEB2021	2/3	1	Yes		NA	R (28FEB2021)	N/N
>55/ C4591001 1080 10801126	MUSC	Myalgia/ muscle aches#	3	26FEB2021	2/3	1	Yes		NA	R (28FEB2021)	N/N
>55/ C4591001 1080 10801130	MUSC	Pain in extremity/ Sore left arm#	3	13JAN2021	2/1	1	Yes		NA	R (13JAN2021)	N/N
>55/ C4591001 1080 10801133	GENRL	Fatigue/ Fatigue#	4	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1080 10801134	GENRL	Injection site pain/ injection site pain left arm#	3	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/Y
>55/ C4591001 1080 10801134	GENRL	Pain/ Generalized body aches	1	02SEP2020	1/3	2	Yes		NA	R (04SEP2020)	N/N
	GASTR	Nausea/ Nausea	1	03SEP2020	2/6	1	Yes		NA	R (08SEP2020)	N/N
		Oral discomfort/ Mouth hotness	1	03SEP2020	2/4	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Injection site erythema/ Redness at injection site (R)	1	03SEP2020	2/5	1	Yes		NA	R (07SEP2020)	N/N
		Injection site swelling/ Arm swelling at injection site (R)	1	03SEP2020	2/5	2	Yes		NA	R (07SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1080 10801150	GENRL	Pyrexia/ Low grade fever (101 F)	1	03SEP2020	2/6	2	Yes		NA	R (08SEP2020)	N/N	
		Chills/ Chills	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N	
		Pain/ Generalised Body Aches	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N	
		Pyrexia/ Fever	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N	
	GENRL	Chills/ chills#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N	
	NERV	Injection site pain/ injection site pain#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N	
>55/ C4591001 1080 10801152	NERV	Pyrexia/ low grade fever 100.9F#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N	
		Headache/ headache#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N	
	METAB	Fluid retention/ Worsening of WATER RETENTION in lower extremities	1	16SEP2020	13/3	3	No	O	NA/TC	R (18SEP2020)	Y/N	
>55/ C4591001 1080 10801156	VASC	Hypertension/ Worsening of HYPERTENSION	1	16SEP2020	13/3	3	No	O	NA/TC	R (18SEP2020)	Y/N	
	GENRL	Injection site pain/ injection site arm pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N	
>55/ C4591001	GENRL	Chills/ Chills	2	29SEP2020	2/3	2	Yes		NA	R (01OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1080 10801164		Pain/ Body Aches	2	29SEP2020	2/3	2	Yes		NA	R (01OCT2020)	N/N	
>55/ C4591001 1080 10801167	INJ&P	Procedural pain/ Sore Muscles after hip replacement (left hip and knee)#	3	20JAN2021	6/C	1	No	O	NA	N	N/N	
>55/ C4591001 1080 10801171	GENRL	Injection site pain/ Injection site tenderness#	3	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N	
>55/ C4591001 1080 10801175	GENRL	Pain/ Body aches#	4	02FEB2021	1/1	1	Yes		NA	R (02FEB2021)	N/N	
>55/ C4591001 1080 10801176	GENRL	Pyrexia/ Fever 100.5# Chills/ Chills	4 1	02FEB2021 11SEP2020	1/2 2/1	1 1	Yes Yes		NA NA	R (03FEB2021) R (11SEP2020)	N/N N/N	
>55/ C4591001 1080 10801177	GENRL	Fatigue/ Fatigue Tiredness	1 1	11SEP2020 12SEP2020	2/1 3/1	1 1	Yes Yes		NA NA	R (11SEP2020) R (12SEP2020)	N/N N/N	
	MUSC	Myalgia/ MUSCLE ACHES	1	12SEP2020	3/2	2	Yes		NA/TC	R (13SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pain/ Body aches	1	15SEP2020	6/3	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	06OCT2020	6/2	1	Yes		NA	R (07OCT2020)	N/N
>55/ C4591001 1080 10801188	GENRL	Injection site pain/ pain at injection site#	3	19JAN2021	1/3	2	Yes		NA/TC	R (21JAN2021)	N/N
>55/ C4591001 1080 10801191	GENRL	Pain/ Body ache	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	20OCT2020	7/2	1	Yes		NA	R (21OCT2020)	N/N
>55/ C4591001 1080 10801198	GENRL	Chills/ Chills	2	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N
		Fatigue/ Fatigue	2	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N
		Pain/ Body aches	2	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N
>55/ C4591001 1080 10801200	GENRL	Injection site pain/ Pain at injection site#	3	17DEC2020	1/4	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Injection site pruritus/ Itching at injection site#	3	24DEC2020	8/4	1	Yes		NA	R (27DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1080 10801208	GENRL	Chills/ Body Chills	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
		Pyrexia/ Fever	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
>55/ C4591001 1080 10801215	GENRL	Injection site pain/ pain at injection site#	3	21JAN2021	1/1	1	Yes		NA	R (21JAN2021)	N/N
>55/ C4591001 1080 10801223	GENRL	Injection site pain/ Arm pain at injection site#	3	25FEB2021	1/4	1	Yes		NA	R (28FEB2021)	N/N
	MUSC	Arthralgia/ increased joint pain in shoulders and hands#	3	26FEB2021	2/1	1	Yes		NA	R (26FEB2021)	N/N
>55/ C4591001 1081 10811002	INJ&P	Ankle fracture/ Rt Ankle Fracture	2	18JAN2021	141/4	2	No	O	NA/TC/TCN	R (21JAN2021)	N/N
>55/ C4591001 1081 10811011	MUSC	Pain in extremity/ Left arm pain#	4	25FEB2021	1/2	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N
>55/ C4591001 1081 10811024	MUSC	Rotator cuff syndrome/ Right Rotator Cuff Tear	2	20SEP2020	19/39	2	No	O	NA/TC/TCN	R (28OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1081 10811026	INFEC	Urinary tract infection/ Urinary Tract Infection	2	05OCT2020	34/12	1	No	O	NA/TC	R (16OCT2020)	N/N	
	BLOOD	Anaemia/ Worsening of Anemia	2	11OCT2020	40/19	3	No	O	NA	R (29OCT2020)	N/N	
	GASTR	Abdominal pain lower/ lower abdominal pain	2	11OCT2020	40/6	3	No	O	NA/TC/TCN	R (16OCT2020)	N/N	
	NEOPL	Borderline serous tumour of ovary/ Serous borderline tumor of left ovary	2	11OCT2020	40/19	3	No	O	NA/TC/TCN	R (29OCT2020)	Y/N	
>55/ C4591001 1081 10811030	NEOPL	Prostate cancer/ Prostate Cancer	2	10SEP2020	10/C	3	No	O	NA/TCN	RG	Y/N	
>55/ C4591001 1081 10811037	MUSC	Arthralgia/ Right Knee pain	2	28SEP2020	26/8	2	No	O	NA/TC	R (05OCT2020)	N/N	
		Osteoarthritis/ Osteoarthritis right knee (new onset)	2	28SEP2020	26/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1081 10811043	EAR	Ear disorder/ Fluid in Lt ear	2	28SEP2020	21/5	1	No	O	NA/TC	R (02OCT2020)	N/N	
>55/ C4591001 1081 10811045	CARD	Atrial fibrillation/ Atrial Fibrillation with Rapid Ventricular Response	2	17NOV2020	70/15	2	No	O	NA/TC	R (01DEC2020)	Y/N	
	RESP	Sleep apnoea syndrome/ Unspecified Sleep Apnea	2	05JAN2021	119/C	2	No	O	NA	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1081 10811048	INJ&P	Fall/ Fall on stairs at home#	2	12JAN2021	126/1	3	No	O	NA/TC/TCN	R (12JAN2021)	Y/N	
		Hip fracture/ Hip Fracture, right#	2	12JAN2021	126/11	3	No	O	NA/TC/TCN	R (22JAN2021)	Y/N	
>55/ C4591001 1081 10811059	NEOPL	Lipoma/ Lipoma on neck	1	28AUG2020	11/1	1	No	O	NA/TCN	R (28AUG2020)	N/N	
>55/ C4591001 1081 10811061	BLOOD	Lymphadenopathy/ Lymphadenopathy Under left ear	2	10SEP2020	8/14	2	No	O	NA/TC	R (23SEP2020)	N/N	
	SKIN	Dermatitis contact/ Contact Dermatitis on lower extremities	2	11SEP2020	9/12	2	No	O	NA/TC	R (22SEP2020)	N/N	
>55/ C4591001 1081 10811063	INJ&P	Fall/ Fall at work	2	NOV2020	54/	2	No	O	NA/TCN	R	N/N	
		Patella fracture/ fracture to left patella	2	NOV2020	54/	2	No	O	NA/TCN	R	N/N	
>55/ C4591001 1081 10811090	CARD	Myocardial infarction/ Myocardial Infarction	2	15NOV2020	63/4	4	No	O	NA/TC/TCN	R (18NOV2020)	Y/N	
	PSYCH	Suicide attempt/ Suicide attempt	2	15JAN2021	124/4	3	No	O	NA/TC/TCN	R (18JAN2021)	Y/N	
>55/ C4591001	CARD	Atrial fibrillation/ Worsening of Atrial Fibrillation	2	06OCT2020	23/C	2	No	O	NA/TC	RG	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1081 10811093		Atrioventricular block complete/ Intermittent Complete Heart Block	2	06OCT2020	23/C	2	No	O	NA/TC	N	N/N	
		Bradycardia/ Bradycardia	2	06OCT2020	23/C	2	No	O	NA/TC	N	N/N	
	INJ&P	Ankle fracture/ Fractured Lt ankle#	2	01FEB2021	141/C	2	No	O	NA/TCN	RG	N/N	
>55/ C4591001 1081 10811102	CARD	Angina pectoris/ Angina	2	10JAN2021	118/C	2	No	O	NA/TC/TCN	RG	Y/N	
	INFEC	Urinary tract infection/ Urinary Tract Infection#	2	22FEB2021	161/8	1	No	O	NA/TC	R (01MAR2021)	N/N	
	HEPAT	Jaundice/ jaundice#	2	24FEB2021	163/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1081 10811107	GENRL	Non-cardiac chest pain/ non cardiac chest pain	2	06OCT2020	21/2	2	No	O	NA	R (07OCT2020)	N/N	
>55/ C4591001 1081 10811110	INFEC	Empyema/ loculated empyema	2	11OCT2020	26/39	3	No	O	NA/TC	R (18NOV2020)	Y/N	
		Pneumonia/ Right lower lobe pneumonia	2	11OCT2020	26/39	3	No	O	NA/TC	R (18NOV2020)	Y/N	
>55/ C4591001 1081 10811111	MUSC	Back pain/ Low Back Pain#	4	03MAR2021	9/C	2	No	O	NA/TC	RG	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1081 10811113	METAB	Type 2 diabetes mellitus/ Worsening of Type II Diabetes	1	04SEP2020	10/	2	No	O	NA/TC	R	N/N	
	MUSC	Intervertebral disc degeneration/ Worsening of degenerative discs in back	2	30SEP2020	16/C	2	No	O	NA/TC	N	N/N	
	INJ&P	Stress fracture/ Stress fracture Left 3rd metatarsal	2	29DEC2020	106/C	2	No	O	NA/TCN	RG	N/N	
>55/ C4591001 1081 10811117	INJ&P	Tendon rupture/ Torn tendon Rt Bicep	2	03JAN2021	111/C	1	No	O	NA	N	N/N	
>55/ C4591001 1081 10811139	INFEC	Bronchitis/ Worsening Bronchitis	1	12SEP2020	13/7	1	No	O	NA/TC	R (18SEP2020)	N/N	
>55/ C4591001 1081 10811150	SKIN	Rash pruritic/ Pruritic rash, generalized	1	06SEP2020	6/15	2	No	O	NA/TC	R (20SEP2020)	N/N	
>55/ C4591001 1081 10811158	MUSC	Osteoarthritis/ Worsening RT Shoulder Osteoarthritis	1	SEP2020	1/	3	No	O	NA/TC/TCN	R (15FEB2021)	N/N	
>55/ C4591001 1081 10811159	INJ&P	Fall/ Fall while walking	1	03SEP2020	2/1	2	No	O	NA/TCN	R (03SEP2020)	N/N	
		Foot fracture/ Broke Toes 2,3,& 4 on Lt Foot	1	03SEP2020	2/49	2	No	O	NA/TCN	R (21OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Ligament sprain/ Sprained Rt Ankle	1	03SEP2020	2/49	2	No	O	NA/TCN	R (21OCT2020)	N/N
>55/ C4591001 1081 10811162	INFEC	Cellulitis/ Cellulitis of great toe on RT foot	1	11SEP2020	10/11	1	No	O	NA/TC	R (21SEP2020)	N/N
>55/ C4591001 1081 10811170	NEOPL	Prostate cancer/ Malignant Neoplasm of Prostate	2	04NOV2020	43/C	3	No	O	NA/TCN	N	Y/N
>55/ C4591001 1081 10811179	MUSC	Osteoarthritis/ worsening-Left Big Toe Osteoarthritis	2	14OCT2020	21/1	2	No	O	NA/TCN	R (14OCT2020)	N/N
	NEOPL	Breast cancer stage II/ Stage II Breast Cancer (Left)#	4	23FEB2021	6/C	3	No	CD	NA/TC	N	Y/N
>55/ C4591001 1081 10811180	GENRL	Pyrexia/ Fever#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
>55/ C4591001 1081 10811204	CARD	Cardiac failure congestive/ Worsening of CHF	2	06JAN2021	91/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1081 10811208	EAR	Tinnitus/ Bilateral tinnitus#	4	12MAR2021	2/C	1	No	O	NA	RG	N/N
>55/ C4591001	MUSC	Arthritis/ Arthritis L knee	1	01OCT2020	15/5	2	No	O	NA/TC	R (05OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1081 10811211 >55/ C4591001	GENRL	Swelling face/ facial swelling	2	10OCT2020	45/6	1	No	O	NA/TC	R (15OCT2020)	N/N	
1082 10821055	SKIN	Rash/ rash to trunk	2	10OCT2020	45/6	1	No	O	NA/TC	R (15OCT2020)	N/N	
	SKIN	Rash/ rash/skin irritation (dorsal side above sacrum, bilaterally below cervical vertebrae)	2	28OCT2020	63/8	1	No	O	NA/TC	R (04NOV2020)	N/N	
>55/ C4591001	HEPAT	Cholelithiasis/ cholelithiasis	1	13AUG2020	7/3	3	No	O	NA/TCN	R (15AUG2020)	Y/N	
1082 10821076	METAB	Type 2 diabetes mellitus/ New onset type 2 diabetes	2	05NOV2020	66/C	1	No	O	NA/TC	N	Y/N	
>55/ C4591001	MUSC	Muscle spasms/ muscle spasms	2	20OCT2020	9/C	2	No	O	NA/TC	N	N/N	
1082 10821167	MUSC	Myalgia/ muscle pain of bilateral lower extremities#	4	19FEB2021	24/3	1	No	O	NA	R (21FEB2021)	N/N	
1082 10821182	SKIN	Hyperhidrosis/ Intermittent Profuse Sweating	2	28AUG2020	8/7	1	Yes		NA	R (03SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1083 10831003	INJ&P	Fall/ Fall	1	01AUG2020	2/1	1	No	O	NA/TC	R (01AUG2020)	N/N
>55/ C4591001 1083 10831014	MUSC	Arthralgia/ Right Knee Pain	1	01AUG2020	2/2	1	No	O	NA/TC	R (02AUG2020)	N/N
>55/ C4591001 1083 10831016	INJ&P	Ligament sprain/ Sprained Left Knee	2	14SEP2020	25/C	2	No	O	NA	N	N/N
>55/ C4591001 1083 10831019	MUSC	Osteoarthritis/ Osteoarthritis-Left knee	2	16SEP2020	27/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1083 10831019	SURG	Rotator cuff repair/ Rotator Cuff Surgery-Right	2	18DEC2020	120/1	2	No	O	NA/TC	R (18DEC2020)	N/N
>55/ C4591001 1083 10831023	NEOPL	Fibroma/ Fibroid Cyst Rib Cage-Left#	2	15FEB2021	179/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1083 10831023	EAR	Deafness neurosensory/ Sudden sensorineural hearing loss - Left Ear	2	18OCT2020	56/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1083 10831024	GENRL	Fatigue/ Fatigue#	3	24JAN2021	20/3	1	Yes		NA	R (26JAN2021)	N/N
>55/ C4591001 1083 10831024	GENRL	Chills/ Chills#	3	25JAN2021	21/2	1	Yes		NA	R (26JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1083 10831027	MUSC	Muscle spasms/ Leg cramps	1	11AUG2020	8/13	1	No	O	NA	R (23AUG2020)	N/N	
	MUSC	Muscle spasms/ Leg Cramps	1	24AUG2020	21/32	1	No	O	NA	R (24SEP2020)	N/N	
	IMMUN	Seasonal allergy/ Worsening of Allergic Rhinitis-Seasonal	2	27OCT2020	65/C	2	No	O	NA	RG	N/N	
>55/ C4591001 1083 10831031	RESP	Cough/ Intermittent Cough	1	20AUG2020	17/2	1	No	O	NA	R (21AUG2020)	N/N	
	NEOPL	Lipoma/ Lipoma-Behind the Right Elbow	2	27SEP2020	35/31	1	No	O	NA	R (27OCT2020)	N/N	
	SKIN	Dry skin/ Dry Skin-Bilateral Feet	2	02FEB2021	163/C	1	No	O	NA/TC	RG	N/N	
	CARD	Atrial fibrillation/ Atrial fibrillation#	2	11FEB2021	172/2	2	No	O	NA/TC	R (12FEB2021)	N/N	
	GENRL	Pain/ Body Aches#	3	13JAN2021	23/4	2	Yes		NA/TC	R (16JAN2021)	N/N	
>55/ C4591001 1083 10831036		Pyrexia/ Fever 102.0 Fahrenheit#	3	13JAN2021	23/4	2	Yes		NA/TC	R (16JAN2021)	N/N	
	IMMUN	Seasonal allergy/ Worsening of Seasonal Allergies#	2	08FEB2021	168/C	2	No	O	NA/TC	RG	N/N	
	RENAL	Urethral stenosis/ Urethral Strictures	2	22OCT2020	59/26	2	No	O	NA/TC/TCN	R (16NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1083 10831042 >55/ C4591001 1083 10831050	MUSC	Musculoskeletal stiffness/ Neck Stiffness	1	29AUG2020	25/4	1	No	O	NA	R (01SEP2020)	N/N
	INJ&P	Fall/ Fall	1	01SEP2020	28/1	2	No	O	NA	R (01SEP2020)	N/N
	MUSC	Rotator cuff syndrome/ Rotator Cuff Seperation-Right	1	01SEP2020	28/C	2	No	O	NA	RG	N/N
	INJ&P	Contusion/ Brusing-Bilateral Legs	2	30SEP2020	28/C	1	No	O	NA	RG	N/N
		Fall/ Fall	2	30SEP2020	28/1	1	No	O	NA	R (30SEP2020)	N/N
		Skin abrasion/ Scrapping -Bilateral Legs	2	30SEP2020	28/C	1	No	O	NA	RG	N/N
	GASTR	Acute abdomen/ Acute Abdomen#	2	04MAR2021	183/C	2	No	O	NA/TC/TCN	RG	Y/N
>55/ C4591001 1083 10831075	INJ&P	Muscle strain/ Intermittent Muscle Strain-Under Left Armpit	2	26OCT2020	57/64	1	No	O	NA	R (28DEC2020)	N/N
>55/ C4591001 1083 10831077	SKIN	Dermatitis contact/ Contact Dermatitis-Chest	1	01SEP2020	23/23	2	No	CD	NA/TC	R (23SEP2020)	N/N
>55/ C4591001 1083 10831103	METAB	Hypercholesterolaemia/ Hypercholesterolemia	1	27AUG2020	14/C	1	No	CD	NA/TC	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	METAB	Type 2 diabetes mellitus/ Type 2 diabetes	2	01JAN2021	122/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1083 10831104	MUSC	Back pain/ Low back Pain	1	23AUG2020	10/4	1	No	O	NA/TC	R (26AUG2020)	N/N	
	MUSC	Pain in extremity/ Bilateral Thumb Pain	1	26AUG2020	13/8	1	No	O	NA	R (02SEP2020)	N/N	
>55/ C4591001 1083 10831107	CARD	Atrial fibrillation/ Atrial Fibrillation	2	20NOV2020	73/50	2	No	O	NA/TC/TCN	R (08JAN2021)	N/N	
>55/ C4591001 1083 10831108	GENRL	Injection site pain/ Site Injection Pain-Right Arm#	2	23DEC2020	107/2	1	Yes		NA	R (24DEC2020)	N/N	
	GENRL	Fatigue/ Fatigue#	3	24DEC2020	2/2	1	Yes		NA	R (25DEC2020)	N/N	
>55/ C4591001 1083 10831110	INFEC	Onychomycosis/ Toe Nail Fungus#	3	15JAN2021	16/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1083 10831114	GENRL	Pyrexia/ Fever	1	08SEP2020	22/2	2	Yes		NA/TC	R (09SEP2020)	N/N	
	GENRL	Injection site pain/ Sore Arm at Injection Site-Left	2	09SEP2020	2/1	2	Yes		NA/TC	R (09SEP2020)	N/N	
>55/ C4591001	GENRL	Injection site pain/ Injection site pain-Left Arm#	2	18JAN2021	131/2	1	Yes		NA	R (19JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1083 10831115 >55/ C4591001	GENRL	Pain/ Body Aches	2	11SEP2020	3/3	1	Yes		NA	R (13SEP2020)	N/N
1083 10831125	MUSC	Arthralgia/ Right Shoulder Pain	2	11SEP2020	3/3	1	Yes		NA	R (13SEP2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ Intermittent Pain at injection site-Right*		20AUG2020	1/C	1	Yes		NA	RG	N/N
1083 10831134	INFEC	Urinary tract infection/ Urinary tract infection	1	31AUG2020	8/16	1	No	O	NA/TC	R (15SEP2020)	N/N
>55/ C4591001	SKIN	Rash/ Rash-Upper thighs,chest,axillary- Bilateral	1	28AUG2020	5/3	1	Yes		NA/TC	R (30AUG2020)	N/N
1083 10831149	INFEC	Tooth infection/ Tooth Infection	1	12OCT2020	47/23	2	No	O	NA	R (03NOV2020)	N/N
>55/ C4591001	NEOPL	Prostate cancer/ Prostate Cancer	1	02NOV2020	68/C	3	No	O	NA/TC/TCN	RG	Y/N
1083 10831173	SURG	Tooth extraction/ Tooth Extraction	1	20NOV2020	86/1	1	No	O	NA/TC	R (20NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness-Left Arm#	1	12MAR2021	198/2	1	Yes		NA	R (13MAR2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1083 10831175	GENRL	Injection site pain/ Injection Site Pain-Left Arm#	3	06MAR2021	45/4	1	Yes		NA	R (09MAR2021)	N/N
>55/ C4591001 1083 10831184	INFEC	Urinary tract infection/ Urinary Tract Infection	2	22DEC2020	93/11	2	No	O	NA/TC	R (01JAN2021)	N/N
>55/ C4591001 1083 10831189	NERV	Migraine/ Intermittent Migraine Headache	1	08SEP2020	6/3	1	No	O	NA	R (10SEP2020)	N/N
>55/ C4591001 1083 10831200	GENRL	Injection site pain/ Injection Site Pain-Left#	2	31DEC2020	94/4	1	Yes		NA	R (03JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness-Left#	4	19JAN2021	1/3	1	Yes		NA	R (21JAN2021)	N/N
	MUSC	Pain in extremity/ Bilateral Leg Aches#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	NERV	Headache/ Headache#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Chills/ Chills#	4	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
		Injection site swelling/ Injection Site Swelling-Left#	4	20JAN2021	2/4	1	Yes		NA	R (23JAN2021)	N/N
		Pyrexia/ Low Grade Temperature-99.6 degrees fahrenheit#	4	20JAN2021	2/2	1	Yes		NA/TC	RS (21JAN2021)	N/N
>55/ C4591001	INFEC	Urinary tract infection/ Urinary Tract Infection	2	05OCT2020	7/11	2	No	O	NA/TC	R (15OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1083 10831206 >55/ C4591001 1083 10831218	GENRL	Injection site pain/ Injection Site Pain-Left Deltoid	1	30SEP2020	21/2	1	Yes		NA/TC	R (01OCT2020)	N/N
>55/ C4591001 1083 10831224	GENRL	Pain/ Body Aches	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
>55/ C4591001 1083 10831224	GASTR	Large intestine polyp/ Colon Polyps-Benign	1	21SEP2020	11/C	1	No	O	NA	N	N/N
>55/ C4591001 1083 10831229	MUSC	Arthralgia/ Joint Pain-Wrist and Shoulder	1	12SEP2020	2/C	1	No	O	NA	RG	N/N
	GENRL	Fatigue/ Fatigue#	3	01FEB2021	22/4	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Injection Site Soreness-Left#	3	01FEB2021	22/4	1	Yes		NA	R (04FEB2021)	N/N
	MUSC	Myalgia/ Muscle Pain#	3	01FEB2021	22/4	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	3	01FEB2021	22/4	1	Yes		NA	R (04FEB2021)	N/N
	METAB	Decreased appetite/ Loss of Appetite#	4	02FEB2021	2/3	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1083 10831234	INJ&P	Fall/ Traumatic fall	2	08OCT2020	8/1	1	No	O	NA	R (08OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1083 10831236	GASTR	Joint dislocation/ Open wound dislocation Left 5th Finger	2	08OCT2020	8/32	2	No	O	NA/TC	R (08NOV2020)	N/N
		Flatulence/ Gas Pain Gastrointestinal Discomfort	1	23SEP2020	13/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1083 10831237	INV	Blood testosterone increased/ High Testosterone	2	07OCT2020	8/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1083 10831257	INJ&P	Epicondylitis/ Tennis Elbow-Left	1	29SEP2020	7/23	1	No	O	NA/TC	R (21OCT2020)	N/N
	GENRL	Injection site pain/ Right Arm Pain at Injection Site	1	13OCT2020	21/2	1	Yes		NA/TC	R (14OCT2020)	N/N
	GENRL	Injection site erythema/ 2 centimeter redness at injection site- Right Arm	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
		Injection site swelling/ 2cm swelling at Injection Site Right Arm	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
	MUSC	Arthralgia/ Joint Pain- Knees,Hips,Toes,Fingers	2	14OCT2020	2/1	2	Yes		NA/TC	R (14OCT2020)	N/N
>55/ C4591001 1083 10831261	INFEC	Myalgia/ Muscle Body Aches	2	14OCT2020	2/1	2	Yes		NA/TC	R (14OCT2020)	N/N
		Bronchitis/ Bronchitis	2	30DEC2020	77/13	1	No	O	NA/TC	R (11JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1083 10831280	EAR	Vertigo/ Vertigo	2	04DEC2020	24/C	2	No	O	NA	RG	N/N	
>55/ C4591001 1083 10831283	GENRL	Chills/ Chills	2	13NOV2020	3/1	1	Yes		NA	R (13NOV2020)	N/N	
		Pyrexia/ Fever 100.9 Fahrenheit	2	13NOV2020	3/1	1	Yes		NA	R (13NOV2020)	N/N	
	MUSC	Arthralgia/ Left Hip Pain	2	13NOV2020	3/C	1	No	O	NA	RG	N/N	
		Pain in extremity/ Bilateral Thumb Pain	2	13NOV2020	3/C	1	No	O	NA	RG	N/N	
>55/ C4591001 1084 10841010	INFEC	Urinary tract infection/ urinary tract infection#	3	18JAN2021	4/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1084 10841011	INJ&P	Muscle strain/ LEFT CALF STRAIN	2	24AUG2020	7/32	2	No	O	NA/TC	R (24SEP2020)	N/N	
	SKIN	Urticaria/ hives/rash thighs upper arms back	2	09JAN2021	145/C	1	No	O	NA	N	N/N	
>55/ C4591001 1084 10841024	METAB	Hypertriglyceridaemia/ hypertriglyceridemia#	2	09FEB2021	170/C	2	No	CD	NA/TC	N	N/N	
>55/ C4591001	EYE	Vitreous detachment/ posterior vitreous detachment left eye	2	16SEP2020	24/C	1	No	O	NA	N	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1084 10841032 >55/ C4591001	SKIN	Pruritus/ Generalized Pruritus	2	21SEP2020	27/C	2	No	O	NA/TC	N	N/N
1084 10841049 >55/ C4591001	INJ&P	Animal bite/ Cat Bite on Right Forearm#	2	30JAN2021	158/4	2	No	O	NA/TC	R (02FEB2021)	N/N
1084 10841052 >55/ C4591001	GENRL	Chills/ chills	2	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
1084 10841063	INJ&P	Fall/ Fall#	2	15FEB2021	172/1	2	No	O	NA	R (15FEB2021)	N/N
		Ligament sprain/ right wrist sprain#	2	15FEB2021	172/C	2	No	O	NA/TC/TCN	N	N/N
>55/ C4591001 1084 10841077	IMMUN	Seasonal allergy/ seasonal allergies	1	14AUG2020	8/C	1	No	O	NA/TC	N	N/N
	MUSC	Rheumatoid arthritis/ Rheumatoid Arthritis	2	17SEP2020	21/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1084 10841093	MUSC	Joint noise/ Clicking in the Left forearm*		07AUG2020	1/C	1	No	O	NA	RG	N/N
>55/ C4591001	MUSC	Pain in jaw/ Jaw pain	2	14SEP2020	15/8	1	No	O	NA	R (21SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1084 10841103	NERV	Headache/ Headache	2	14SEP2020	15/1	1	No	O	NA	R (14SEP2020)	N/N	
>55/ C4591001 1084 10841108	GASTR	Constipation/ CONSTIPATION	1	17AUG2020	8/16	2	No	O	NA	R (01SEP2020)	N/N	
>55/ C4591001 1084 10841112	SKIN	Urticaria/ Generalized hives (all over body)#	2	15JAN2021	138/2	2	No	O	NA/TC/TCN	R (16JAN2021)	N/N	
>55/ C4591001 1084 10841125	VASC	Peripheral vascular disorder/ Peripheral vascular disease#	2	03FEB2021	157/8	3	No	O	NA	R (10FEB2021)	N/N	
>55/ C4591001 1084 10841127	CARD	Supraventricular tachycardia/ Atypical supracentricular tachycardia	2	25SEP2020	24/68	3	No	O	NA	RS (01DEC2020)	N/N	
	CARD	Supraventricular tachycardia/ Atypical supraventricular Tachycardia	2	25SEP2020	24/68	3	No	O	NA	RS (01DEC2020)	N/N	
	CARD	Supraventricular tachycardia/ Worsening atypical supra ventricular tachycardia	2	02DEC2020	92/1	3	No	O	NA/TC	R (02DEC2020)	N/N	
>55/ C4591001 1084 10841134	INJ&P	Hand fracture/ Metacarpal Fracture	2	05NOV2020	65/C	2	No	O	NA/TCN	RG	N/N	
>55/ C4591001	INFEC	Localised infection/ Right Greater Toe Infection	1	22AUG2020	11/C	3	No	O	NA/TCN	N	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1084 10841135 >55/ C4591001 1084 10841147	SKIN	Rash pruritic/ Pruitic/Burning Rash to Left and Right First and Second Interphalangeal Spaces	1	19AUG2020	8/C	2	No	O	NA/TC	N	N/N
	INJ&P	Fall/ Fall#	2	15FEB2021	167/1	2	No	O	NA	R (15FEB2021)	N/N
		Humerus fracture/ right upper humerus fracture#	2	15FEB2021	167/C	3	No	O	NA/TC/TCN	N	N/N
	NERV	Sciatica/ Worsening sciatica - right leg#	2	18FEB2021	170/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1084 10841158	INFEC	Fungal skin infection/ Fungal infection to groin area	2	SEP2020	1/	2	No	O	NA/TC	R (05OCT2020)	N/N
>55/ C4591001 1084 10841162	NERV	Syncope/ Syncope	2	05SEP2020	2/1	1	No	O	NA	R (05SEP2020)	N/N
	INV	Blood glucose increased/ Elevated Blood Glucose	2	14SEP2020	11/3	2	No	O	NA/TC	R (16SEP2020)	N/N
>55/ C4591001 1084 10841173	METAB	Diabetes mellitus inadequate control/ UNCONTROLLED DIABETES MELLITUS TYPE II	1	22AUG2020	9/12	2	No	O	NA/TC	R (02SEP2020)	N/N
>55/ C4591001 1084 10841180	METAB	Vitamin D deficiency/ Vitamin D deficiency	1	31AUG2020	18/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1084 10841183	GENRL	Injection site pain/ Moderate Injection Site Pain	1	15AUG2020	2/2	1	Yes		NA	R (16AUG2020)	N/N
	MUSC	Myalgia/ muscle pain to lower extremities	2	05SEP2020	2/4	2	Yes		NA	R (08SEP2020)	N/N
>55/ C4591001 1084 10841190	SURG	Toe operation/ right hammer toe surgery - digits 2, 3, 4, and 5	2	19DEC2020	102/1	3	No	O	NA/TC	R (19DEC2020)	N/N
>55/ C4591001 1084 10841192	NERV	Headache/ Headache	1	17AUG2020	1/3	2	Yes		NA	R (19AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	18AUG2020	2/1	3	Yes		NA	R (18AUG2020)	N/N
	MUSC	Myalgia/ Muscle Pain	1	18AUG2020	2/1	2	Yes		NA	R (18AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	19AUG2020	3/3	1	Yes		NA	R (21AUG2020)	N/N
	MUSC	Myalgia/ Muscle Pain	1	19AUG2020	3/1	1	Yes		NA	R (19AUG2020)	N/N
	NERV	Headache/ Headache	1	20AUG2020	4/1	1	Yes		NA	R (20AUG2020)	N/N
	NERV	Headache/ Headache	1	18AUG2020	2/1	1	Yes		NA/TC	R (18AUG2020)	N/N
>55/ C4591001 1084 10841194	GENRL	Fatigue/ Fatigue	1	19AUG2020	3/1	1	Yes		NA	R (19AUG2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	1	21AUG2020	5/1	1	Yes		NA	R (21AUG2020)	N/N
	NERV	Headache/ Headache	1	22AUG2020	6/1	1	Yes		NA/TC	R (22AUG2020)	N/N
>55/ C4591001 1084 10841198	NERV	Headache/ Headache	1	18AUG2020	2/1	2	Yes		NA	R (18AUG2020)	N/N
	NERV	Headache/ Headache	1	20AUG2020	4/1	1	Yes		NA	R (20AUG2020)	N/N
>55/ C4591001 1084 10841202	NERV	Headache/ Headache	1	21AUG2020	5/1	2	Yes		NA	R (21AUG2020)	N/N
>55/ C4591001 1084 10841204	GENRL	Chills/ Chills	1	18AUG2020	2/1	2	Yes		NA	R (18AUG2020)	N/N
		Fatigue/ Fatigue	1	18AUG2020	2/1	2	Yes		NA	R (18AUG2020)	N/N
		Injection site pain/ Injection Site Pain	1	18AUG2020	2/1	2	Yes		NA	R (18AUG2020)	N/N
	MUSC	Myalgia/ Muscle Pain	1	18AUG2020	2/1	2	Yes		NA/TC	R (18AUG2020)	N/N
>55/ C4591001 1084 10841206	GENRL	Injection site pain/ Injection Site Pain	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
>55/ C4591001	GENRL	Fatigue/ Fatigue	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1084 10841207		Injection site pain/ Injection Site Pain	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N
>55/ C4591001 1084 10841211	MUSC	Musculoskeletal stiffness/ Stiff neck#	3	28JAN2021	18/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1084 10841217	GENRL	Fatigue/ Fatigue	1	22AUG2020	6/1	2	Yes		NA	R (22AUG2020)	N/N
>55/ C4591001 1084 10841218	GENRL	Injection site pain/ Injection Pain	1	18AUG2020	2/3	1	Yes		NA	R (20AUG2020)	N/N
>55/ C4591001 1084 10841219	GENRL	Fatigue/ Fatigue	1	20AUG2020	4/1	1	Yes		NA	R (20AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	21AUG2020	5/1	1	Yes		NA	R (21AUG2020)	N/N
	REPRO	Ovarian cyst/ Left ovarian cyst, benign tumor	1	24AUG2020	8/27	2	No	O	NA/TC/TCN	R (19SEP2020)	Y/N
		Uterine prolapse/ Prolapsed uterus	1	24AUG2020	8/27	2	No	O	NA/TC/TCN	R (19SEP2020)	Y/N
>55/ C4591001 1084 10841221	GENRL	Chills/ Chills	1	18AUG2020	2/1	2	Yes		NA	R (18AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1084 10841226	GENRL	Fatigue/ Fatigue	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N	
		Injection site erythema/ Redness at Injection Site	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N	
		Injection site pain/ Injection Site Pain	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N	
		Chills/ Chills	1	21AUG2020	5/1	2	Yes		NA	R (21AUG2020)	N/N	
	GASTR	Diarrhoea/ Diarrhea	1	23AUG2020	7/1	2	Yes		NA	R (23AUG2020)	N/N	
	GASTR	Hiatus hernia/ Hiatal Hernia#	2	04FEB2021	149/C	1	No	O	NA	N	N/N	
	GENRL	Fatigue/ Fatigue	1	19AUG2020	1/1	1	Yes		NA	R (19AUG2020)	N/N	
	INV	Blood cholesterol increased/ high cholesterol	2	10DEC2020	93/C	1	No	O	NA/TC	N	N/N	
	>55/ C4591001 1084 10841227	GENRL	Injection site pain/ Injection Site Pain	1	21AUG2020	3/1	1	Yes		NA	R (21AUG2020)	N/N
	>55/ C4591001 1084 10841232	GENRL	Injection site pain/ Injection Site Pain	1	20AUG2020	2/1	2	Yes		NA	R (20AUG2020)	N/N
	NERV	Headache/ Headache	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	1	21AUG2020	3/3	1	Yes		NA	R (23AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1084 10841233	GENRL	Fatigue/ Fatigue	1	19AUG2020	1/1	1	Yes		NA	R (19AUG2020)	N/N
	NERV	Headache/ Headache	1	19AUG2020	1/1	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	21AUG2020	3/1	1	Yes		NA	R (21AUG2020)	N/N
>55/ C4591001 1084 10841235	NERV	Headache/ Headache	1	21AUG2020	3/1	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	21AUG2020	3/1	1	Yes		NA	R (21AUG2020)	N/N
	EYE	Diabetic retinopathy/ Right Eye Diabetic Retinopathy	2	21SEP2020	11/C	2	No	O	NA/TC/TCN	N	N/N
>55/ C4591001 1084 10841236	GENRL	Fatigue/ Fatigue	1	19AUG2020	1/2	2	Yes		NA	R (20AUG2020)	N/N
	NERV	Headache/ Headache	1	19AUG2020	1/1	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N
>55/ C4591001 1084 10841238	INFEC	Urinary tract infection/ Urinary Tract Infection	2	04JAN2021	118/15	1	No	O	NA/TC	R (18JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1084 10841243	INFEC	Cellulitis/ cellulitis of right, lower extremity#	4	04MAR2021	23/C	1	No	O	NA/TC	N	N/N
	GENRL	Fatigue/ Fatigue	1	19AUG2020	1/1	2	Yes		NA	R (19AUG2020)	N/N
		Injection site pain/ Injection Site Pain	1	19AUG2020	1/1	1	Yes		NA	R (19AUG2020)	N/N
	NERV	Headache/ Headache	1	19AUG2020	1/1	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	20AUG2020	2/6	1	Yes		NA	R (25AUG2020)	N/N
	MUSC	Myalgia/ Muscle Pain	1	21AUG2020	3/1	1	Yes		NA/TC	R (21AUG2020)	N/N
	NERV	Headache/ Headache	1	21AUG2020	3/1	1	Yes		NA	R (21AUG2020)	N/N
	NERV	Headache/ Headache	1	23AUG2020	5/1	1	Yes		NA	R (23AUG2020)	N/N
>55/ C4591001 1084 10841244	INJ&P	Cartilage injury/ Partial tear bilateral labrum	2	26NOV2020	77/C	1	No	O	NA	N	N/N
>55/ C4591001 1084 10841246	INFEC	Tooth infection/ Upper Left Tooth Infection	2	28SEP2020	20/16	1	No	O	NA	R (13OCT2020)	N/N
>55/ C4591001 1084 10841258	INFEC	Eye infection/ Right Eye Infection	1	29AUG2020	8/C	2	No	O	NA/TC	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1084 10841266	MUSC	Muscular weakness/ Left lower extremity weakness	2	28OCT2020	45/C	2	No	O	NA	RG	N/N	
	MUSC	Rhabdomyolysis/ Rhabdomyolysis	2	02NOV2020	50/12	2	No	O	NA/TCN	R (13NOV2020)	N/N	
	CARD	Atrial fibrillation/ Atrial Fibrillation with RVR	2	03NOV2020	51/C	2	No	O	NA/TC	RG	N/N	
	INFEC	Emphysematous cholecystitis/ Acute Emphysematous Cholecystitis	2	03NOV2020	51/71	4	No	O	NA/TC/TCN/W	F (12JAN2021)	Y/N	
		Sepsis/ Sepsis	2	03NOV2020	51/71	4	No	O	NA/TC/TCN/W	F (12JAN2021)	Y/N	
	RENAL	Acute kidney injury/ Acute Kidney Injury	2	03NOV2020	51/C	2	No	O	NA/TCN	RG	N/N	
>55/ C4591001 1084 10841276	INJ&P	Fall/ Fall	2	03JAN2021	115/1	2	No	O	NA	R (03JAN2021)	N/N	
		Tibia fracture/ Tibial Plateau Fracture	2	03JAN2021	115/C	2	No	O	NA	N	N/N	
>55/ C4591001 1084 10841293	INFEC	Hordeolum/ Right Eye Stye	1	13SEP2020	19/26	1	No	O	NA/TC	R (08OCT2020)	N/N	
	PSYCH	Depression/ Depression	2	04JAN2021	111/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1084 10841297	NERV	Headache/ Headache	1	05SEP2020	11/1	1	No	O	NA/TC	R (05SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1084 10841320	NERV	Migraine/ increased migraine	1	29AUG2020	2/C	2	No	O	NA/TC	N	N/N	
	INV	Blood pressure abnormal/ Worsening blood pressure	2	02JAN2021	107/1	2	No	O	NA	R (02JAN2021)	N/N	
	MUSC	Myalgia/ Left Shoulder Muscle Pain	2	02JAN2021	107/1	2	No	O	NA	R (02JAN2021)	N/N	
>55/ C4591001 1084 10841329	INV	Hepatic enzyme increased/ Elevated liver enzymes	1	16SEP2020	17/C	1	No	O	NA	N	N/N	
>55/ C4591001 1084 10841367	MUSC	Back pain/ Sharp Pain in Lower Right Back	1	15SEP2020	7/C	2	No	O	NA	N	N/N	
>55/ C4591001 1084 10841377	INJ&P	Stoma site rash/ Rash to Abdomen Around Ostomy Bag	1	15SEP2020	5/10	2	No	CD	NA/TC	R (24SEP2020)	N/N	
>55/ C4591001 1084 10841380	SKIN	Rash/ Rash on cheek	2	21OCT2020	20/7	2	No	O	NA/TC	R (27OCT2020)	N/N	
>55/ C4591001 1084 10841395	METAB	Hypercholesterolaemia/ hypercholesterolemia	2	17NOV2020	44/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001	INJ&P	Ankle fracture/ broken ankle	1	01OCT2020	18/C	2	No	O	NA/TCN	N	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1084 10841397		Fall/ Fall	1	01OCT2020	18/1	2	No	O	NA	R (01OCT2020)	N/N
>55/ C4591001 1084 10841398	NERV	Syncope/ Fainted	2	28OCT2020	24/1	1	No	O	NA	R (28OCT2020)	N/N
>55/ C4591001 1084 10841440	INFEC	Urinary tract infection/ Urinary Tract Infection	2	15OCT2020	2/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1084 10841470	GENRL	Multiple organ dysfunction syndrome/ Mutli-system organ failure	2	31DEC2020	72/12	4	No	O	NA/TC/TCN	F (11JAN2021)	Y/N
	INFEC	COVID-19/ COVID-19 Infection	2	31DEC2020	72/12	4	No	O	NA/TC/TCN/W	F (11JAN2021)	Y/N
>55/ C4591001 1084 10841471	INJ&P	Contusion/ Left Bruised Heel	1	05OCT2020	6/C	1	No	O	NA/TC/TCN	N	N/N
>55/ C4591001 1084 10841490	MUSC	Back pain/ Back Pain	1	05NOV2020	21/1	2	No	O	NA/TC	R (05NOV2020)	N/N
>55/ C4591001 1084 10841497	INFEC	Tooth abscess/ tooth abscess - #17 and #18#	3	02FEB2021	12/1	3	No	O	NA/TC/TCN	R (02FEB2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1084 10841504	INJ&P	Arthropod bite/ bug bite on left leg	1	08NOV2020	21/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1084 10841507	NERV	Headache/ Headaches	1	26OCT2020	8/73	1	No	O	NA	RS (06JAN2021)	N/N	
>55/ C4591001 1084 10841528	INJ&P	Fall/ Fall	1	08NOV2020	17/1	1	No	O	NA	R (08NOV2020)	N/N	
		Skin abrasion/ ABRASION to FOREHEAD	1	08NOV2020	17/1	1	No	O	NA	R (08NOV2020)	N/N	
>55/ C4591001 1085 10851005	INJ&P	Post procedural haemorrhage/ nose bleed (post Swab)*		30JUL2020	1/1	1	No	O	NA	R (30JUL2020)	N/N	
>55/ C4591001 1085 10851045	GASTR	Gingival bleeding/ Bleeding Gums#	3	15JAN2021	3/4	1	No	O	NA	R (18JAN2021)	N/N	
		Oral mucosal blistering/ Oral Blisters#	3	15JAN2021	3/4	1	No	O	NA	R (18JAN2021)	N/N	
>55/ C4591001 1085 10851073	INFEC	Respiratory tract infection viral/ Viral Respiratory Infection	2	08SEP2020	13/11	1	No	O	NA	R (18SEP2020)	N/N	
>55/ C4591001	CARD	Acute myocardial infarction/ ACUTE NON ST ELEVATION	2	26DEC2020	108/4	4	No	O	NA/TC/TCN	R (29DEC2020)	Y/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1085 10851116		MYOCARDIAL INFARCTION (MI) - NSTEMI									
		Cardiac failure congestive/ ACUTE DIASTOLIC CONGESTIVE HEART FAILURE (CHF)	2	26DEC2020	108/4	3	No	O	NA/TC/TCN	RS (29DEC2020)	Y/N
	RENAL	Acute kidney injury/ Acute Kidney Injury	2	26DEC2020	108/4	3	No	O	NA	R (29DEC2020)	Y/N
	RESP	Haemoptysis/ MILD HEMOPTYSIS	2	26DEC2020	108/5	2	No	O	NA	R (30DEC2020)	N/N
>55/ C4591001 1085 10851160	VASC	Hypertension/ hypertension	2	NOV2020	46/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1085 10851168	GENRL	Chills/ CHILLS	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ FEVER	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C4591001 1085 10851182	INFEC	Sinusitis/ Sinus Infection#	3	08FEB2021	18/10	1	No	O	NA/TC	R (17FEB2021)	N/N
>55/ C4591001 1085 10851183	GASTR	Diarrhoea/ Diarrhea	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ Headache	2	18SEP2020	1/2	1	Yes		NA/TC	R (19SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	RESP	Oropharyngeal pain/ Sore throat	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1085 10851216	INJ&P	Fall/ Fall in hole	2	17OCT2020	25/1	1	No	O	NA	R (17OCT2020)	N/N
		Lower limb fracture/ Left leg fracture of tibia/fibula	2	17OCT2020	25/2	1	No	O	NA/TC/TCN	R (18OCT2020)	Y/N
>55/ C4591001 1085 10851268	GENRL	Chills/ Chills	2	01OCT2020	1/2	2	Yes		NA/TC	R (02OCT2020)	N/N
		Pyrexia/ Fever	2	01OCT2020	1/3	2	Yes		NA/TC	R (03OCT2020)	N/N
	GENRL	Injection site urticaria/ Localized Urticaria Injection Site	2	05OCT2020	5/2	1	Yes		NA	R (06OCT2020)	N/N
>55/ C4591001 1085 10851274	GASTR	Umbilical hernia/ umbilical hernia	2	02JAN2021	94/18	1	No	O	NA	R (19JAN2021)	N/N
>55/ C4591001 1085 10851293	GENRL	Pain/ body aches	2	05OCT2020	4/2	1	Yes		NA/TC	R (06OCT2020)	N/N
>55/ C4591001 1085 10851318	GENRL	Injection site pain/ injection site pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001	GENRL	Pyrexia/ Fever	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1085 10851324 >55/ C4591001	GASTR	Diarrhoea/ Diarrhea	1	20SEP2020	7/1	1	Yes		NA	R (20SEP2020)	N/N
1085 10851326 >55/ C4591001	NERV	Headache/ HEADACHE	2	21OCT2020	58/2	1	No	O	NA	R (22OCT2020)	N/N
1087 10871001 >55/ C4591001	METAB	Hypercholesterolaemia/ Hypercholesterolemia#	3	21JAN2021	3/C	2	No	O	NA/TC	RG	N/N
1087 10871002 >55/ C4591001	INJ&P	Arthropod bite/ ANT BITES	1	14AUG2020	9/2	1	No	O	NA/TC	R (15AUG2020)	N/N
1087 10871003 >55/ C4591001	GENRL	Pyrexia/ Fever#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
1087 10871004 >55/ C4591001	EYE	Cataract/ WORSENING OF CATARACTS (RIGHT EYE)	1	21AUG2020	15/1	1	No	O	NA/TC/TCN	R (21AUG2020)	N/N
1087 10871009 >55/ C4591001	INJ&P	Ligament rupture/ ACL Tear - Right	2	OCT2020	35/	3	No	O	NA/TC/TCN	R (08JAN2021)	N/N
1087 10871012											

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Meniscus injury/ Meniscus Tear - Right	2	OCT2020	35/	3	No	O	NA/TC/TCN	R (08JAN2021)	N/N	
>55/ C4591001 1087 10871016	GENRL	Chills/ Chills#	4	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N	
	MUSC	Myalgia/ Muscle Pain#	4	12JAN2021	2/3	1	Yes		NA	R (14JAN2021)	N/N	
	NERV	Headache/ Worsening of Headache#	4	12JAN2021	2/3	1	Yes		NA	R (14JAN2021)	N/N	
>55/ C4591001 1087 10871023	GASTR	Diarrhoea/ Loose Bowel Movement	2	08SEP2020	14/1	1	No	O	NA	R (08SEP2020)	N/N	
	MUSC	Arthralgia/ generalized joint pain	2	17OCT2020	53/2	1	No	O	NA	R (18OCT2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain - Left Deltoid#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N	
>55/ C4591001 1087 10871024	INFEC	Cellulitis/ CELLULITIS R HAND MIDDLE FINGER	1	13AUG2020	7/58	2	No	O	NA/TC	R (09OCT2020)	N/N	
>55/ C4591001 1087 10871029	GASTR	Abdominal pain/ Functional Abdominal Pain	2	28OCT2020	64/9	2	No	O	NA/TC	R (05NOV2020)	N/N	
		Diverticulum/ Diverticulosis	2	28OCT2020	64/C	2	No	O	NA	N	N/N	
		Hiatus hernia/ Small Hiatal Hernia	2	28OCT2020	64/C	1	No	O	NA	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	HEPAT	Gallbladder disorder/ Distended Gallbladder	2	28OCT2020	64/C	1	No	O	NA	N	N/N	
	INFEC	Urinary tract infection/ Urinary Tract Infection	2	28OCT2020	64/9	2	No	O	NA	R (05NOV2020)	N/N	
	NERV	Toxic encephalopathy/ Acute Toxic Metabolic Encephalopathy	2	28OCT2020	64/9	3	No	CD	NA/TC	R (05NOV2020)	Y/N	
>55/ C4591001 1087 10871031	MUSC	Arthralgia/ RIGHT KNEE PAIN	2	08SEP2020	14/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1087 10871034	GENRL	Fatigue/ Fatigue#	4	04JAN2021	1/1	1	Yes		NA	R (04JAN2021)	N/N	
>55/ C4591001 1087 10871037	INFEC	Ear infection/ EAR INFECTION (RIGHT)	2	13SEP2020	18/12	2	No	O	NA/TC	R (24SEP2020)	N/N	
>55/ C4591001 1087 10871040	MUSC	Muscle spasms/ Leg Cramps - Bilateral Legs#	2	09FEB2021	163/3	1	No	O	NA	R (11FEB2021)	N/N	
	VASC	Deep vein thrombosis/ New Onset Deep Vein Thrombosis#	2	09FEB2021	163/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1087 10871043	SKIN	Rosacea/ Worsening of Rosacea	2	07SEP2020	8/7	1	No	O	NA/TC	R (13SEP2020)	N/N	
	NERV	Headache/ mild headache#	4	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1087 10871047	MUSC	Periarthritis/ Worsening of Frozen Shoulder	2	02NOV2020	64/C	1	No	O	NA	N	N/N	
>55/ C4591001 1087 10871048	GASTR	Diarrhoea/ DIARRHEAL EPISODE	1	30AUG2020	21/2	1	No	O	NA	R (31AUG2020)	N/N	
	INFEC	Sinusitis/ SINUS INFECTION	2	21SEP2020	22/7	1	No	O	NA/TC	R (27SEP2020)	N/N	
>55/ C4591001 1087 10871056	GENRL	Fatigue/ Fatigue#	4	29JAN2021	2/2	2	Yes		NA	R (30JAN2021)	N/N	
		Pyrexia/ Low Grade Fever#	4	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N	
	NERV	Headache/ Mild Headache#	4	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N	
>55/ C4591001 1087 10871057	GASTR	Nausea/ NAUSEA	2	14SEP2020	15/22	1	No	O	NA/TC	R (05OCT2020)	N/N	
>55/ C4591001 1087 10871070	CARD	Acute coronary syndrome/ ACUTE CORONARY SYNDROME	2	08SEP2020	8/3	3	No	O	NA/TC/TCN	R (10SEP2020)	Y/N	
		Angina unstable/ UNSTABLE ANGINA	2	08SEP2020	8/3	2	No	O	NA	R (10SEP2020)	N/N	
>55/ C4591001	NERV	Carpal tunnel syndrome/ Worsening of Carpal Tunnel	1	AUG2020	1/	2	No	O	NA/TCN	R (16OCT2020)	N/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1087 10871075 >55/ C4591001 1087 10871090	GENRL	Chills/ Chills	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
>55/ C4591001 1087 10871093	GENRL	Pyrexia/ Fever Chills/ Chills#	2 4	09SEP2020 11FEB2021	2/1 4/2	1 1	Yes Yes		NA NA	R (09SEP2020) R (12FEB2021)	N/N N/N
>55/ C4591001 1087 10871101	GENRL	Injection site pain/ Injection Site Pain - Left Deltoid#	3	21JAN2021	2/1	1	Yes		NA/TC	R (21JAN2021)	N/N
>55/ C4591001 1087 10871121	BLOOD	Pyrexia/ Fever# Blood loss anaemia/ Acute blood loss anemia	3 1	21JAN2021 07SEP2020	2/1 20/3	1 3	Yes No		NA/TC NA	R (21JAN2021) R (09SEP2020)	N/N N/N
	GASTR	Thrombocytopenia/ Thrombocytopenia Gastrointestinal haemorrhage/ GI Bleed Haematochezia/ Hematochezia Oesophageal ulcer/ Worsening of esophageal ulcers	1 1 1 1	07SEP2020 07SEP2020 07SEP2020 07SEP2020	20/C 20/3 20/3 20/3	3 3 3 3	No No No No	O O O O	NA P/TC/TCN/W NA/TC NA/TC/TCN	N R (09SEP2020) R (09SEP2020) R (09SEP2020)	N/N Y/N N/N N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Varices oesophageal/ Worsening of esophageal varices	1	07SEP2020	20/3	3	No	O	NA/TC/TCN	R (09SEP2020)	N/N
	HEPAT	Cirrhosis alcoholic/ Worsening of alcoholic cirrhosis	1	07SEP2020	20/C	3	No	O	NA	N	N/N
>55/ C4591001 1087 10871122	METAB	Hypernatraemia/ Hypernatremia	1	07SEP2020	20/3	2	No	O	NA	R (09SEP2020)	N/N
	GENRL	Chills/ Chills#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
>55/ C4591001 1087 10871124	NEOPL	Acrochordon/ WORSENING OF Skin Tag - eye, bilateral	1	08SEP2020	21/1	1	No	O	NA/TCN	R (08SEP2020)	N/N
	NEOPL	Glomus tumour/ WORSENING OF BENIGN GLOMUS TUMOR ON LEFT RING FINGER	2	15SEP2020	7/1	2	No	O	NA/TCN	R (15SEP2020)	N/N
>55/ C4591001 1087 10871125	GENRL	Fatigue/ Fatigue	1	25AUG2020	7/10	2	No	O	NA	R (03SEP2020)	N/N
	METAB	Dehydration/ Dehydration	1	25AUG2020	7/10	1	No	O	NA	R (03SEP2020)	N/N
>55/ C4591001 1087 10871128	GENRL	Pyrexia/ Fever	2	08OCT2020	30/1	1	No	O	NA	R (08OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	11SEP2020	2/5	1	Yes		NA	R (15SEP2020)	N/N
	RESP	Cough/ COUGH	2	25SEP2020	16/14	1	No	O	NA	R (08OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1087 10871150	INFEC	Pharyngitis streptococcal/ STREP THROAT	1	25AUG2020	5/12	3	No	O	NA/TC	R (05SEP2020)	N/N
	BLOOD	Lymphadenopathy/ Prominent Reactive Lymph nodes in Cervical Area	1	01SEP2020	12/5	2	No	O	NA	R (05SEP2020)	N/N
	GASTR	Abdominal pain/ Abdominal Pain	1	01SEP2020	12/5	2	No	O	NA	R (05SEP2020)	N/N
		Femoral hernia/ Femoral Hernia - Right	1	01SEP2020	12/C	2	No	O	NA	N	N/N
		Odynophagia/ Odynophagia	1	01SEP2020	12/5	2	No	O	NA	R (05SEP2020)	N/N
	GENRL	Swelling/ Right Anterior Cervical Swelling	1	01SEP2020	12/5	2	No	O	NA	R (05SEP2020)	N/N
	INFEC	Peritonsillar abscess/ Tonsillar Abscess - Right	1	01SEP2020	12/5	3	No	O	NA/TC	R (05SEP2020)	Y/N
		Urinary tract infection/ Urinary Tract Infection	1	01SEP2020	12/5	2	No	O	NA/TC	R (05SEP2020)	N/N
	METAB	Hypokalaemia/ Hypokalemia	1	01SEP2020	12/5	2	No	O	NA	R (05SEP2020)	N/N
	MUSC	Neck pain/ Right Anterior Cervical Tenderness	1	01SEP2020	12/5	2	No	O	NA	R (05SEP2020)	N/N
	RENAL	Pollakiuria/ Urinary Frequency	1	01SEP2020	12/5	2	No	O	NA/TC	R (05SEP2020)	N/N
	VASC	Hypertension/ Worsening of Hypertension	1	01SEP2020	12/3	2	No	O	NA	R (03SEP2020)	N/N
>55/ C4591001	GENRL	Chills/ Chills#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1087 10871154		Pain/ Generalized body ache#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N	
>55/ C4591001 1087 10871156	NEOPL	Squamous cell carcinoma of skin/ SQUAMOUS CELL CARCINOMA (RIGHT, FACE)	1	01SEP2020	12/43	2	No	O	NA	R (13OCT2020)	N/N	
>55/ C4591001 1087 10871169	GENRL	Chills/ Chills	1	12SEP2020	20/1	1	No	O	NA	R (12SEP2020)	N/N	
	GENRL	Chills/ Chills	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N	
		Fatigue/ Fatigue	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N	
	MUSC	Myalgia/ generalized muscle Soreness	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N	
>55/ C4591001 1087 10871170	NEOPL	Malignant melanoma of eyelid/ MELANOMA OF RIGHT LOWER EYELID	2	21SEP2020	8/66	3	No	O	NA	R (25NOV2020)	N/N	
	EYE	Cataract/ Worsening of Cataract - left eye	2	01NOV2020	49/24	3	No	O	NA/TCN	R (24NOV2020)	N/N	
>55/ C4591001 1087 10871174	MUSC	Muscle spasms/ Muscle Spasms	2	04JAN2021	113/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001	INFEC	Urinary tract infection/ UTI	1	31AUG2020	7/8	1	No	O	NA/TC	R (07SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1087 10871183 >55/ C4591001	GENRL	Chills/ Chills#	4	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N	
1087 10871184 >55/ C4591001	MUSC	Osteoarthritis/ OSTEOARTHRITIS RIGHT KNEE	1	02SEP2020	9/C	1	No	O	NA/TC	RG	N/N	
1087 10871187 >55/ C4591001	BLOOD	Monoclonal B-cell lymphocytosis/ Monoclonal B-Cell Lymphocytosis	2	NOV2020	47/C	2	No	O	NA	N	N/N	
1087 10871188 >55/ C4591001	GENRL	Chills/ CHILLS	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
1087 10871190	MUSC	Myalgia/ MUSCLE PAIN	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
	NERV	Headache/ HEADACHE	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
>55/ C4591001 1087 10871200	NERV	Neuropathy peripheral/ WORSENING OF NEUROPATHY	1	08SEP2020	15/29	2	No	O	NA/TCN	R (06OCT2020)	N/N	
	INFEC	Cystitis/ BLADDER INFECTION	2	10OCT2020	26/11	2	No	O	NA/TC	R (20OCT2020)	N/N	
	RENAL	Haematuria/ HEMATURIA	2	10OCT2020	26/11	2	No	O	NA/TC	R (20OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1087 10871204	RESP	Rhinorrhoea/ RUNNY NOSE	2	27SEP2020	13/8	1	No	O	NA	R (04OCT2020)	N/N
>55/ C4591001 1087 10871206	GENRL	Chills/ Chills	2	17SEP2020	3/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	17SEP2020	3/2	1	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C4591001 1087 10871216	MUSC	Intervertebral disc degeneration/ Degenerative Disc Disease	2	11DEC2020	87/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1087 10871218	GENRL	Chills/ Chills#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1087 10871222	EYE	Vitreous detachment/ POSTERIOR VITREOUS DETACHMENT	1	03SEP2020	9/C	2	No	O	NA	N	N/N
	GASTR	Diarrhoea/ DIARRHEA	2	17SEP2020	4/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1087 10871223	VASC	Flushing/ FACIAL FLUSHING	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001	INFEC	Gingival abscess/ ABSCESS ON GUM	1	04SEP2020	10/14	2	No	O	NA/TC/TCN	R (17SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1087 10871224 >55/ C4591001 1087 10871228	CARD	Atrial fibrillation/ PAROXYSMAL ATRIAL Fibrillation	1	03SEP2020	9/6	2	No	O	NA	R (08SEP2020)	N/N
		Cardiac failure congestive/ Worsening of Chronic Congestive Heart Failure	1	03SEP2020	9/6	3	No	O	P/TC/W	R (08SEP2020)	Y/N
	INFEC	Urinary tract infection/ Urinary Tract Infection	1	03SEP2020	9/6	2	No	O	NA/TC	R (08SEP2020)	N/N
	METAB	Dehydration/ DEHYDRATION	1	03SEP2020	9/2	2	No	O	NA/TCN	R (04SEP2020)	N/N
	RENAL	Acute kidney injury/ Acute Kidney Injury	1	03SEP2020	9/5	2	No	O	NA	R (07SEP2020)	N/N
	RESP	Acute respiratory failure/ Acute Respiratory Failure	1	03SEP2020	9/2	3	No	O	NA/TC	R (04SEP2020)	N/N
		Dyspnoea/ SHORTNESS OF BREATH	1	03SEP2020	9/2	3	No	O	NA	R (04SEP2020)	N/N
		Pulmonary oedema/ BILATERAL PULMONARY EDEMA	1	03SEP2020	9/3	2	No	O	NA	R (05SEP2020)	N/N
	VASC	Accelerated hypertension/ Accelerated Hypertension	1	03SEP2020	9/4	3	No	O	NA	R (06SEP2020)	N/N
	METAB	Hypokalaemia/ HYPOKALEMIA	1	04SEP2020	10/3	2	No	O	NA/TC	R (06SEP2020)	N/N
	GENRL	Pyrexia/ LOW-GRADE FEVER	1	05SEP2020	11/2	2	No	O	NA	R (06SEP2020)	N/N
	MUSC	Pain in extremity/ WORSENING OF BILATERAL FOOT PAIN	1	05SEP2020	11/2	2	No	O	NA/TC	R (06SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Dizziness/ Dizziness	1	05SEP2020	11/4	2	No	O	NA/TCN	R (08SEP2020)	N/N
	VASC	Hypotension/ Hypotension	1	05SEP2020	11/3	2	No	O	NA	R (07SEP2020)	N/N
>55/ C4591001 1087 10871232	EAR	Ear pain/ ear ache	2	01OCT2020	16/1	1	No	O	NA	R (01OCT2020)	N/N
>55/ C4591001 1087 10871238	RESP	Asthma/ WORSENING OF ASTHMA	1	30AUG2020	5/78	1	No	O	NA	R (15NOV2020)	N/N
>55/ C4591001 1087 10871256	GASTR	Diarrhoea/ DIARRHEAL EPISODE	1	06SEP2020	7/3	1	No	O	NA	R (08SEP2020)	N/N
>55/ C4591001 1087 10871257	GENRL	Pyrexia/ FEVER	2	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C4591001 1087 10871261	GENRL	Chills/ Chills	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
	MUSC	Myalgia/ Generalized muscle aches	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
	NERV	Headache/ Headache	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1087 10871266	NEOPL	Gallbladder cancer stage II/ Gallbladder Cancer - Stage 2	2	20NOV2020	61/C	4	No	O	NA/TC/TCN	RG	Y/N	
>55/ C4591001 1087 10871275	GASTR	Paraesthesia oral/ TONGUE TINGLING	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/Y	
>55/ C4591001 1087 10871284	NEOPL	Basal cell carcinoma/ BASAL CELL CARCINOMA OF LEFT EYE LID	1	08SEP2020	8/30	2	No	O	NA/TCN	R (07OCT2020)	N/N	
>55/ C4591001 1087 10871286	BLOOD	Blood loss anaemia/ Acute Blood Loss Anemia	2	04NOV2020	44/2	3	No	O	NA/TCN	R (05NOV2020)	N/N	
	GASTR	Gastrointestinal haemorrhage/ Gastrointestinal Bleed	2	04NOV2020	44/3	3	No	O	NA/TC/TCN	R (06NOV2020)	Y/N	
		Haematochezia/ Hematochezia	2	04NOV2020	44/4	2	No	O	NA	R (07NOV2020)	N/N	
	INV	Haemoglobin decreased/ Decreased Hemoglobin	2	04NOV2020	44/62	2	No	O	NA	R (04JAN2021)	N/N	
	CONG	Gastrointestinal arteriovenous malformation/ Arteriovenous Malformation of the Colon	2	06NOV2020	46/2	3	No	O	NA/TCN	R (07NOV2020)	N/N	
	GASTR	Gastric antral vascular ectasia/ Gastric Antral Vascular Ectasia	2	06NOV2020	46/2	3	No	O	NA/TCN	R (07NOV2020)	N/N	
>55/ C4591001	BLOOD	Lymphadenopathy/ Enlarged right inguinal lymph nodes	2	16NOV2020	56/9	3	No	O	NA/TC/TCN	R (24NOV2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1087 10871289	GENRL	Peripheral swelling/ Severe Soft Tissue Swelling of Right Lower Extremity	2	16NOV2020	56/9	3	No	O	NA/TC/TCN	R (24NOV2020)	N/N	
	INFEC	Device related infection/ Worsening of Chronic Recurrent Infection of Right Total Knee Replacement	2	16NOV2020	56/9	3	No	O	NA/TC/TCN	R (24NOV2020)	Y/N	
	INJ&P	Patella fracture/ Fragmentation of the Patella	2	16NOV2020	56/9	3	No	O	NA/TC/TCN	R (24NOV2020)	N/N	
	MUSC	Arthralgia/ Right Knee Pain	2	16NOV2020	56/9	3	No	O	NA/TC/TCN	R (24NOV2020)	N/N	
		Bone disorder/ Cortical Irregularity of medial distal femur	2	16NOV2020	56/9	3	No	O	NA/TC/TCN	R (24NOV2020)	N/N	
>55/ C4591001 1087 10871290	GENRL	Fatigue/ Fatigue#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	
		Injection site pain/ Left Deltoid Injection Site Pain#	4	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N	
>55/ C4591001 1087 10871291	MUSC	Arthralgia/ WORSENING OF RIGHT KNEE PAIN	1	14SEP2020	14/40	1	No	O	NA/TC	R (23OCT2020)	N/N	
>55/ C4591001 1087 10871304	INJ&P	Tooth fracture/ CRACKED TOOTH	2	28SEP2020	8/8	2	No	O	NA/TCN	R (05OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	RENAL	Hypertonic bladder/ Over-Active Bladder	2	JAN2021	103/C	2	No	O	NA/TC	N	N/N
	GASTR	Gastroesophageal reflux disease/ GERD#	2	01FEB2021	134/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1087 10871315	GENRL	Chills/ Chills#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1087 10871317	GASTR	Gastroesophageal reflux disease/ new onset gastroesophageal reflux disease	2	24SEP2020	2/39	1	No	O	NA/TC	R (01NOV2020)	N/N
	RESP	Nasal polyps/ new onset nasal polyps	2	24SEP2020	2/39	1	No	O	NA/TC	R (01NOV2020)	N/N
>55/ C4591001 1087 10871331	MUSC	Pain in extremity/ Left Arm Soreness	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
>55/ C4591001 1087 10871334	MUSC	Back pain/ WORSENING OF BACK PAIN	2	20OCT2020	29/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1087 10871337	VASC	Hypertension/ Hypertension	2	31JAN2021	130/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1087 10871350	MUSC	Arthralgia/ Shoulder Pain - Left	2	09JAN2021	103/2	2	No	O	NA/TC	R (10JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1087 10871353	GENRL	Injection site pain/ Left Deltoid Injection Site Pain	1	08SEP2020	1/C	2	Yes		NA	N	N/N
	GENRL	Chills/ Chills#	4	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
		Pain/ Generalized Body Ache#	4	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1087 10871370	INFEC	Otitis media acute/ ACUTE OTITIS MEDIA (LEFT)	2	18OCT2020	19/7	2	No	O	NA/TC	R (24OCT2020)	N/N
>55/ C4591001 1087 10871371	NERV	Cervical radiculopathy/ cervical radiculopathy	2	19OCT2020	20/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1087 10871385	REPRO	Benign prostatic hyperplasia/ WORSENING OF BENIGN PROSTATIC HYPERPLASIA*		10SEP2020	-5/22	2	No	O	NA/TC	R (01OCT2020)	N/N
	RESP	Rhinitis perennial/ WORSENING OF PERENNIAL ALLERGIC RHINITIS	1	28SEP2020	14/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1087 10871386	SKIN	Actinic keratosis/ Actinic Keratosis	1	12OCT2020	21/27	2	No	O	NA/TC	R (07NOV2020)	N/N
>55/ C4591001 1087 10871392	SKIN	Actinic keratosis/ Actinic Keratosis	2	12OCT2020	13/C	2	No	O	NA/TC	N	N/N

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>55/ C4591001 1087 10871396	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
		Injection site pain/ Soreness at Injection Site	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
		Pyrexia/ Fever	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
>55/ C4591001 1087 10871397	INFEC	Sinusitis/ Sinus Infection	2	07OCT2020	7/10	2	No	O	NA/TC	R (16OCT2020)	N/N
>55/ C4591001 1087 10871407	RESP	Oropharyngeal pain/ Sore Throat	1	17SEP2020	8/2	1	No	O	NA	R (18SEP2020)	N/N
>55/ C4591001 1087 10871413	GENRL	Chills/ Chills#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
		Fatigue/ Fatigue#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
		Pyrexia/ Fever#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
>55/ C4591001 1087 10871416	GENRL	Fatigue/ Fatigue	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
		Pyrexia/ Fever	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1087 10871418	RESP	Asthma/ ASTHMA EXACERBATION	1	16SEP2020	7/10	2	No	O	NA/TC	R (25SEP2020)	N/N
>55/ C4591001 1087 10871422	MUSC	Muscle spasms/ RIGHT ARM MUSCLE SPASM	1	12SEP2020	2/81	1	Yes		NA/TC	R (01DEC2020)	N/N
		Myalgia/ GENERALIZED RIGHT ARM MUSCLE PAIN	1	12SEP2020	2/81	1	Yes		NA	R (01DEC2020)	N/N
		Tendonitis/ Bicep Tendonitis - Right	1	12SEP2020	2/81	2	No	O	NA/TCN	R (01DEC2020)	N/N
>55/ C4591001 1087 10871430	GENRL	Chills/ CHILLS	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1087 10871431	GENRL	Fatigue/ Fatigue	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ Headache	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	RESP	Rhinitis allergic/ Allergic Rhinitis	2	22OCT2020	22/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1087 10871432	GENRL	Chills/ CHILLS	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
		Pyrexia/ FEVER	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1087 10871437	MUSC	Myalgia/ MUSCLE ACHES	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1087 10871442		Pyrexia/ Fever#	3	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Pyrexia/ fever	1	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
>55/ C4591001 1087 10871450	GASTR	Diarrhoea/ Diarrhea	2	06OCT2020	2/4	2	Yes		NA	R (09OCT2020)	N/N
		Nausea/ Nausea	2	06OCT2020	2/4	2	Yes		NA	R (09OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	06OCT2020	2/4	2	Yes		NA	R (09OCT2020)	N/N
	NERV	Dizziness/ lightheadedness	2	06OCT2020	2/4	2	Yes		NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
		Pain/ body aches	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
		Pyrexia/ fever	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1087 10871463	INFEC	Cellulitis/ CELLULITIS RIGHT LEG	1	29SEP2020	14/7	2	No	O	NA/TC	R (05OCT2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain - Left deltoid#	4	04FEB2021	2/3	1	Yes		NA	R (06FEB2021)	N/N	
>55/ C4591001 1087 10871466	INV	Prostatic specific antigen increased/ PSA LEVELS ELEVATED	1	28SEP2020	13/8	1	No	O	NA/TC	R (05OCT2020)	N/N	
>55/ C4591001 1087 10871467	GENRL	Chills/ Chills#	4	03FEB2021	2/2	1	Yes		NA/TC	R (04FEB2021)	N/N	
		Pyrexia/ Fever#	4	03FEB2021	2/2	1	Yes		NA/TC	R (04FEB2021)	N/N	
>55/ C4591001 1087 10871475	GASTR	Nausea/ Nausea#	4	02MAR2021	2/2	1	Yes		NA	R (03MAR2021)	N/N	
>55/ C4591001 1087 10871478	MUSC	Spinal osteoarthritis/ Osteoarthritis - Spine	2	28OCT2020	20/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1087 10871495	VASC	Hypertension/ WORSENING OF HYTPERTENSION	2	19OCT2020	8/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001	GENRL	Chills/ Chills#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1087 10871497		Pain/ Body Ache#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N	
	NERV	Headache/ Headache#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N	
>55/ C4591001 1087 10871502	REPRO	Erectile dysfunction/ ERECTION DYSFUNCTION	2	30OCT2020	19/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1087 10871509	GENRL	Chills/ Chills	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
	MUSC	Myalgia/ Generalized Muscle Pain	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
>55/ C4591001 1087 10871524	EAR	Vertigo/ VERTIGO	1	02OCT2020	8/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1087 10871537	REPRO	Benign prostatic hyperplasia/ Worsening of Benign Prostatic Hyperplasia	1	12OCT2020	1/1	1	No	O	NA/TCN	R (12OCT2020)	N/N	
>55/ C4591001 1087 10871538	INFEC	Eye infection bacterial/ UNSPECIFIED RIGHT EYE BACTERIAL INFECTION	1	12OCT2020	1/6	2	No	O	NA/TC	R (17OCT2020)	N/N	
>55/ C4591001	MUSC	Myalgia/ Generalized muscle aches	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1087 10871564 >55/ C4591001 1087 10871566	GENRL	Chills/ Chills	2	21NOV2020	2/2	1	Yes		NA	R (22NOV2020)	N/N	
>55/ C4591001 1087 10871578	MUSC	Injection site pain/ Injection Site Pain Myalgia/ generalized muscle pain	2	21NOV2020	2/2	1	Yes		NA	R (22NOV2020)	N/N	
>55/ C4591001 1088 10881014	MUSC	Osteoarthritis/ Osteoarthritis#	2	18FEB2021	171/C	2	No	O	NA/TCN	N	N/N	
>55/ C4591001 1088 10881034	MUSC	Arthralgia/ Joint pain in hands#	4	11JAN2021	1/25	1	Yes		NA	R (04FEB2021)	N/N	
>55/ C4591001 1088 10881105	INJ&P	Fall/ Subject fell	1	30AUG2020	4/1	1	No	O	NA/TCN	R (30AUG2020)	N/N	
		Humerus fracture/ Fractured Left Humerus	1	30AUG2020	4/1	2	No	O	NA/TCN	R (30AUG2020)	N/N	
	INFEC	Urinary tract infection/ Urinary Tract Infection	1	06SEP2020	11/14	2	No	CD	NA/TC	R (19SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1088 10881106	INFEC	Herpes zoster/ Subject diagnosed with shingles on back of neck and side of face	2	06OCT2020	22/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1088 10881121	INFEC	Urinary tract infection/ UTI	2	09DEC2020	80/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1088 10881126	INFEC	COVID-19/ COVID-19	2	29NOV2020	68/C	4	No	O	NA	UNK	Y/N	
	CARD	Cardiac arrest/ cardiac arrest	2	01DEC2020	70/1	4	No	O	NA/W	F (01DEC2020)	Y/N	
		Coronary artery disease/ Coronary Artery Disease	2	01DEC2020	70/1	4	No	O	NA	UNK (01DEC2020)	Y/N	
>55/ C4591001 1088 10881138	EYE	Retinal artery occlusion/ left retinal artery branch occlusion	2	19DEC2020	90/C	2	No	O	NA	N	N/N	
>55/ C4591001 1088 10881139	NEOPL	Metastases to lung/ Metastases to the lungs#	2	24FEB2021	133/11	4	No	O	NA/W	F (06MAR2021)	Y/N	
		Pancreatic carcinoma metastatic/ Metastatic pancreatic cancer#	2	24FEB2021	133/C	4	No	O	NA	N	Y/N	
>55/ C4591001 1088 10881149	SURG	Blepharoplasty/ Blepharoplasty#	3	11FEB2021	9/1	1	No	CND	NA	R (11FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1088 10881164	INFEC	Sinusitis/ sinus infection	1	14SEP2020	7/16	2	No	O	NA/TC	R (29SEP2020)	N/N
	INFEC	Sinusitis/ SINUS INFECTION	2	23OCT2020	25/10	1	No	O	NA/TC	R (01NOV2020)	N/N
>55/ C4591001 1088 10881172	NERV	Migraine/ Migraine Headache#	3	01FEB2021	14/C	1	No	CND	NA/TC	RG	N/N
>55/ C4591001 1088 10881178	INJ&P	Wrist fracture/ Broken left wrist	1	23OCT2020	16/C	2	No	O	NA/TCN	RG	N/N
>55/ C4591001 1088 10881179	INJ&P	Forearm fracture/ Right forearm broken	2	24DEC2020	86/56	1	No	O	NA/TCN	R (17FEB2021)	N/N
>55/ C4591001 1088 10881202	MUSC	Pain in extremity/ Soreness/arm pain in left arm	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
>55/ C4591001 1089 10891004	INV	White blood cell count increased/ elevated white count	1	10AUG2020	13/C	2	No	O	NA/TC	N	N/N
	INV	Blood pressure increased/ Elevated blood pressure#	4	09MAR2021	28/C	2	No	CND	NA/TC	N	N/N
>55/ C4591001	EAR	Vertigo/ vertigo#	2	01FEB2021	167/9	2	No	O	NA	R (09FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1089 10891023 >55/ C4591001	GASTR	Nausea/ Nausea	2	14SEP2020	27/1	2	No	O	NA	R (14SEP2020)	N/N	
1089 10891026 >55/ C4591001	RENAL	Nephrolithiasis/ left kidney stone#	2	05JAN2021	135/6	2	No	O	NA	R (10JAN2021)	N/N	
1089 10891028 >55/ C4591001	INV	Blood cholesterol increased/ Elevated Cholesterol	1	AUG2020	1/C	2	No	O	NA/TC	N	N/N	
1089 10891042 >55/ C4591001	BLOOD	Lymphadenopathy/ Left Para clavicular lymph node enlargement	2	28AUG2020	3/68	1	Yes		NA	R (03NOV2020)	N/N	
1089 10891073 >55/ C4591001	RESP	Chronic obstructive pulmonary disease/ Worsening of COPD	2	12NOV2020	70/1	4	No	O	NA/W	F (12NOV2020)	Y/N	
1089 10891088 >55/ C4591001	NERV	Dementia Alzheimer's type/ Worsening of Dementia (Alzheimer's).	2	20DEC2020	115/11	4	No	O	NA/W	F (30DEC2020)	Y/N	
1089 10891093 >55/ C4591001	INJ&P	Fall/ Fell out of Bed	1	15AUG2020	6/1	1	No	O	NA	R (15AUG2020)	N/N	
		Muscle strain/ pulled muscle right arm	1	15AUG2020	6/	2	No	O	NA/TC	R	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1089 10891110	MUSC	Back pain/ Back Pain	1	15AUG2020	4/6	1	No	O	NA/TC	R (20AUG2020)	N/N	
>55/ C4591001 1089 10891146	GENRL	Pyrexia/ Fever	2	16NOV2020	70/1	2	No	O	NA	R (16NOV2020)	N/N	
	INFEC	Cystitis/ bladder infection	2	16NOV2020	70/5	2	No	O	NA/TC	R (20NOV2020)	N/N	
		Kidney infection/ kidney infection	2	16NOV2020	70/5	2	No	O	NA/TC	R (20NOV2020)	N/N	
	RENAL	Nephrolithiasis/ Kidney Stone in Right Kidney (6mm stone)	2	16NOV2020	70/C	2	No	O	NA	N	N/N	
		Nephrolithiasis/ Kidney stone in Left kidney (7mm stone)	2	16NOV2020	70/C	2	No	O	NA	N	N/N	
>55/ C4591001 1089 10891150	CARD	Atrial fibrillation/ Chronic atrial fibrillation with RVR'	2	04OCT2020	26/2	3	No	O	NA/TC/TCN	R (05OCT2020)	Y/N	
>55/ C4591001 1089 10891160	INJ&P	Ankle fracture/ right ankle fracture	1	07SEP2020	19/116	2	No	O	NA	R (31DEC2020)	N/N	
		Fall/ fall	1	07SEP2020	19/1	2	No	O	NA	R (07SEP2020)	N/N	
>55/ C4591001	GENRL	Injection site erythema/ redness at injection site	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1089 10891164		Injection site pain/ Muscle pain at injection site	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N	
>55/ C4591001 1089 10891169	EAR	Vertigo/ worsening of Vertigo	2	09SEP2020	1/3	1	No	O	NA	R (11SEP2020)	N/N	
>55/ C4591001 1089 10891172	INJ&P	Fall/ Subject fell#	2	28FEB2021	167/1	2	No	O	NA	R (28FEB2021)	N/N	
		Wrist fracture/ rt wrist fracture#	2	28FEB2021	167/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1089 10891190	NERV	Sciatica/ sciatic pain	2	17OCT2020	32/C	1	No	O	NA	N	N/N	
>55/ C4591001 1089 10891242	REPRO	Benign prostatic hyperplasia/ BPH	2	20OCT2020	28/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1089 10891270	GENRL	Injection site pain/ Muscle pain in left deltoid at injection site	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N	
>55/ C4591001 1089 10891282	NERV	Nerve compression/ pinched nerve back	2	07OCT2020	7/7	2	No	O	NA/TC	R (13OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1089 10891301	MUSC	Pain in extremity/ Left arm pain#	3	29JAN2021	4/C	1	No	O	NA	RG	N/N	
>55/ C4591001 1089 10891322	INFEC	Conjunctivitis/ left pink eye	1	30SEP2020	15/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1090 10901004	NEOPL	Prostate cancer/ Prostate cancer-early stage	2	OCT2020	42/	2	No	O	NA/TCN	R (11NOV2020)	N/N	
>55/ C4591001 1090 10901013	GENRL	Pyrexia/ Fever#	4	09FEB2021	2/1	1	Yes		NA/TC	R (09FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	09FEB2021	2/1	2	Yes		NA/TC/TCN	R (09FEB2021)	N/N	
>55/ C4591001 1090 10901027	RENAL	Nephrolithiasis/ kidney stone	2	11SEP2020	19/4	3	No	O	NA/TC	R (14SEP2020)	N/N	
	GENRL	Chills/ Chills#	4	09MAR2021	2/2	2	Yes		NA	R (10MAR2021)	N/N	
		Fatigue/ Fatigue#	4	09MAR2021	2/2	2	Yes		NA	R (10MAR2021)	N/N	
>55/ C4591001 1090 10901036	GENRL	Chills/ Chills#	3	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Fatigue/ Fatigue#	3	22JAN2021	2/2	2	Yes		NA	R (23JAN2021)	N/N
	NERV	Headache/ Headache#	3	22JAN2021	2/2	2	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	12FEB2021	2/2	2	Yes		NA	R (13FEB2021)	N/N
	NERV	Headache/ Headache#	4	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N
>55/ C4591001 1090 10901059	GENRL	Injection site pain/ Injection site pain#	3	30JAN2021	2/3	2	Yes		NA	R (01FEB2021)	N/N
>55/ C4591001 1090 10901060	INJ&P	Muscle strain/ pulled hamstring, left	2	23SEP2020	27/8	2	No	O	NA/TC	R (30SEP2020)	N/N
	MUSC	Arthralgia/ right shoulder pain	2	26SEP2020	30/1	1	No	O	NA/TC	R (26SEP2020)	N/N
>55/ C4591001 1090 10901063	GENRL	Injection site pain/ Injection site pain-left arm#	4	16FEB2021	1/2	2	Yes		NA/TC	R (17FEB2021)	N/N
>55/ C4591001 1090 10901078	VASC	Lymphorrhoea/ lymph fluid leakage, left groin area	2	31AUG2020	4/6	1	No	O	NA/TC	R (05SEP2020)	N/N
>55/ C4591001 1090 10901080	SKIN	Drug eruption/ drug eruption rash	2	20SEP2020	24/23	2	No	O	NA/TC	R (12OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1090 10901083	INJ&P	Ligament sprain/ left ankle, twisted	2	12SEP2020	16/26	1	No	O	NA/TC	R (07OCT2020)	N/N	
>55/ C4591001 1090 10901089	RENAL	Haematuria/ hematuria	2	18SEP2020	22/13	2	No	O	NA/TC	R (30SEP2020)	N/N	
>55/ C4591001 1090 10901113	ENDO	Goitre/ Goiter	1	08AUG2020	2/106	1	No	O	NA	R (21NOV2020)	N/N	
>55/ C4591001 1090 10901142	GENRL	Injection site pain/ Injection site pain-left arm#	3	02MAR2021	2/2	2	Yes		NA	R (03MAR2021)	N/N	
>55/ C4591001 1090 10901143	GENRL	Injection site pain/ Injection site pain-left arm#	4	16FEB2021	1/3	1	Yes		NA	R (18FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/1	2	Yes		NA	R (17FEB2021)	N/N	
>55/ C4591001 1090 10901153	MUSC	Arthralgia/ right thumb, joint pain	2	15SEP2020	16/115	1	No	O	NA	R (07JAN2021)	N/N	
>55/ C4591001 1090 10901158	INFEC	Urinary tract infection/ UTI	1	15AUG2020	4/18	1	No	O	NA/TC	R (01SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1090 10901159	GENRL	Pyrexia/ Fever#	4	04FEB2021	2/2	2	Yes		NA/TC	R (05FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	04FEB2021	2/2	2	Yes		NA/TC	R (05FEB2021)	N/N	
>55/ C4591001 1090 10901162	INJ&P	Contusion/ bruised right torso	2	23SEP2020	21/62	1	No	O	NA	R (23NOV2020)	N/N	
		Fall/ fall	2	23SEP2020	21/1	1	No	O	NA	R (23SEP2020)	N/N	
>55/ C4591001 1090 10901166	GENRL	Fatigue/ Fatigue#	4	09FEB2021	2/2	3	Yes		NA	R (10FEB2021)	N/N	
		Injection site pain/ Injection site pain-left arm#	4	09FEB2021	2/4	2	Yes		NA	R (12FEB2021)	N/N	
	MUSC	Arthralgia/ Arthralgia-Generalized#	4	09FEB2021	2/2	2	Yes		NA	R (10FEB2021)	N/N	
	NERV	Headache/ Headache#	4	09FEB2021	2/2	2	Yes		NA/TC	R (10FEB2021)	N/N	
>55/ C4591001 1090 10901175	INJ&P	Clavicle fracture/ left clavicle, fractured	2	07NOV2020	65/27	2	No	O	NA/TC	R (03DEC2020)	N/N	
		Concussion/ concussion	2	07NOV2020	65/8	2	No	O	NA/TC/TCN	R (14NOV2020)	Y/N	
		Contusion/ left scalp contusion	2	07NOV2020	65/8	2	No	O	NA	R (14NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Rib fracture/ broken ribs	2	07NOV2020	65/27	2	No	O	NA/TC	R (03DEC2020)	N/N	
		Road traffic accident/ bike accident	2	07NOV2020	65/1	3	No	O	NA/TC	R (07NOV2020)	Y/N	
	NERV	Intraventricular haemorrhage/ intraventricular hemorrhage, left occipital horn	2	07NOV2020	65/8	2	No	O	NA/TC	RS (14NOV2020)	Y/N	
>55/ C4591001 1090 10901186	EAR	Ear pain/ Earache	1	28AUG2020	15/5	1	No	O	NA	R (01SEP2020)	N/N	
>55/ C4591001 1090 10901189	METAB	Type 2 diabetes mellitus/ diabetes type II	1	30AUG2020	17/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1090 10901191	GENRL	Fatigue/ Fatigue#	4	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	26FEB2021	2/2	1	Yes		NA/TC	R (27FEB2021)	N/N	
>55/ C4591001 1090 10901195	GENRL	Pyrexia/ FEVER#	4	10FEB2021	1/3	2	Yes		NA/TC	R (12FEB2021)	N/N	
>55/ C4591001 1090 10901196	SKIN	Eczema/ worsening eczema, right elbow	2	25SEP2020	18/25	1	No	O	NA/TC	R (19OCT2020)	N/N	
>55/ C4591001	GENRL	Fatigue/ Fatigue	2	11SEP2020	2/3	2	Yes		NA	R (13SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1090 10901202		Injection site pain/ Injection site pain-left arm	2	11SEP2020	2/3	2	Yes		NA	R (13SEP2020)	N/N	
		Pain/ Body aches-generalized	2	11SEP2020	2/3	2	Yes		NA	R (13SEP2020)	N/N	
>55/ C4591001 1090 10901207	MUSC	Pain in extremity/ Left arm soreness#	4	11FEB2021	1/2	2	Yes		NA	R (12FEB2021)	N/N	
	MUSC	Arthralgia/ Arthralgia-generalized#	4	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N	
>55/ C4591001 1090 10901209	MUSC	Musculoskeletal stiffness/ stiffness in left arm	1	17AUG2020	1/4	2	Yes		NA/TC	R (20AUG2020)	N/N	
>55/ C4591001 1090 10901214	NERV	Headache/ Headache#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N	
>55/ C4591001 1090 10901217	GENRL	Injection site pain/ injection pain, left arm	1	17AUG2020	1/4	2	Yes		NA	R (20AUG2020)	N/N	
>55/ C4591001 1090 10901218	GASTR	Dyspepsia/ Heart burn	2	22SEP2020	15/3	1	No	O	NA	R (24SEP2020)	N/N	
>55/ C4591001	GENRL	Injection site pain/ Injection site pain-left arm#	3	17FEB2021	1/4	2	Yes		NA	R (20FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1090 10901223	MUSC	Myalgia/ Myalgia#	3	17FEB2021	1/4	2	Yes		NA/TC	R (20FEB2021)	N/N	
	NERV	Headache/ Headache#	3	17FEB2021	1/4	2	Yes		NA/TC	R (20FEB2021)	N/N	
>55/ C4591001 1090 10901229	CARD	Arrhythmia/ abnormal heart rhythm, idiopathic	2	14SEP2020	7/C	1	No	O	NA	RG	N/N	
>55/ C4591001 1090 10901236	INFEC	Sinusitis/ sinus infection, head	2	08OCT2020	29/15	1	No	O	NA/TC	R (22OCT2020)	N/N	
>55/ C4591001 1090 10901237	GENRL	Chills/ Chills	2	04SEP2020	1/2	2	Yes		NA/TC	R (05SEP2020)	N/N	
	SKIN	Hyperhidrosis/ Sweats	2	04SEP2020	1/2	2	Yes		NA/TC	R (05SEP2020)	N/N	
	GENRL	Pyrexia/ Fever	2	05SEP2020	2/1	1	Yes		NA/TC	R (05SEP2020)	N/N	
	MUSC	Myalgia/ Muscle pain	2	05SEP2020	2/1	1	Yes		NA/TC	R (05SEP2020)	N/N	
	NERV	Headache/ Headache	2	05SEP2020	2/2	1	Yes		NA/TC	R (06SEP2020)	N/N	
>55/ C4591001 1090 10901240	NERV	Headache/ Headache#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1090 10901242	GASTR	Diarrhoea/ Diarrhea#	3	29JAN2021	2/3	2	Yes		NA	R (31JAN2021)	N/N
>55/ C4591001 1090 10901243	MUSC	Myalgia/ Myalgia#	4	19JAN2021	2/2	2	Yes		NA/TC	R (20JAN2021)	N/N
>55/ C4591001 1090 10901247	GENRL	Chills/ Chills	2	11SEP2020	2/1	2	Yes		NA	R (11SEP2020)	N/N
		Pain/ Body aches	2	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
	NERV	Headache/ Headache	2	12SEP2020	3/1	2	Yes		NA/TC	R (12SEP2020)	N/N
>55/ C4591001 1090 10901255	GENRL	Injection site pain/ Injection site pain-Left arm	1	19AUG2020	1/3	2	Yes		NA	R (21AUG2020)	N/N
	GENRL	Injection site pain/ left arm injection site pain	2	08SEP2020	1/2	2	Yes		NA	R (09SEP2020)	N/N
	MUSC	Mobility decreased/ Decreased mobility of left arm	2	08SEP2020	1/2	2	Yes		NA	R (09SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
		Pyrexia/ Low grade fever	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
>55/ C4591001	GENRL	Chills/ Chills	2	05OCT2020	28/2	1	No	O	NA	R (06OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1090 10901259 >55/ C4591001 1090 10901261	GENRL   NERV	Injection site pain/ Injection site pain-left arm#  Headache/ Headache#	3	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N
>55/ C4591001 1090 10901272	GENRL   GENRL	Injection site pain/ injection site pain-left arm  Injection site swelling/ Swelling at injection site-left arm  Fatigue/ Fatigue	1	19AUG2020	1/4	2	Yes		NA/TC	R (22AUG2020)	N/N
>55/ C4591001 1090 10901273	GENRL   NERV	Fatigue/ Fatigue#  Headache/ Headache#	3	26FEB2021	2/3	1	Yes		NA	R (28FEB2021)	N/N
>55/ C4591001 1090 10901274	GENRL   MUSC  GENRL	Pyrexia/ Fever  Myalgia/ Muscle aches  Chills/ Chills	1	01SEP2020	1/2	1	Yes		NA/TC	R (02SEP2020)	N/N
			2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Pyrexia/ Fever	2	21SEP2020	1/1	1	Yes		NA/TC	R (21SEP2020)	N/N	
>55/ C4591001 1090 10901275	GENRL	Injection site pain/ Injection site pain-left arm#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N	
>55/ C4591001 1090 10901282	GENRL	Chills/ Chills	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
		Injection site pain/ Injection site pain	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
		Pyrexia/ Low grade fever	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
	MUSC	Myalgia/ Generalized muscle aches	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N	
>55/ C4591001 1090 10901284	SKIN	Pruritus/ pruritus, generalized	2	21SEP2020	1/5	1	Yes		NA	R (25SEP2020)	N/N	
>55/ C4591001 1090 10901286	MUSC	Arthralgia/ Generalized Arthralgia#	4	12JAN2021	1/2	1	Yes		NA/TC	R (13JAN2021)	N/N	
>55/ C4591001 1090 10901292	GENRL	Chills/ Chills	2	21SEP2020	1/2	3	Yes		NA	R (22SEP2020)	N/N	
		Pain/ Body aches	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1090 10901296	NERV	Headache/ Headache	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N	
	GENRL	Pyrexia/ Fever	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
	GENRL	Chills/ Chills	2	21SEP2020	1/2	3	Yes		NA	R (22SEP2020)	N/N	
			Injection site pain/ Injection site pain-Left arm	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
			Pain/ Body aches	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
>55/ C4591001 1090 10901299		Pyrexia/ Fever	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N	
	GENRL	Pyrexia/ Low grade fever	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
>55/ C4591001 1090 10901300	IMMUN	Anaphylactic shock/ anaphylactic shock	2	09OCT2020	19/1	4	No	O	NA/TC	R (09OCT2020)	Y/N	
	INJ&P	Arthropod bite/ ant bite, left ankle	2	09OCT2020	19/2	1	No	O	NA	R (10OCT2020)	N/N	
>55/ C4591001 1090 10901306	NERV	Headache/ Headache	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N	
	GASTR	Nausea/ Nausea	2	22SEP2020	2/1	2	Yes		NA	R (22SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1090 10901307	EAR	Tinnitus/ tinnitus, pulsatile	1	05SEP2020	4/18	1	No	O	NA	R (22SEP2020)	N/N	
>55/ C4591001 1090 10901310	GENRL	Injection site pain/ Injection site pain-Left arm	1	02SEP2020	1/3	2	Yes		NA/TC	R (04SEP2020)	N/N	
	GENRL	Chills/ Chills	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N	
		Pain/ Body aches	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N	
		Pyrexia/ Low grade fever	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N	
	NERV	Post herpetic neuralgia/ Post herpetic neuralgia, worsening	2	24SEP2020	2/4	2	Yes		NA	R (27SEP2020)	N/N	
>55/ C4591001 1090 10901331	GENRL	Fatigue/ Fatigue#	4	20FEB2021	2/2	2	Yes		NA	R (21FEB2021)	N/N	
>55/ C4591001 1090 10901337	GENRL	Pyrexia/ Fever	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
	MUSC	Musculoskeletal pain/ Left shoulder and neck muscle pain	1	09SEP2020	2/2	1	Yes		NA/TC	R (10SEP2020)	N/N	
>55/ C4591001 1090 10901340	GENRL	Injection site pain/ Left injection site pain	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/Y	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1090 10901342	GENRL	Chills/ Chills	2	01OCT2020	2/1	2	Yes		NA	R (01OCT2020)	N/N
		Fatigue/ fatigue	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		Pyrexia/ fever	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
	INJ&P	Fall/ Fall	1	20SEP2020	13/1	2	No	O	NA/TC	R (20SEP2020)	N/N
		Ligament sprain/ Ankle sprain-left	1	20SEP2020	13/6	2	No	O	NA/TC	R (25SEP2020)	N/N
>55/ C4591001 1090 10901352	VASC	Ligament sprain/ Arm sprain-right	1	20SEP2020	13/37	2	No	O	NA/TC	R (26OCT2020)	N/N
>55/ C4591001 1090 10901352	VASC	Hypertension/ Hypertension#	4	13FEB2021	5/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1090 10901354	GENRL	Chills/ Chills	2	28SEP2020	1/5	2	Yes		NA	R (02OCT2020)	N/N
		Fatigue/ Fatigue	2	28SEP2020	1/5	2	Yes		NA	R (02OCT2020)	N/N
	NERV	Injection site pain/ Injection site pain-left arm	2	28SEP2020	1/7	2	Yes		NA/TC	R (04OCT2020)	N/N
		Headache/ Headache	2	28SEP2020	1/5	1	Yes		NA/TC	R (02OCT2020)	N/N
SKIN	Night sweats/ Night sweats	2	28SEP2020	1/4	2	Yes		NA	R (01OCT2020)	N/Y	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	BLOOD	Lymphadenopathy/ Swollen left axillary lymph node	2	29SEP2020	2/6	2	Yes		NA	R (04OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N
>55/ C4591001 1090 10901359	NERV	Headache/ Headache#	3	25FEB2021	1/2	1	Yes		NA	R (26FEB2021)	N/N
>55/ C4591001 1090 10901361	GENRL	Injection site pain/ Left injection site pain	2	29SEP2020	1/5	2	Yes		NA/TC	R (03OCT2020)	N/Y
	CARD	Tachycardia/ Tachycardia	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
>55/ C4591001 1090 10901376	GENRL	Injection site pain/ injection site pain	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1090 10901396	GENRL	Injection site pain/ Injection site pain-left arm	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
>55/ C4591001 1090 10901403	GENRL	Fatigue/ Fatigue#	3	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
		Injection site pain/ Injection site pain-left arm#	3	15JAN2021	2/2	2	Yes		NA	R (16JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache#	3	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
	GASTR	Diarrhoea/ worsening Diarrhea#	3	18JAN2021	5/4	1	Yes		NA/TC	R (21JAN2021)	N/N
	MUSC	Pain in extremity/ Arm pain-left arm, whole#	4	03FEB2021	1/4	2	Yes		NA	R (06FEB2021)	N/N
	GENRL	Chills/ Chills#	4	04FEB2021	2/3	1	Yes		NA	R (06FEB2021)	N/N
		Pyrexia/ Fever#	4	04FEB2021	2/3	1	Yes		NA	R (06FEB2021)	N/N
	MUSC	Arthralgia/ Generalized arthralgia#	4	04FEB2021	2/3	2	Yes		NA	R (06FEB2021)	N/N
		Myalgia/ Myalgia#	4	04FEB2021	2/3	1	Yes		NA	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	4	04FEB2021	2/3	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1090 10901406	GENRL	Chills/ chills	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
		Pain/ Body aches	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
>55/ C4591001 1090 10901412	GENRL	Fatigue/ Fatigue	2	09OCT2020	2/4	1	Yes		NA	R (12OCT2020)	N/N
>55/ C4591001 1090 10901415	INFEC	Sinusitis/ sinus infection, possible	1	30SEP2020	14/43	2	No	O	NA/TC	R (11NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	VASC	Hypertension/ hypertension	1	09OCT2020	23/C	2	No	O	P/TC	N	N/N
>55/ C4591001 1090 10901420	GENRL	Injection site pain/ Injection site pain-left arm	2	08OCT2020	1/3	2	Yes		NA	R (10OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	09OCT2020	2/6	3	Yes		NA	R (14OCT2020)	N/N
	NERV	Headache/ Headache	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
>55/ C4591001 1090 10901430	INFEC	Herpes zoster/ shingles, on back (near bra hooks)	1	29SEP2020	9/60	1	No	O	NA	R (27NOV2020)	N/N
>55/ C4591001 1090 10901434	NERV	Headache/ Headache	2	14OCT2020	1/2	1	Yes		NA/TC	R (15OCT2020)	N/N
>55/ C4591001 1090 10901436	GENRL	Chills/ Chills#	4	22FEB2021	1/1	1	Yes		NA	R (22FEB2021)	N/N
	NERV	Headache/ Headache#	4	22FEB2021	1/1	1	Yes		NA	R (22FEB2021)	N/N
>55/ C4591001 1090 10901439	GENRL	Fatigue/ Fatigue#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ Injection site pain-left arm#	4	23FEB2021	1/2	1	Yes		NA/TC	R (24FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1090 10901444	GENRL	Injection site pain/ Injection site soreness	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Musculoskeletal stiffness/ Muscle stiffness-whole right arm	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain, right arm	2	13OCT2020	1/1	1	Yes		NA	R (13OCT2020)	N/Y
	GENRL	Chills/ chills	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
		Pain/ body aches	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
>55/ C4591001 1090 10901449	GENRL	Chills/ Chills#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
		Pyrexia/ Fever#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
>55/ C4591001 1090 10901450	MUSC	Intervertebral disc protrusion/ Bulging disc-lumbar	2	15OCT2020	2/7	2	No	O	NA/TC	R (21OCT2020)	N/N
>55/ C4591001 1090 10901459	NERV	Headache/ Headache	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
		Lethargy/ Lethargy	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C4591001	GENRL	Chills/ chills	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1090 10901460		Non-cardiac chest pain/ Chest pain-non cardiac	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
		Pyrexia/ fever	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
	SKIN	Rash/ Rash-chest	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
>55/ C4591001 1090 10901472	GENRL	Injection site pain/ Injection site pain-left arm	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1090 10901478	GENRL	Injection site pain/ Injection site pain-left arm	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
>55/ C4591001 1090 10901486	GASTR	Duodenal obstruction/ duodenal obstruction	2	13JAN2021	80/4	4	No	O	NA/TC/TCN	R (16JAN2021)	Y/N
>55/ C4591001 1090 10901487	GENRL	Chills/ Chills#	4	17FEB2021	2/2	2	Yes		NA	R (18FEB2021)	N/N
>55/ C4591001 1090 10901488	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/4	2	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Fatigue/ Tiredness	2	29OCT2020	2/2	2	Yes		NA	R (30OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1090 10901492	GENRL	Injection site pain/ Injection site pain-right arm	2	29OCT2020	2/3	2	Yes		NA	R (31OCT2020)	N/N
		Fatigue/ Fatigue#	4	23FEB2021	2/2	1	Yes		NA/W	R (24FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	2/2	1	Yes		NA/TC	R (24FEB2021)	N/N
>55/ C4591001 1090 10901493	GENRL	Pain/ Body aches	2	07NOV2020	2/2	1	Yes		NA	R (08NOV2020)	N/N
		Pyrexia/ Fever	2	07NOV2020	2/2	1	Yes		NA/TC	R (08NOV2020)	N/N
>55/ C4591001 1090 10901500	GENRL	Injection site pain/ Injection site pain-left arm	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
>55/ C4591001 1090 10901511	GENRL	Injection site pain/ Injection site pain-left arm	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
		MUSC	Myalgia/ Myalgia	2	11NOV2020	1/2	2	Yes		NA	R (12NOV2020)
	NERV	Headache/ Headache	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
>55/ C4591001 1090 10901521	GENRL	Fatigue/ fatigue	2	12NOV2020	2/2	3	Yes		NA	R (13NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Bursitis/ bursitis, left shoulder	2	14NOV2020	4/C	2	Yes		NA	N	N/N
>55/ C4591001 1090 10901531	GENRL	Fatigue/ Fatigue#	4	27FEB2021	2/2	2	Yes		NA	R (28FEB2021)	N/N
>55/ C4591001 1090 10901533	GENRL	Fatigue/ Fatigue	1	23OCT2020	2/2	1	Yes		NA/TC	R (24OCT2020)	N/N
	NERV	Headache/ Headache	1	23OCT2020	2/2	1	Yes		NA/TC	R (24OCT2020)	N/N
	NERV	Headache/ Headache	2	11NOV2020	1/1	1	Yes		NA/TC	R (11NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain-left arm#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
>55/ C4591001 1090 10901534	GENRL	Injection site pain/ Injection site pain-left arm	1	22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N
>55/ C4591001 1090 10901541	GENRL	Pyrexia/ Fever	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Pain/ Body Aches	2	14NOV2020	2/3	1	Yes		NA/TC	R (16NOV2020)	N/N
		Pyrexia/ Fever	2	14NOV2020	2/3	1	Yes		NA/TC	R (16NOV2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ Injection site pain-left arm	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1090 10901549	GENRL	Chills/ Chills	2	16NOV2020	1/2	1	Yes		NA	R (17NOV2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	16NOV2020	1/2	2	Yes		NA	R (17NOV2020)	N/N	
>55/ C4591001 1090 10901553	EAR	Vertigo positional/ positional vertigo, intermittent	1	27OCT2020	2/8	2	Yes		NA	R (03NOV2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	17NOV2020	2/2	1	Yes		NA	R (18NOV2020)	N/N	
	NERV	Headache/ Headache	2	17NOV2020	2/2	1	Yes		NA/TC	R (18NOV2020)	N/N	
>55/ C4591001 1090 10901555	GENRL	Fatigue/ Tiredness	2	17NOV2020	2/3	2	Yes		NA	R (19NOV2020)	N/N	
		Pain/ Bodyaches	2	17NOV2020	2/3	2	Yes		NA	R (19NOV2020)	N/N	
	NERV	Headache/ Headache	2	17NOV2020	2/3	2	Yes		NA	R (19NOV2020)	N/N	
>55/ C4591001 1090 10901560	GENRL	Chills/ Chills	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N	
		Injection site pain/ Injection site pain-left arm	2	18NOV2020	2/3	1	Yes		NA	R (20NOV2020)	N/N	
		Pain/ Body aches	2	18NOV2020	2/2	2	Yes		NA/TC	R (19NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1090 10901568	GENRL	Injection site pain/ Injection site pain-left arm	1	31OCT2020	2/3	1	Yes		NA	R (02NOV2020)	N/N
>55/ C4591001 1090 10901569	GENRL	Fatigue/ Fatigue	1	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	21NOV2020	2/4	2	Yes		NA	R (24NOV2020)	N/N
		Injection site pain/ Injection site pain-left arm	2	21NOV2020	2/3	1	Yes		NA	R (23NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/3	2	Yes		NA	R (20FEB2021)	N/N
>55/ C4591001 1091 10911001	INJ&P	Arthropod bite/ INSECT BITE OF RIGHT ARM	1	14AUG2020	16/4	1	No	O	NA/TC	R (17AUG2020)	N/N
>55/ C4591001 1091 10911002	INFEC	Otitis media/ BILATERAL SERIOUS OTITIS MEDIA	1	16AUG2020	18/178	1	No	O	NA/TC	R (09FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Left subclavicular lymph node enlargement#	4	03FEB2021	2/4	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1091 10911021	MUSC	Joint instability/ worsening of unstable left kneecap	1	10AUG2020	8/4	1	No	O	NA	R (13AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1091 10911026	INFEC	Urinary tract infection/ urinary tract infection	2	15SEP2020	1/4	1	No	O	NA/TC	R (18SEP2020)	N/N
	INJ&P	Ligament sprain/ left ankle sprain	2	16JAN2021	124/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1091 10911029	GENRL	Chills/ Chills#	3	24FEB2021	2/5	1	Yes		NA	R (28FEB2021)	N/N
>55/ C4591001 1091 10911041	INJ&P	Arthropod bite/ insect bite	2	28AUG2020	3/21	1	No	O	NA/TC	R (17SEP2020)	N/N
>55/ C4591001 1091 10911045	NERV	Headache/ headache#	3	01FEB2021	21/1	1	No	CD	NA/TC	R (01FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
>55/ C4591001 1091 10911047	GENRL	Chills/ Chills#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	04FEB2021	2/1	2	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1091 10911050	INJ&P	Fall/ Fall	1	21AUG2020	17/1	1	No	O	NA	R (21AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Skin abrasion/ left knee abrasion	1	21AUG2020	17/8	1	No	O	NA	R (28AUG2020)	N/N
		Arthralgia/ left knee pain	1	21AUG2020	17/8	1	No	O	NA	R (28AUG2020)	N/N
		Flank pain/ left flank pain	1	21AUG2020	17/8	1	No	O	NA	R (28AUG2020)	N/N
>55/ C4591001 1091 10911055	INFEC	Herpes zoster/ shingles	2	18SEP2020	26/15	2	No	O	NA/TC	R (02OCT2020)	N/N
>55/ C4591001 1091 10911059	INJ&P	Muscle rupture/ Torn left hamstring	2	30AUG2020	4/19	2	No	O	NA/TC	RS (17SEP2020)	N/N
	VASC	Hypotension/ hypotension	2	30AUG2020	4/1	2	No	O	NA/TCN	R (30AUG2020)	N/N
>55/ C4591001 1091 10911074	GENRL	Fatigue/ fatigue#	3	28DEC2020	1/5	2	Yes		NA	R (01JAN2021)	N/N
		Injection site pain/ pain at injection site#	3	28DEC2020	1/4	2	Yes		NA	R (31DEC2020)	N/N
>55/ C4591001 1091 10911080	GENRL	Chills/ chills#	4	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
		Injection site pain/ injection site pain#	4	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1091 10911081	GASTR	Diarrhoea/ diarrhea	2	27SEP2020	33/3	1	No	O	NA	R (29SEP2020)	N/N	
	INFEC	Otitis media/ otitis media, bilateral	2	30SEP2020	36/3	2	No	O	NA/TC	R (02OCT2020)	N/N	
		Sinusitis/ sinusitis	2	30SEP2020	36/3	2	No	O	NA/TC	R (02OCT2020)	N/N	
>55/ C4591001 1091 10911084	MUSC	Osteoarthritis/ Worsening of B/L hand osteoarthritis	2	01JAN2021	128/11	2	No	O	NA/TC	R (11JAN2021)	N/N	
>55/ C4591001 1091 10911101	GENRL	Injection site pain/ Injection site pain#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	
>55/ C4591001 1091 10911109	NERV	Headache/ intermittent headache	1	13AUG2020	2/1	1	Yes		NA	R (13AUG2020)	N/N	
	PSYCH	Disorientation/ disorientation	1	13AUG2020	2/1	1	Yes		NA	R (13AUG2020)	N/N	
>55/ C4591001 1091 10911110	GENRL	Injection site pain/ injection site pain#	3	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N	
	GENRL	Injection site pain/ injection site pain#	4	27JAN2021	1/2	1	Yes		NA/TC	R (28JAN2021)	N/N	
>55/ C4591001	GENRL	Injection site pain/ injection site pain	2	19SEP2020	19/4	1	Yes		NA	R (22SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1091 10911112 >55/ C4591001 1091 10911114	MUSC	Myalgia/ Generalized myalgia#	4	17FEB2021	2/1	1	Yes		NA/TC	R (17FEB2021)	N/N	
	NERV	Headache/ Headache#	4	17FEB2021	2/1	1	Yes		NA/TC	R (17FEB2021)	N/N	
>55/ C4591001 1091 10911127	MUSC	Pain in extremity/ left arm pain	2	15SEP2020	2/5	1	Yes		NA	R (19SEP2020)	N/N	
	MUSC	Myalgia/ myalgia	2	16SEP2020	3/1	1	Yes		NA	R (16SEP2020)	N/N	
>55/ C4591001 1091 10911128	GENRL	Fatigue/ Fatigue#	4	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N	
		Injection site pain/ Injection site pain#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N	
>55/ C4591001 1091 10911135	GENRL	Injection site pain/ injection site pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
	NERV	Headache/ headache#	4	07JAN2021	1/1	1	Yes		NA	R (07JAN2021)	N/N	
>55/ C4591001 1091 10911153	GENRL	Chills/ chills	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INFEC	Otitis media/ bilateral Otitis Media	2	JAN2021	116/	1	No	O	NA/TC	R	N/N
>55/ C4591001 1091 10911161	GENRL	Fatigue/ fatigue#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1091 10911168	GENRL	Injection site pain/ injection site pain#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
>55/ C4591001 1091 10911170	BLOOD	Lymphadenopathy/ enlarged left axillary lymph node	1	03SEP2020	10/28	1	Yes		NA	R (30SEP2020)	N/N
>55/ C4591001 1091 10911180	GENRL	Injection site pain/ injection site pain#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
>55/ C4591001 1091 10911181	GASTR	Nausea/ nausea#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
		Injection site pain/ injection site pain#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1091 10911184	GENRL	Fatigue/ Fatigue#	4	22FEB2021	1/2		Yes		NA	R (23FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1091 10911190	MUSC	Pain in extremity/ left arm pain	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
>55/ C4591001 1091 10911191	MUSC	Myalgia/ generalized myalgias	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C4591001 1091 10911193	MUSC	Pain in extremity/ left arm pain	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
>55/ C4591001 1091 10911194	GENRL	Injection site pain/ Injection site pain#	4	06JAN2021	1/4	2	Yes		NA	R (09JAN2021)	N/N
	GENRL	Chills/ chills#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
		Fatigue/ fatigue#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	4	07JAN2021	2/2	2	Yes		NA	R (08JAN2021)	N/N
>55/ C4591001 1091 10911195	GENRL	Pain/ generalized body aches	1	29AUG2020	2/7	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	15SEP2020	1/6	1	Yes		NA	R (20SEP2020)	N/N
		Injection site pain/ injection site pain	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Pain/ generalized body aches	2	15SEP2020	1/6	1	Yes		NA	R (20SEP2020)	N/N	
>55/ C4591001 1091 10911199	NERV	Headache/ headache#	3	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N	
>55/ C4591001 1091 10911201	GENRL	Injection site pain/ injection site soreness	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/Y	
>55/ C4591001 1091 10911205	GENRL	Injection site pain/ soreness at injection	1	03SEP2020	4/3	1	Yes		NA	R (05SEP2020)	N/N	
>55/ C4591001 1091 10911209	GENRL	Injection site pain/ Soreness at injection site	1	01SEP2020	1/4	1	Yes		NA	R (04SEP2020)	N/N	
	MUSC	Myalgia/ General muscle pain	1	11SEP2020	11/9	1	No	O	NA	R (19SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	12SEP2020	12/75	1	No	O	NA	R (25NOV2020)	N/N	
	GENRL	Pyrexia/ fever	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
	EAR	Vertigo/ Vertigo	2	JAN2021	103/	3	No	CD	NA/TC	R	N/N	
>55/ C4591001 1091 10911211	GENRL	Injection site pain/ injection site soreness	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1091 10911213	GENRL	Injection site pain/ injection site pain#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N	
		Injection site pain/ Injection site pain#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N	
		Injection site pain/ injection site soreness	1	02SEP2020	2/8	1	Yes		NA	R (09SEP2020)	N/N	
		Injection site erythema/ injection site redness	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N	
		Injection site pain/ injection site pain	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N	
		Myocardial infarction/ Myocardial Infarction	2	06NOV2020	47/1	4	No	O	NA/TC/TCN	R (06NOV2020)	Y/N	
	>55/ C4591001 1091 10911222	GENRL	Injection site pain/ Soreness at injection site	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ Injection site pain	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
	NERV	Headache/ Headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
>55/ C4591001	GASTR	Nausea/ nausea#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1091 10911225	GENRL	Fatigue/ fatigue#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
		Injection site pain/ injection site pain#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
>55/ C4591001 1091 10911230	GENRL	Injection site pain/ Left arm pain at injection site	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Chills/ Chills	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		Injection site pain/ Left arm pain at injection site	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1091 10911231	MUSC	Myalgia/ myalgia	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
		Pain in extremity/ left arm pain	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	MUSC	Myalgia/ generalized myalgia	2	22SEP2020	2/3	1	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C4591001 1091 10911234	MUSC	Myalgia/ Myalgia	2	24SEP2020	1/3	1	Yes		NA/TC	R (26SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	26SEP2020	3/1	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001	GENRL	Chills/ chills (without fever)	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1091 10911242		Fatigue/ fatigue	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N	
	NERV	Headache/ Headache	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N	
>55/ C4591001 1091 10911243	GENRL	Chills/ chills (without fever)	1	06SEP2020	4/3	1	Yes		NA	R (08SEP2020)	N/N	
>55/ C4591001 1091 10911247	GASTR	Dental caries/ dental cavity	1	17SEP2020	15/1	1	No	O	NA	R (17SEP2020)	N/N	
	INJ&P	Arthropod sting/ Itching due to Beestings	1	17SEP2020	15/5	2	No	O	NA/TC	R (21SEP2020)	N/N	
		Arthropod sting/ Swelling due to Beestings	1	17SEP2020	15/5	1	No	O	NA/TC	R (21SEP2020)	N/N	
	SKIN	Dermatitis/ Dermatitis of unknown origin on chest and bilateral arms	2	JAN2021	102/C	1	No	O	NA/TC/W	RG	N/N	
>55/ C4591001 1091 10911248	GENRL	Fatigue/ Fatigue#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N	
	MUSC	Myalgia/ Worsening of Generalized myalgia#	4	15FEB2021	1/2	1	Yes		NA/TC	R (16FEB2021)	N/N	
>55/ C4591001 1091 10911249	MUSC	Pain in extremity/ Right arm pain	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ R arm injection site pain	2	22SEP2020	1/7	1	Yes		NA	R (28SEP2020)	N/N
	GENRL	Chills/ Chills	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
	EAR	Vertigo positional/ Benign Paroxysmal Positional Vertigo	2	17OCT2020	26/4	2	No	O	NA/TC	R (20OCT2020)	N/N
>55/ C4591001 1091 10911258	INFEC	Otitis media bacterial/ L ear bacterial otitis media (medical history)	1	14SEP2020	6/51	2	No	O	NA/TC	R (03NOV2020)	N/N
	GENRL	Injection site pain/ injection site pain#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1091 10911264	GENRL	Injection site pain/ injection site pain#	3	14JAN2021	1/1	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ headache#	3	14JAN2021	1/1	1	Yes		NA	R (14JAN2021)	N/N
>55/ C4591001 1091 10911267	GENRL	Chills/ Chills#	4	25FEB2021	2/2	2	Yes		NA/TC	R (26FEB2021)	N/N
		Fatigue/ Fatigue#	4	25FEB2021	2/2	2	Yes		NA/TC	R (26FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	25FEB2021	2/2	2	Yes		NA/TC	R (26FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1091 10911268	MUSC	Musculoskeletal stiffness/ Generalized muscle stiffness#	4	25FEB2021	2/2	2	Yes		NA/TC	R (26FEB2021)	N/N	
	NERV	Headache/ Headache#	4	25FEB2021	2/2	2	Yes		NA/TC	R (26FEB2021)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	2	28SEP2020	1/5	1	Yes		NA	R (02OCT2020)	N/N	
	GENRL	Malaise/ Malaise	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N	
	>55/ C4591001 1091 10911269	GENRL	Fatigue/ fatigue	1	10SEP2020	2/8	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Injection site pain/ Pain at Injection site	1	10SEP2020	2/8	1	Yes		NA	R (17SEP2020)	N/N	
	NERV	Headache/ headache	1	10SEP2020	2/8	1	No	O	NA/TC	R (17SEP2020)	N/N	
	RESP	Rhinalgia/ Right Nostril Pain	1	10SEP2020	2/8	1	No	O	NA	R (17SEP2020)	N/N	
	RESP	Throat irritation/ throat irritation	1	12SEP2020	4/6	1	No	O	NA	R (17SEP2020)	N/N	
	GASTR	Toothache/ Toothache, Unspecified Right Side	1	19SEP2020	11/8	1	No	O	NA/TC	R (26SEP2020)	N/N	
INFEC	Tooth infection/ Infection of tooth	1	19SEP2020	11/8	1	No	O	NA/TC	R (26SEP2020)	N/N		
GENRL	Injection site pain/ Injection Site Pain	2	29SEP2020	1/11	1	Yes		NA	R (09OCT2020)	N/N		
GENRL	Fatigue/ Fatigue	2	30SEP2020	2/8	1	Yes		NA	R (07OCT2020)	N/N		



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1091 10911272	NERV	Headache/ Headaches	2	30SEP2020	2/8	1	Yes		NA/TC	R (07OCT2020)	N/N	
	GENRL	Injection site pain/ Mild pain right arm at injection site	1	10SEP2020	1/8	1	Yes		NA	R (17SEP2020)	N/N	
	GENRL	Injection site pain/ Mild Pain R Arm at Injection Site	2	29SEP2020	1/4	1	Yes		NA	R (02OCT2020)	N/N	
	GENRL	Fatigue/ fatigue	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N	
>55/ C4591001 1091 10911274		Malaise/ malaise	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N	
	SKIN	Angioedema/ periorbital angioedema	1	11SEP2020	2/3	1	No	O	NA/TC	R (13SEP2020)	N/N	
	SKIN	Angioedema/ periorbital angioedema	1	27SEP2020	18/2	1	No	O	NA/TC/TCN	R (28SEP2020)	N/N	
	NERV	Headache/ headache#	3	16DEC2020	1/1	1	Yes		NA	R (16DEC2020)	N/N	
>55/ C4591001 1091 10911292	GENRL	Injection site pain/ pain at injection site#	3	17DEC2020	2/2	1	Yes		NA	R (18DEC2020)	N/N	
	GENRL	Fatigue/ fatigue#	4	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue	1	18SEP2020	8/44	2	No	O	NA	R (31OCT2020)	N/N	
		Malaise/ malaise	1	18SEP2020	8/43	1	No	O	NA	R (30OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1091 10911294	METAB	Decreased appetite/ loss of appetite	1	18SEP2020	8/44	1	No	O	NA	R (31OCT2020)	N/N
	GENRL	Chills/ Chills#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	03FEB2021	2/3	1	Yes		NA	R (05FEB2021)	N/N
	NERV	Headache/ Intermittent headaches#	4	03FEB2021	2/2	1	Yes		NA/TC	R (04FEB2021)	N/N
	NERV	Headache/ headache	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		Injection site pain/ injection site pain	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		Pyrexia/ fever	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
	MUSC	Arthralgia/ arthralgias	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
	>55/ C4591001 1091 10911296	GENRL	Chills/ chills#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)
>55/ C4591001		Fatigue/ fatigue#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
		Injection site pain/ site injection pain#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ headache#	4	09FEB2021	2/1	2	Yes		NA	R (09FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1091 10911299	BLOOD	Lymphadenopathy/ Swollen left lymph node on neck#	4	12FEB2021	5/20	1	Yes		NA	R (03MAR2021)	N/N
>55/ C4591001 1091 10911307	GENRL	Chills/ chills#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
>55/ C4591001 1091 10911316	GENRL	Injection site pain/ injection site pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
>55/ C4591001 1091 10911318	GENRL	Injection site pain/ Injection Site Pain	2	06OCT2020	1/4	1	Yes		NA	R (09OCT2020)	N/N
>55/ C4591001 1091 10911323	GENRL	Chills/ chills#	4	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N
		Fatigue/ fatigue#	4	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N
>55/ C4591001 1091 10911330	GENRL	Injection site pain/ Injection site pain#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001	GENRL	Chills/ chills	2	14OCT2020	1/1	1	Yes		NA	R (14OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1091 10911335	MUSC	Myalgia/ myalgia	2	14OCT2020	1/1	1	Yes		NA	R (14OCT2020)	N/N
	NERV	Headache/ headache	2	14OCT2020	1/1	1	Yes		NA	R (14OCT2020)	N/N
>55/ C4591001 1091 10911337	GENRL	Fatigue/ fatigue	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
		Pyrexia/ fever	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
	NERV	Headache/ headache	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
>55/ C4591001 1091 10911345	GENRL	Injection site pain/ injection site pain	2	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Chills/ chills	2	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N
		Fatigue/ fatigue	2	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N
>55/ C4591001 1091 10911346	GENRL	Injection site pain/ injection site pain	1	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	19DEC2020	2/1	1	Yes		NA	R (19DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1091 10911347	GENRL	Injection site pain/ injection site pain#	4	07JAN2021	1/4	1	Yes		NA	R (10JAN2021)	N/N
>55/ C4591001 1091 10911354	GENRL	Injection site pain/ Injection Site Pain	1	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
>55/ C4591001 1091 10911364	GENRL	Injection site pain/ Injection site pain	1	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
	NERV	Dizziness/ light headedness	2	05NOV2020	1/1	1	Yes		NA	R (05NOV2020)	N/N
		Headache/ headache	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	06NOV2020	2/4	1	Yes		NA	R (09NOV2020)	N/N
		Pyrexia/ Fever	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
	MUSC	Myalgia/ Myalgias	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
	RESP	Nasal congestion/ nasal congestion	2	06NOV2020	2/4	1	No	O	NA	R (09NOV2020)	N/N
>55/ C4591001 1091 10911365	NERV	Headache/ Headache	2	05NOV2020	1/4	1	Yes		NA/TC	R (08NOV2020)	N/N
	MUSC	Joint swelling/ joint swelling bilateral knees	2	06NOV2020	2/6	2	No	O	NA/TC	R (11NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	EYE	Eye inflammation/ worsen of inflammation bilateral eyes recurrent	2	10NOV2020	6/C	1	No	O	NA	N	N/N
	GENRL	Chills/ Chills#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
		Fatigue/ Fatigue#	4	12FEB2021	1/2	2	Yes		NA	R (13FEB2021)	N/N
		Pyrexia/ Fever#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
>55/ C4591001 1091 10911369	GENRL	Malaise/ malaise#	4	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
>55/ C4591001 1091 10911370	SKIN	Pruritus/ itching	2	14NOV2020	4/2	1	No	O	NA	R (15NOV2020)	N/N
>55/ C4591001 1091 10911374	GENRL	Pyrexia/ fever	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
	MUSC	Myalgia/ myalgia	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
	NERV	Headache/ headache	2	10NOV2020	2/3	1	Yes		NA	R (12NOV2020)	N/N
>55/ C4591001 1092 10921005	GENRL	Pain/ Body aches#	4	07JAN2021	1/2	2	Yes		NA/TC	R (08JAN2021)	N/N
		Pyrexia/ Fever#	4	07JAN2021	1/2	2	Yes		NA/TC	R (08JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache#	4	07JAN2021	1/2	2	Yes		NA/TC	R (08JAN2021)	N/N
>55/ C4591001 1092 10921006	RESP	Paranasal sinus discomfort/ sinus pressure	1	19AUG2020	1/3	1	Yes		NA/TC	R (21AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	09SEP2020	2/1	1	No	O	NA	R (09SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea#	4	25FEB2021	4/6	1	No	O	NA	R (02MAR2021)	N/N
>55/ C4591001 1092 10921007	GENRL	Chills/ Chills	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	MUSC	Myalgia/ myalgia	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
>55/ C4591001 1092 10921010	INFEC	Vulvovaginitis/ Vulvovaginitis	1	03SEP2020	16/40	1	No	O	NA/TC	R (12OCT2020)	N/N
	GASTR	Abdominal pain upper/ Worsening Intermittent Stomach Pain#	2	02FEB2021	147/C	2	No	O	NA/TC	N	Y/N
>55/ C4591001 1092 10921015	CARD	Atrial fibrillation/ Arrhythmia atrial fibrillation	1	26AUG2020	8/2	2	No	O	NA/TC	R (27AUG2020)	Y/N
	INV	Troponin increased/ Elevated troponin	1	26AUG2020	8/1	1	No	O	NA	R (26AUG2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ Injection Arm Pain (Left)#	4	10FEB2021	1/3	2	Yes		NA/TC	R (12FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1092 10921016	NERV	Headache/ Headache#	4	10FEB2021	1/3	2	Yes		NA/TC	R (12FEB2021)	N/N	
>55/ C4591001 1092 10921019	GENRL	Chills/ Chills#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N	
		Injection site pain/ Injection site soreness#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N	
		Pyrexia/ Fever#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N	
	GENRL	Chills/ Chills#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N	
		Injection site pain/ Injection site soreness#	4	23FEB2021	2/2	2	Yes		NA/TC	R (24FEB2021)	N/N	
		Pain/ Body aches#	4	23FEB2021	2/2	2	Yes		NA/TC	R (24FEB2021)	N/N	
		Pyrexia/ Fever#	4	23FEB2021	2/2	1	Yes		NA/TC	R (24FEB2021)	N/N	
>55/ C4591001 1092 10921021	GENRL	Chills/ Chills#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N	
		Pain/ Body Aches#	3	02FEB2021	1/2	2	Yes		NA/TC	R (03FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N	
		Pain/ Body aches#	4	23FEB2021	1/2	2	Yes		NA/TC/W	R (24FEB2021)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1092 10921023	GENRL	Pyrexia/ Fever#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N	
		Fatigue/ Fatigue#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N	
			4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N	
		Injection site pain/ Injection arm soreness#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N	
		NERV Headache/ Headache#	4	23FEB2021	2/2	2	Yes		NA/TC	R (24FEB2021)	N/N	
>55/ C4591001 1092 10921039	SKIN	Dermatitis/ Dermatitis Exacerbation#	4	04MAR2021	11/C	1	Yes		NA	N	N/N	
	SKIN	Rash/ Rash (from Neck to knees)	2	11OCT2020	31/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1092 10921040	EAR	Vertigo positional/ intermittent positional vertigo	1	05SEP2020	16/7	1	No	O	NA/TC	R (11SEP2020)	N/N	
	MUSC	Back pain/ constant right low back pain	1	05SEP2020	16/5	1	No	O	NA/TC	R (09SEP2020)	N/N	
	GENRL	Pyrexia/ Fever	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
	NERV	Lethargy/ Lethargy	2	11SEP2020	3/4	1	Yes		NA	R (14SEP2020)	N/N	
	INFEC	Sinusitis/ sinus infection	2	15SEP2020	7/6	1	No	O	NA/TC	R (20SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1092 10921046	RESP	Sinus congestion/ sinus congestion	2	15SEP2020	7/6	1	No	O	NA/TC	R (20SEP2020)	N/N
	GENRL	Pyrexia/ Fever	1	25AUG2020	2/2	1	Yes		NA/TC	R (26AUG2020)	N/N
>55/ C4591001 1092 10921048	RESP	Asthma/ Asthma exacerbation	2	21SEP2020	8/9	1	No	O	NA/TC	R (29SEP2020)	N/N
	CARD	Atrial fibrillation/ Atrial Fibrillation	2	23NOV2020	71/3	2	No	O	NA/TC	R (25NOV2020)	Y/N
>55/ C4591001 1092 10921049	NERV	Headache/ Headache	1	24AUG2020	1/3	1	Yes		NA/TC	R (26AUG2020)	N/N
>55/ C4591001	GENRL	Pyrexia/ Fever	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N
	MUSC	Myalgia/ generalized myalgia	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		Pyrexia/ Fever	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ Headache	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1092 10921050 >55/ C4591001 1092 10921057	INJ&P	Animal bite/ dog bite	2	26SEP2020	12/1	1	No	O	NA/TC	R (26SEP2020)	N/N
>55/ C4591001 1092 10921058	RENAL	Pollakiuria/ Frequent Urination	2	03NOV2020	50/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1092 10921062	INFEC	Localised infection/ Infection on finger	2	12JAN2021	120/8	2	No	O	NA/TC	R (19JAN2021)	N/N
>55/ C4591001 1092 10921062	RESP	Respiratory tract congestion/ Chest Congestion	2	18SEP2020	5/10	1	No	O	NA/TC	R (27SEP2020)	N/N
>55/ C4591001 1092 10921071		Upper respiratory tract congestion/ Head congestion	2	18SEP2020	5/10	1	No	O	NA/TC	R (27SEP2020)	N/N
	INFEC	Laryngitis/ Laryngitis	2	28SEP2020	15/14	1	No	O	NA/TC	R (11OCT2020)	N/N
	RESP	Asthma/ Asthma exacerbation	2	28SEP2020	15/14	1	No	O	NA/TC	R (11OCT2020)	N/N
>55/ C4591001 1092 10921071	MUSC	Back pain/ Intermittent back pain	1	26AUG2020	2/1	1	No	O	NA	R (26AUG2020)	N/N
	GENRL	Injection site pain/ Injection site soreness#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Injection site sorness#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1092 10921072	GENRL	Chills/ chills	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
	NERV	Dizziness/ continuous lightheadedness	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
		Headache/ generalized dull headache	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
		Lethargy/ continuous lethargy	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
	GENRL	Injection site pain/ Injection site soreness#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Injection site soreness#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N
>55/ C4591001 1092 10921074	GENRL	Fatigue/ Fatigue#	4	26FEB2021	2/1	1	Yes		NA	R (26FEB2021)	N/N
	INV	Heart rate increased/ Elevated Heart rate#	4	26FEB2021	2/1	1	Yes		NA	R (26FEB2021)	N/N
>55/ C4591001 1092 10921077	GASTR	Nausea/ Nausea#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Chills/ Chills#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
		Pain/ Body aches#	4	23FEB2021	2/2	2	Yes		NA/TC	R (24FEB2021)	N/N
		Pyrexia/ Fever#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1092 10921086	GENRL	Chills/ Chills#	4	03MAR2021	2/2	2	Yes		NA/TC	R (04MAR2021)	N/N
		Injection site pain/ Injection arm soreness#	4	03MAR2021	2/2	2	Yes		NA/TC	R (04MAR2021)	N/N
		Pain/ Body Aches#	4	03MAR2021	2/2	2	Yes		NA/TC	R (04MAR2021)	N/N
		Pyrexia/ Fever (101.5 high)#	4	03MAR2021	2/2	2	Yes		NA/TC	R (04MAR2021)	N/N
>55/ C4591001 1092 10921088	GENRL	Injection site pain/ Injection Site Soreness#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1092 10921089	GENRL	Pain/ generalized achiness	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ fever	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001 1092 10921092	GENRL	Chills/ Chills#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
		Injection site pain/ Injection site soreness#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
	NERV	Headache/ Headache#	4	15FEB2021	1/2	2	Yes		NA/TC	R (16FEB2021)	N/N
	GASTR	Vomiting/ Vomit#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1092 10921094	NERV	Lethargy/ lethargy	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
>55/ C4591001 1092 10921095	GENRL	Fatigue/ Tiredness#	3	28JAN2021	1/5	1	Yes		NA	R (01FEB2021)	N/N
	GENRL	Injection site erythema/ Injection site redness#	3	01FEB2021	5/4	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pruritus/ Injection site itching#	3	01FEB2021	5/4	1	Yes		NA	R (04FEB2021)	N/N
	INFEC	Herpes zoster/ Shingles#	4	01MAR2021	12/C	2	Yes		NA/TC	RG	N/N
>55/ C4591001 1092 10921108	SKIN	Rash pruritic/ pruritic rash	1	06SEP2020	3/164	1	No	O	NA/TC	R (16FEB2021)	N/N
	INFEC	Urinary tract infection/ Urinary Tract Infection	2	24DEC2020	92/5	1	No	O	NA/TC	R (28DEC2020)	N/N
	NERV	Nerve compression/ Pinched Nerve in Back	2	24DEC2020	92/10	1	No	O	NA/TC	R (02JAN2021)	N/N
>55/ C4591001 1092 10921115	INFEC	Skin infection/ skin infection left elbow	1	03SEP2020	4/4	1	No	O	NA/TC	R (06SEP2020)	N/N
	INFEC	Paronychia/ paronychia right middle finger	2	10OCT2020	20/8	1	No	O	NA/TC	R (17OCT2020)	N/N
>55/ C4591001	INJ&P	Fall/ Fall off ladder	1	07SEP2020	8/1	2	No	O	NA	R (07SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1092 10921116		Mouth injury/ laceration of mouth	1	07SEP2020	8/11	2	No	O	NA/TC	R (17SEP2020)	N/N	
		Skin laceration/ laceration left hand	1	07SEP2020	8/11	2	No	O	NA/TC	R (17SEP2020)	N/N	
		Skin laceration/ laceration right elbow	1	07SEP2020	8/11	2	No	O	NA/TC	R (17SEP2020)	N/N	
	GENRL	Injection site pain/ Injection of Site soreness#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N	
>55/ C4591001 1092 10921120	INFEC	Urinary tract infection/ Urinary Tract Infection	2	06OCT2020	15/5	1	No	O	NA/TC	R (10OCT2020)	N/N	
	EAR	Vertigo/ Vertigo	2	16JAN2021	117/3	3	No	O	NA/TC	R (18JAN2021)	Y/N	
	GASTR	Nausea/ Nausea	2	16JAN2021	117/1	2	No	O	NA/TC	R (16JAN2021)	N/N	
	INV	Blood pressure increased/ Elevated Blood Pressure	2	16JAN2021	117/1	1	No	O	NA	R (16JAN2021)	N/N	
	METAB	Hypokalaemia/ Hypokalemia	2	16JAN2021	117/1	1	No	O	NA	R (16JAN2021)	N/N	
	NERV	Transient ischaemic attack/ Transient Ischemic Attack (TIA)	2	16JAN2021	117/1	3	No	O	NA/TC	R (16JAN2021)	Y/N	
>55/ C4591001 1092 10921123	EYE	Eye swelling/ Swelling of eyes	1	17SEP2020	17/2	2	No	CD	NA/TC	R (18SEP2020)	N/N	
	GASTR	Lip swelling/ Swelling of lip	1	17SEP2020	17/2	2	No	CD	NA/TC	R (18SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	SKIN	Urticaria/ Hives (Urticaria)	1	17SEP2020	17/2	2	No	CD	NA/TC	R (18SEP2020)	N/N
	GASTR	Abdominal pain upper/ Epigastric Pain	1	07OCT2020	37/2	3	No	O	NA/TC	R (08OCT2020)	Y/N
		Chronic gastritis/ Chronic Focally Active Gastritis	1	07OCT2020	37/C	2	No	O	NA	N	N/N
>55/ C4591001 1092 10921135	MUSC	Muscular weakness/ Injection Arm (Left) Weakness#	4	08JAN2021	1/3	2	Yes		NA/TC	R (10JAN2021)	N/N
>55/ C4591001 1092 10921136	GENRL	Injection site induration/ induration at injection site	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/Y
		Injection site pain/ left arm injection site pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/Y
	NERV	Headache/ headache unknown type	1	02SEP2020	2/2	2	Yes		NA/TC	R (03SEP2020)	N/N
	NERV	Lethargy/ lethargy	1	03SEP2020	3/3	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ pain in arm at injection site	1	20SEP2020	20/4	1	Yes		NA	R (23SEP2020)	N/N
	NERV	Headache/ headache	2	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N
		Lethargy/ lethargy	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1092 10921137	NERV	Lethargy/ lethargy	2	23SEP2020	1/4	1	Yes		NA/TC	R (26SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1092 10921138	GENRL	Injection site pain/ Injection site soreness#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	NERV	Headache/ Headache#	3	28JAN2021	1/2	2	Yes		NA/TC	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
>55/ C4591001 1092 10921140	GENRL	Injection site pain/ left arm muscle pain at injection site	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
>55/ C4591001 1092 10921152	GASTR	Nausea/ nausea	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Chills/ chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		Injection site pain/ injection site pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	SKIN	Hyperhidrosis/ sweating	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	EAR	Vertigo/ vertigo	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
	GASTR	Retching/ dry heaves	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
	GENRL	Malaise/ malaise	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
	INV	Respiratory rate increased/ increased respiratory rate	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1092 10921155	GASTR	Diarrhoea/ Diarrhea	1	09SEP2020	7/4	1	No	O	NA	R (12SEP2020)	N/N
	GENRL	Pyrexia/ Fever	1	09SEP2020	7/4	1	No	O	NA	R (12SEP2020)	N/N
	GASTR	Diarrhoea/ diarrhea	2	11OCT2020	4/2	1	Yes		NA	R (12OCT2020)	N/N
	NERV	Headache/ headache	2	11OCT2020	4/2	1	Yes		NA	R (12OCT2020)	N/N
>55/ C4591001 1092 10921156	GENRL	Injection site pain/ Injection site soreness#	3	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N
>55/ C4591001 1092 10921163	PSYCH	Anxiety/ anxiety	2	01DEC2020	65/C	1	No	O	NA/TC	RG	N/N
		Depression/ depression	2	01DEC2020	65/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1092 10921164	GENRL	Injection site pain/ Injection site pain#	4	12JAN2021	2/4	1	Yes		NA	R (15JAN2021)	N/N
	MUSC	Muscular weakness/ Lower extremity bilateral weakness#	4	15JAN2021	5/C	3	Yes		NA	N	N/N
		Pain in extremity/ Lower extremity bilateral pain#	4	15JAN2021	5/13	2	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ Injection site soreness#	3	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1092 10921170 >55/ C4591001	MUSC	Back pain/ lower back pain	2	25OCT2020	26/8	1	No	O	NA/TC	R (01NOV2020)	N/N
1092 10921171 >55/ C4591001	NERV	Headache/ headache	1	13SEP2020	5/3	1	No	O	NA/TC	R (15SEP2020)	N/N
1092 10921172 >55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/4	1	Yes		NA	R (29JAN2021)	N/N
1092 10921174	GENRL	Chills/ Chills#	4	17FEB2021	1/3	2	Yes		NA/TC	R (19FEB2021)	N/N
		Pyrexia/ Fever (100.4)#	4	17FEB2021	1/3	2	Yes		NA/TC	R (19FEB2021)	N/N
	MUSC	Pain in extremity/ Left Injection Arm Soreness#	4	17FEB2021	1/3	2	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	17FEB2021	1/3	2	Yes		NA/TC	R (19FEB2021)	N/N
>55/ C4591001 1092 10921180	GENRL	Injection site pain/ Injection site tenderness	1	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
	INJ&P	Contusion/ contusion to head	1	25SEP2020	16/1	2	No	O	NA/TC	R (25SEP2020)	N/N
		Fall/ fall	1	25SEP2020	16/1	2	No	O	NA/TC	R (25SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Skin laceration/ laceration left elbow	1	25SEP2020	16/4	2	No	O	NA/TC	R (28SEP2020)	N/N	
>55/ C4591001 1092 10921187	CARD	Cardiac failure congestive/ Congestive heart failure	1	01OCT2020	17/3	2	No	O	NA/TC	R (03OCT2020)	Y/N	
>55/ C4591001 1092 10921194	INJ&P	Head injury/ hit head on steering wheel	2	02NOV2020	20/1	1	No	O	NA	R (02NOV2020)	N/N	
		Road traffic accident/ motor vehicle accident while subject was driving	2	02NOV2020	20/1	1	No	O	NA	R (02NOV2020)	N/N	
	NERV	Headache/ headache	2	02NOV2020	20/2	2	No	O	NA	R (03NOV2020)	N/N	
>55/ C4591001 1092 10921196	GENRL	Injection site pain/ Injection site tenderness	1	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N	
	GENRL	Injection site pain/ Injection Site Tenderness	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N	
>55/ C4591001 1092 10921212	INFEC	Urinary tract infection/ Urinary Tract Infection	1	27OCT2020	21/11	1	No	O	NA/TC	R (06NOV2020)	N/N	
>55/ C4591001 1092 10921214	NERV	Headache/ headache	1	09OCT2020	2/3	1	Yes		NA	R (11OCT2020)	N/N	
	NERV	Headache/ headache	2	30OCT2020	2/4	1	Yes		NA	R (02NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1092 10921217	VASC	Hypertension/ Hypertension	2	30OCT2020	2/C	1	No	O	NA/TC	N	N/N	
	GASTR	Nausea/ Nausea#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N	
	GENRL	Injection site pain/ Injection Site Soreness#	4	08JAN2021	1/3	2	Yes		NA/TC	R (10JAN2021)	N/N	
	NERV	Dizziness/ Dizziness#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N	
>55/ C4591001 1092 10921221	GENRL	Chills/ Chills	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N	
		Injection site pain/ Injection site tenderness	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N	
		Pyrexia/ Fever	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N	
	NERV	Headache/ Headache	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N	
>55/ C4591001 1092 10921222	GASTR	Nausea/ Nausea#	4	23FEB2021	1/1	1	Yes		NA	R (23FEB2021)	N/N	
	GENRL	Chills/ Chills#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N	
		Pain/ Body aches#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N	
>55/ C4591001	GASTR	Nausea/ Nausea#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1092 10921224	GENRL	Injection site pain/ Injection Site Soreness#	3	09FEB2021	2/3	1	Yes		NA	R (11FEB2021)	N/N	
>55/ C4591001 1092 10921226	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N	
		Injection site pain/ Injection Arm (Left) Soreness#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N	
	NERV	Headache/ Headache#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N	
>55/ C4591001 1092 10921230	GENRL	Pyrexia/ Fever of 99.2	1	14OCT2020	3/2	1	Yes		NA/TC	R (15OCT2020)	N/N	
	GENRL	Pyrexia/ Fever	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N	
>55/ C4591001 1092 10921244	GENRL	Injection site pain/ Injection site soreness#	2	27JAN2021	84/4	1	Yes		NA	R (30JAN2021)	N/N	
	GENRL	Fatigue/ Tiredness#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N	
>55/ C4591001 1092 10921251	GENRL	Chills/ Chills#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
		Pain/ Body aches#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1092 10921254	NERV	Pyrexia/ Fever#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Headache/ Headaches#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
>55/ C4591001 1092 10921256	GENRL	Injection site pain/ Injection site soreness#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
>55/ C4591001 1092 10921258	VASC	Hypertension/ Hypertension	2	10JAN2021	61/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1092 10921259	GENRL	Chills/ Chills#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
		Fatigue/ Tiredness#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	MUSC	Pain/ Body Aches#	3	05FEB2021	1/2	2	Yes		NA/TC	R (06FEB2021)	N/N
		Pain in extremity/ Left Injection Arm Soreness#	3	05FEB2021	1/2	2	Yes		NA/TC	R (06FEB2021)	N/N
		GENRL	Pain/ body aches	2	12NOV2020	2/4	1	Yes		NA	R (15NOV2020)
		Pyrexia/ fever	2	12NOV2020	2/4	1	Yes		NA	R (15NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1092 10921264	NERV	Paraesthesia/ paresthesia of left limb	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Injection site tenderness	1	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
	NERV	Paraesthesia/ paresthesia of left limb	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/Y
>55/ C4591001 1092 10921266	INFEC	Cellulitis/ Cellulitis ( of the left calf)	1	28OCT2020	8/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1092 10921269	GENRL	Chills/ Chills#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	13JAN2021	1/7	2	Yes		NA/TC	R (19JAN2021)	N/N
		Pyrexia/ Fever#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
>55/ C4591001 1092 10921275	GENRL	Injection site pain/ injection site pain	1	28OCT2020	1/4	2	Yes		NA	R (31OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	18NOV2020	1/5	2	Yes		NA	R (22NOV2020)	N/N
>55/ C4591001 1092 10921278	INFEC	Herpes zoster/ Herpes Zoster	2	22DEC2020	33/14	1	No	O	NA/TC	R (04JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	VASC	Hypertension/ Hypertension#	2	22JAN2021	64/C	2	No	O	NA/TC	N	N/N
	GENRL	Chills/ Chills#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ Injection Site soreness#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001 1093 10931005	INFEC	Otitis media/ BILATERAL INNER OTITIS MEDIA	1	03SEP2020	20/18	1	No	O	NA/TC	R (20SEP2020)	N/N
>55/ C4591001 1093 10931023	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	21AUG2020	3/33	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Fatigue/ FATIGUE	2	09SEP2020	1/17	1	Yes		NA	R (25SEP2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	09SEP2020	1/22	1	Yes		NA/TC	R (30SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	SKIN	Hyperhidrosis/ SWEATING	2	09SEP2020	1/17	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1093 10931026	VASC	Hypertension/ HYPERTENSION	2	30DEC2020	113/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001	MUSC	Arthralgia/ LEFT SHOULDER PAIN#	2	02FEB2021	142/C	1	No	O	NA	RG	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1093 10931046 >55/ C4591001 1093 10931054	GENRL	Chills/ CHILLS	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
		Pain/ BODY ACHES	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
>55/ C4591001 1093 10931060	CARD	Atrial fibrillation/ ATRIAL FIBRILLATION	2	03NOV2020	50/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1093 10931076	INFEC	Tooth infection/ infected tooth#	3	25FEB2021	17/5	1	No	O	NA/TC	R (01MAR2021)	N/N
>55/ C4591001 1093 10931080	GENRL	Chills/ CHILLS	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001 1093 10931086	NERV	Headache/ HEADACHE	1	02SEP2020	6/1	1	No	O	NA/TC	R (02SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	PSYCH	Depression/ DEPRESSION	2	10OCT2020	23/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1093 10931092	INFEC	Onychomycosis/ ONYCHOMYCOSIS#	2	11MAR2021	172/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1093 10931120	SOCCL	Menopause/ WORSENING MENOPAUSE	2	20OCT2020	19/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1093 10931122	RESP	Asthma/ ASTHMA EXACERBATION	2	16OCT2020	17/5	2	No	O	NA/TCN	R (20OCT2020)	N/N	
>55/ C4591001 1093 10931128	VASC	Hypertension/ WORSENING HYPERTENSION	1	30SEP2020	20/22	1	No	O	P/TC	R (21OCT2020)	N/N	
>55/ C4591001 1093 10931141	INFEC	Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2	26DEC2020	74/3	1	No	O	NA/TC	R (28DEC2020)	Y/N	
		Urinary tract infection/ URINARY TRACT INFECTION	2	26DEC2020	74/3	1	No	O	NA/TC	R (28DEC2020)	Y/N	
>55/ C4591001 1093 10931151	GASTR	Abdominal pain lower/ LOWER ABDOMINAL PAIN	1	29SEP2020	7/2	1	No	O	NA	R (30SEP2020)	N/N	
	GENRL	Pyrexia/ FEVER	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1093 10931192	VASC	Deep vein thrombosis/ RIGHT LEG DEEP VEIN THROMBOSIS	2	30NOV2020	22/C	2	No	O	NA/TC	RG	N/N	
	NERV	Headache/ HEADACHE	2	29DEC2020	51/1	1	No	O	NA/TC	R (29DEC2020)	N/N	
>55/ C4591001 1093 10931212	GASTR	Diarrhoea/ DIARRHEA	1	31OCT2020	6/3	2	Yes		NA	R (02NOV2020)	N/N	
		Nausea/ NAUSEA	1	31OCT2020	6/3	2	Yes		NA	R (02NOV2020)	N/N	
	GENRL	Fatigue/ MODERATE FATIGUE	1	31OCT2020	6/3	2	Yes		NA	R (02NOV2020)	N/N	
	MUSC	Myalgia/ MUSCLE ACHES	1	31OCT2020	6/3	2	Yes		NA	R (02NOV2020)	N/N	
>55/ C4591001 1093 10931227	GENRL	Chills/ CHILLS	2	19NOV2020	2/1	1	Yes		NA	R (19NOV2020)	N/N	
>55/ C4591001 1094 10941009	SKIN	Erythema/ Redness left and right arm	2	23SEP2020	23/1	2	No	O	NA	R (23SEP2020)	N/N	
	INFEC	Urinary tract infection/ urinary tract infection	2	28SEP2020	28/7	2	No	O	NA/TC	R (04OCT2020)	N/N	
	INJ&P	Road traffic accident/ motor vehicle accident#	3	11FEB2021	24/1	2	No	O	NA	R (11FEB2021)	N/N	
	MUSC	Arthralgia/ right shoulder pain#	3	11FEB2021	24/C	2	No	O	NA/TC	RG	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Back pain/ right low back pain#	3	11FEB2021	24/C	2	No	O	NA/TC	RG	N/N
		Neck pain/ right-sided neck pain#	3	11FEB2021	24/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1094 10941014	CARD	Palpitations/ palpitation	2	03OCT2020	32/46	1	No	O	NA	R (17NOV2020)	N/N
	RESP	Pulmonary embolism/ Non-acute pulmonary embolism	2	09NOV2020	69/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1094 10941026	MUSC	Pain in extremity/ left hand pain	2	12OCT2020	35/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1094 10941028	GASTR	Diarrhoea/ diarrhea	2	09SEP2020	3/3	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1094 10941033	INV	SARS-CoV-2 antibody test positive/ COVID-19 SEROLOGY TEST POSITIVE	2	10NOV2020	65/C	1	No	O	NA	N	N/N
>55/ C4591001 1094 10941035	METAB	Vitamin B12 deficiency/ Vitamin B12 Deficiency	2	27OCT2020	33/C	1	No	O	NA/TC	N	N/N
	VASC	Hypertension/ Hypertension	2	14DEC2020	81/C	2	No	O	NA/TC	N	N/N
>55/ C4591001	INV	SARS-CoV-2 antibody test positive/ COVID-19 SEROLOGY TEST POSITIVE#	2	29JAN2021	142/C	1	No	O	NA	RG	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1094 10941037 >55/ C4591001 1094 10941059	EAR	Cerumen impaction/ Impacted cerumen of left ear	2	27OCT2020	41/38	1	No	O	NA/TCN	R (03DEC2020)	N/N
	MUSC	Musculoskeletal chest pain/ chest wall pain	2	03DEC2020	78/29	1	No	O	NA/TC	R (31DEC2020)	N/N
	GENRL	Chest pain/ severe chest pain	2	28DEC2020	103/4	1	No	O	NA	R (31DEC2020)	N/N
>55/ C4591001 1094 10941071	INFEC	Fungal infection/ yeast infection	2	09NOV2020	53/94	1	No	O	NA/TC	R (10FEB2021)	N/N
	INFEC	Urinary tract infection/ lower urinary tract infection	2	18JAN2021	123/24	1	No	O	NA/TC	R (10FEB2021)	N/N
	INJ&P	Fall/ fall	2	08FEB2021	144/1	1	No	O	NA	R (08FEB2021)	N/N
	MUSC	Arthralgia/ left ankle pain	2	08FEB2021	144/C	1	No	O	NA/TC	RG	N/N
	INV	SARS-CoV-2 antibody test positive/ COVID-19 SEROLOGY TEST POSITIVE	2	10FEB2021	146/C	1	No	O	NA	RG	N/N
>55/ C4591001 1094 10941072	NEOPL	Breast cancer/ Right breast cancer	1	10SEP2020	11/	3	No	O	NA/TCN	R	N/N
>55/ C4591001 1094 10941073	MUSC	Pain in extremity/ Left arm musculoskeletal pain	1	01SEP2020	2/C	2	Yes		NA/TC	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1094 10941078	METAB	Vitamin B12 deficiency/ Vitamin B12 Deficiency	1	03SEP2020	3/C	1	No	O	NA/TC	N	N/N	
	ENDO	Hypothyroidism/ Hypothyroidism	2	24NOV2020	62/C	1	No	O	NA/TC	N	N/N	
	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	01DEC2020	69/C	1	No	O	NA/TC	N	N/N	
	VASC	Hypertension/ Worsening of hypertension	2	01DEC2020	69/C	1	No	O	NA/TC	N	N/N	
	EAR	Ear pain/ Left ear pain	2	01JAN2021	100/5	2	No	O	NA/TC	R (05JAN2021)	N/N	
>55/ C4591001 1094 10941085	PSYCH	Dysphemia/ stutter	2	01OCT2020	4/72	1	No	O	NA	R (11DEC2020)	N/N	
	MUSC	Pain in extremity/ right heel pain	2	11DEC2020	75/C	2	No	O	NA	RG	N/N	
>55/ C4591001 1094 10941096	BLOOD	Iron deficiency anaemia/ Iron deficiency anemia	2	30SEP2020	3/C	1	No	O	NA/TC	N	N/N	
	METAB	Vitamin B12 deficiency/ Vitamin B12 DEFICIENCY	2	30SEP2020	3/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1094 10941097	INFEC	Fungal infection/ yeast infection	2	17DEC2020	85/1	1	No	O	NA/TC	R (17DEC2020)	N/N	
>55/ C4591001	GENRL	Asthenia/ General Weakness	1	07SEP2020	1/16	2	Yes		NA	R (22SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1094 10941103	GASTR	Nausea/ Nausea	1	08SEP2020	2/4	2	No	O	NA	R (11SEP2020)	N/N	
	NERV	Dizziness/ Dizziness	1	08SEP2020	2/15	2	No	O	NA	R (22SEP2020)	N/N	
	INJ&P	Skin abrasion/ Left forearm abrasion	2	24OCT2020	27/C	1	No	O	NA	RG	N/N	
>55/ C4591001 1094 10941110	CARD	Palpitations/ Palpitations	1	13SEP2020	6/2	1	No	O	NA	R (14SEP2020)	N/N	
	INFEC	Herpes simplex/ HSV-2 Infection#	4	11MAR2021	23/C	1	No	O	NA	RG	N/N	
>55/ C4591001 1094 10941112	INFEC	COVID-19/ COVID-19 Infection	2	26NOV2020	59/23	4	No	O	NA/TC	F (18DEC2020)	Y/N	
		Pneumonia/ Pneumonia	2	26NOV2020	59/23	4	No	O	NA/TC/TCN	F (18DEC2020)	Y/N	
	RESP	Acute respiratory failure/ Acute hypoxemic respiratory failure	2	28NOV2020	61/21	4	No	O	NA/TC/TCN/W	F (18DEC2020)	Y/N	
>55/ C4591001 1094 10941115	NERV	Hypoesthesia/ left thumb numbness	2	01NOV2020	33/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1094 10941119	CONG	Type V hyperlipidaemia/ mixed hyperlipidemia	2	02NOV2020	33/C	1	No	O	NA/TC	RG	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Pain in extremity/ bilateral hand pain	2	22JAN2021	114/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1094 10941134	EAR	Ear pain/ right ear pain#	3	04MAR2021	9/4	1	No	O	NA	R (07MAR2021)	N/N
>55/ C4591001 1094 10941164	GASTR	Vomiting/ vomiting#	4	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Pain/ body aches#	4	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
		Pyrexia/ fever#	4	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
>55/ C4591001 1094 10941165	MUSC	Pain in extremity/ Left foot pain	1	19OCT2020	19/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1094 10941177	INV	SARS-CoV-2 antibody test positive/ positive COVID-19 serology#	4	04MAR2021	16/C	1	No	O	NA	N	N/N
>55/ C4591001 1094 10941187	REPRO	Erectile dysfunction/ Erectile Dysfunction	1	04NOV2020	7/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1094 10941191†	METAB	Hyperkalaemia/ hyperkalemia	2	28JAN2021	71/37	1	No	CND	NA	R (05MAR2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1095 10951015	MUSC	Neck pain/ NECK PAIN	2	29AUG2020	9/3	1	No	O	NA/TC	R (31AUG2020)	N/N	
>55/ C4591001 1095 10951016	GENRL	Injection site haemorrhage/ left arm injection site ecchymosis	1	31JUL2020	1/15	1	Yes		NA	R (14AUG2020)	N/N	
>55/ C4591001 1095 10951032	INJ&P	Limb injury/ right shoulder pain secondary to injury	2	09SEP2020	17/C	1	No	O	NA	RG	N/N	
>55/ C4591001 1095 10951035	GENRL	Chills/ chills#	4	04MAR2021	2/2	1	Yes		NA	R (05MAR2021)	N/N	
	MUSC	Myalgia/ generalized muscle pain#	4	04MAR2021	2/2	1	Yes		NA/TC	R (05MAR2021)	N/N	
>55/ C4591001 1095 10951043	EYE	Chalazion/ Chalazion of lower right eye	1	23AUG2020	20/6	1	No	O	NA	R (28AUG2020)	N/N	
>55/ C4591001 1095 10951048	INJ&P	Corneal abrasion/ Right Corneal Abrasion	1	20AUG2020	17/2	1	No	O	NA	R (21AUG2020)	N/N	
	GENRL	Chills/ chills#	4	26JAN2021	1/2	2	Yes		NA	R (27JAN2021)	N/N	
		Pyrexia/ fever#	4	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue#	4	27JAN2021	2/C	2	Yes		NA	RG	N/N
	MUSC	Myalgia/ generalized myalgias#	4	27JAN2021	2/5	2	Yes		NA	R (31JAN2021)	N/N
>55/ C4591001 1095 10951052	INJ&P	Ankle fracture/ right medial malleolus fracture	2	07SEP2020	14/C	3	No	O	NA/TC	RG	N/N
		Foot fracture/ bilateral calcaneus fracture	2	07SEP2020	14/C	3	No	O	NA/TC/TCN	RG	N/N
>55/ C4591001 1095 10951078	EYE	Dacryostenosis acquired/ right lacrimal duct obstruction	1	15AUG2020	10/175	1	No	O	NA/TC	R (05FEB2021)	N/N
	INFEC	Gastroenteritis/ Mild gastroenteritis	1	24AUG2020	19/4	1	No	O	NA	R (27AUG2020)	N/N
	EYE	Dacryostenosis acquired/ lacrimal duct obstruction L eye#	4	05MAR2021	1/C	1	No	O	NA	RG	N/Y
>55/ C4591001 1095 10951080	NEOPL	Lobular breast carcinoma in situ/ Left Lobular Breast Cancer, Stage I, Grade I	2	12DEC2020	108/C	2	No	O	NA/TCN	N	Y/N
	GENRL	Injection site pain/ Injection Site Pain#	3	16DEC2020	1/3	1	Yes		NA	R (18DEC2020)	N/Y
>55/ C4591001 1095 10951088	INJ&P	Fall/ FALL	1	13AUG2020	8/1	1	No	O	NA	R (13AUG2020)	N/N
		Skin abrasion/ superficial abrasions on anterior chest	1	13AUG2020	8/18	1	No	O	NA/TC	R (30AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	VASC	Skin laceration/ Superficial laceration to posterior head	1	13AUG2020	8/18	1	No	O	NA	R (30AUG2020)	N/N
		Haematoma/ Hematoma right anterior chest	1	13AUG2020	8/18	1	No	O	NA/TC	R (30AUG2020)	N/N
>55/ C4591001 1095 10951098	GENRL	Injection site erythema/ Erythema to injection site left arm	2	29AUG2020	2/7	1	Yes		NA	R (04SEP2020)	N/N
>55/ C4591001 1095 10951101	RESP	Pulmonary embolism/ Pulmonary Embolism	2	30OCT2020	64/9	3	No	O	NA/TC	R (07NOV2020)	Y/N
>55/ C4591001 1095 10951102	MUSC	Joint effusion/ Left knee effusion	1	13AUG2020	7/C	1	Yes		NA	RG	N/N
>55/ C4591001 1095 10951107	METAB	Hypoglycaemia/ Hypoglycemia	1	12AUG2020	6/1	1	No	O	NA/TCN	R (12AUG2020)	N/N
	NERV	Dizziness/ Dizziness, secondary to Clonidine reaction	2	31AUG2020	5/3	2	No	O	NA	R (02SEP2020)	Y/N
	CARD	Tachyarrhythmia/ Suspected tachy-arrythmia	2	08SEP2020	13/15	3	No	O	NA/TC	R (22SEP2020)	Y/N
>55/ C4591001 1095 10951111	GENRL	Fatigue/ Fatigue	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Injection site pain/ left arm injection site pain	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1095 10951113	GENRL	Injection site pain/ injection site pain	2	10SEP2020	2/4	1	Yes		NA/TC	R (13SEP2020)	N/N
>55/ C4591001 1095 10951117	GENRL	Chills/ chills#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
		Fatigue/ fatigue#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
		Injection site pain/ left arm injection site pain#	3	06JAN2021	2/2	1	Yes		NA/TC	R (07JAN2021)	N/N
>55/ C4591001 1095 10951118	GENRL	Fatigue/ Fatigue	2	13SEP2020	3/2	1	Yes		NA	R (14SEP2020)	N/N
	INV	Body temperature increased/ Elevated temperature	2	13SEP2020	3/2	1	Yes		NA	R (14SEP2020)	N/N
>55/ C4591001 1095 10951123	GENRL	Injection site pain/ injection site pain	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/Y
	PSYCH	Depression/ worsening of Depression	2	17SEP2020	4/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1095 10951125	MUSC	Osteoarthritis/ right knee osteoarthritis	1	01SEP2020	9/C	1	No	O	NA/TCN	RG	N/N
	EYE	Diplopia/ Diplopia#	3	08JAN2021	12/13	1	No	O	NA	R (20JAN2021)	Y/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1095 10951126	GENRL	Fatigue/ Fatigue	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
	GASTR	Diarrhoea/ diarrhea	1	30AUG2020	6/2	1	Yes		NA	R (31AUG2020)	N/N
>55/ C4591001 1095 10951127	GENRL	Injection site pain/ Injection site pain Left arm	1	25AUG2020	1/2	1	Yes		NA/TC	R (26AUG2020)	N/N
>55/ C4591001 1095 10951130	MUSC	Back pain/ Mechanical low back pain	2	13OCT2020	28/1	1	No	O	NA/TC	R (13OCT2020)	N/N
	INJ&P	Bone contusion/ Right Rib Contusion#	2	24FEB2021	162/C	2	No	O	NA	RG	N/N
		Fall/ Fall#	2	24FEB2021	162/1	2	No	O	NA	R (24FEB2021)	N/N
>55/ C4591001 1095 10951131	GENRL	Fatigue/ fatigue#	3	06JAN2021	1/5	1	Yes		NA	R (10JAN2021)	N/N
		Injection site pain/ left arm injection site pain#	3	06JAN2021	1/5	1	Yes		NA	R (10JAN2021)	N/N
>55/ C4591001 1095 10951133	GENRL	Injection site pain/ injection site pain left arm	1	26AUG2020	2/3	1	Yes		NA/TC	R (28AUG2020)	N/N
	MUSC	Muscle spasms/ muscle spasm bilateral thighs	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1095 10951134	CARD	Cardiac arrest/ Cardiac Arrest	2	16OCT2020	32/32	4	No	O	NA/TC/TCN	R (16NOV2020)	Y/N	
	INJ&P	Cervical vertebral fracture/ C6 Fracture	2	16OCT2020	32/C	3	No	O	NA/TC/TCN	RG	N/N	
		Craniocerebral injury/ Traumatic Brain Injury	2	16OCT2020	32/C	4	No	O	NA/TC/TCN	RG	Y/N	
		Facial bones fracture/ multiple facial and orbital fractures	2	16OCT2020	32/C	3	No	O	NA/TC/TCN	RG	N/N	
		Road traffic accident/ Bicycle Accident	2	16OCT2020	32/57	4	No	O	NA/TCN	R (11DEC2020)	Y/N	
		Subdural haematoma/ Subdural hematoma	2	16OCT2020	32/	3	No	O	NA/TC/TCN	R	N/N	
	RESP	Pneumothorax/ Collapsed Lung	2	16OCT2020	32/	3	No	O	NA/TC/TCN	R	N/N	
>55/ C4591001 1095 10951136	INJ&P	Post concussion syndrome/ Post concussion headache	1	04SEP2020	10/10	1	No	O	NA/TC	R (13SEP2020)	N/N	
>55/ C4591001 1095 10951140	GENRL	Injection site pain/ injection site pain left arm	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site, left arm	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	
>55/ C4591001 1095 10951151	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1095 10951162	GENRL	Injection site swelling/ Injection site swelling	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ injection site pain left arm	1	30AUG2020	2/1	1	Yes		NA	R (30AUG2020)	N/N
	INV	Injection site pain/ Injection site pain	2	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1095 10951164	INV	Body temperature increased/ Elevated temperature	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ Injection site reaction left arm-myalgia	1	30AUG2020	2/1	1	Yes		NA/TC	R (30AUG2020)	N/N
	GENRL	Injection site pain/ Injection site reaction-myalgia	2	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	INV	Body temperature increased/ elevated body temperature	2	18SEP2020	2/3	1	Yes		NA/TC	R (20SEP2020)	N/N
	METAB	Decreased appetite/ Anorexia	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Musculoskeletal chest pain/ Chest Wall tightness	2	18SEP2020	2/3	2	Yes		NA	R (20SEP2020)	N/N
>55/ C4591001 1095 10951180	MUSC	Myalgia/ post vaccination myalgia	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
	NERV	Dizziness/ Dizziness	2	05NOV2020	45/2	1	No	O	NA	R (06NOV2020)	Y/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1095 10951181	MUSC	Myalgia/ Post injection myalgia	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain right arm	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1095 10951190	GENRL	Injection site pain/ pain at injection left arm#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Myalgia/ exercise induced muscle pain#	3	07JAN2021	1/1	1	No	O	NA/TC	R (07JAN2021)	N/N
>55/ C4591001 1095 10951204	GENRL	Injection site pain/ injection site pain right arm	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain right arm	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	NEOPL	Bladder cancer/ STAGE I Bladder Cancer	2	02NOV2020	43/3	3	No	O	NA/TCN	R (04NOV2020)	Y/N
>55/ C4591001 1095 10951206	MUSC	Osteoporosis/ osteoporosis right hip	1	22SEP2020	21/55	2	No	O	NA	R (15NOV2020)	N/N
	EYE	Eye haemorrhage/ ruptured blood vessel behind Left eye	2	17NOV2020	55/2	2	No	O	NA/TC/TCN	R (18NOV2020)	Y/N
>55/ C4591001 1095 10951209	METAB	Hypokalaemia/ Hypokalemia secondary to diuretic use	1	17SEP2020	16/C	1	No	CD	NA/TC	RG	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1095 10951211	MUSC	Myalgia/ Myalgia Left Deltoid#	3	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
	INV	Body temperature increased/ elevated temp#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Fatigue/ Post vaccination fatigue	1	02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N
		Injection site pain/ injection site pain right arm	1	02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N
	NERV	Headache/ headache	1	02SEP2020	1/4	1	Yes		NA/TC	R (05SEP2020)	N/N
	GENRL	Injection site pruritus/ pruritis at injection site right arm	1	12SEP2020	11/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Malaise/ malaise post vaccination	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue post vaccination	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1095 10951212		Injection site pain/ injection site pain post vaccination right arm	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Malaise/ malaise	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	INV	Body temperature increased/ elevated temperature	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	RESP	Pleurisy/ Pleuritis	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1095 10951213	GASTR	Nausea/ Nausea post vaccine #2	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Pyrexia/ Fever post vaccination #2	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
	MUSC	Myalgia/ Myalgia post vaccine #2	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	NERV	Headache/ Headache Post Vaccination #2	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C4591001 1095 10951219	INV	Body temperature increased/ Elevated Temperature	2	04NOV2020	42/2	1	No	O	NA/TC	R (05NOV2020)	N/N
>55/ C4591001 1095 10951224	GENRL	Pyrexia/ Fever	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1095 10951226	NERV	Headache/ Headache	1	11SEP2020	8/2	1	Yes		NA/TC	R (12SEP2020)	N/N
>55/ C4591001 1095 10951227	GENRL	Injection site pain/ injection site myalgia left arm	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
>55/ C4591001	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1095 10951228	INFEC	Pneumonia/ Pneumonia	2	13NOV2020	51/29	2	No	O	NA/TC	R (11DEC2020)	Y/N	
	INFEC	Oral herpes/ Herpes simplex on lip	2	17NOV2020	55/32	1	No	O	NA/TC	R (18DEC2020)	N/N	
>55/ C4591001 1095 10951238	GASTR	Nausea/ nausea	1	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N	
		Vomiting/ Vomiting	1	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N	
	PSYCH	Depression/ depression	2	20NOV2020	37/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1095 10951239	GENRL	Injection site pain/ Injection site pain	1	25SEP2020	1/3	1	Yes		NA/TC	R (27SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	2	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N	
		Injection site pain/ injection site pain left arm	2	15OCT2020	1/3	2	Yes		NA/TC	R (17OCT2020)	N/N	
	MUSC	Myalgia/ generalized myalgia	2	15OCT2020	1/4	1	Yes		NA/TC	R (18OCT2020)	N/N	
>55/ C4591001 1095 10951242	GENRL	Fatigue/ Fatigue post vaccine	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N	
	NERV	Headache/ Headache post vaccine #1	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache post-vaccination #2	2	16OCT2020	1/3	1	Yes		NA/TC	R (18OCT2020)	N/N
	GENRL	Malaise/ General malaise post-vaccination #2	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
	MUSC	Back pain/ Myalgias (back muscles) post-vaccination #2	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
>55/ C4591001 1095 10951247	GASTR	Precancerous lesion of digestive tract/ Precancerous Colon polyp	2	15JAN2021	89/1	1	No	O	NA	R (15JAN2021)	N/N
>55/ C4591001 1095 10951252	GENRL	Injection site pain/ Injection site soreness	1	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
>55/ C4591001 1095 10951256	GENRL	Injection site pain/ injection site pain right arm	2	19OCT2020	1/2	1	Yes		NA/TC	R (20OCT2020)	N/N
	NEOPL	Prostate cancer metastatic/ Prostate Cancer with mets	2	26OCT2020	8/C	3	No	O	NA/TC	N	Y/N
>55/ C4591001 1095 10951263	GASTR	Diarrhoea/ diarrhea	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
>55/ C4591001 1095 10951264	GENRL	Injection site pain/ Pain at injection site right arm	1	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1095 10951276	GENRL	Injection site pain/ pain at injection site left arm	1	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
>55/ C4591001 1095 10951300	INJ&P	Fall/ Fall	2	14FEB2021	96/1	1	No	O	NA	R (14FEB2021)	N/N
	MUSC	Arthralgia/ R knee pain	2	14FEB2021	96/C	1	No	O	NA	RG	N/N
		Arthralgia/ R shoulder pain	2	14FEB2021	96/C	1	No	O	NA	RG	N/N
>55/ C4591001 1096 10961002	GASTR	Diarrhoea/ Diarrhea	2	06SEP2020	3/5	3	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1096 10961017	INJ&P	Fall/ Fall	2	29NOV2020	90/1	2	No	O	NA	R (29NOV2020)	N/N
		Fractured sacrum/ BROKEN SACRUM	2	29NOV2020	90/C	2	No	O	NA	RG	N/N
		Head injury/ Head Injury	2	29NOV2020	90/19	3	No	O	NA/TC	R (17DEC2020)	Y/N
	MUSC	Arthralgia/ Right Shoulder Pain	2	30NOV2020	91/C	2	No	O	NA/TC	N	N/N
		Neck pain/ Neck Pain	2	30NOV2020	91/C	2	No	O	NA/TC	N	N/N
>55/ C4591001	GENRL	Injection site erythema/ Erythema around injection vaccine	2	21SEP2020	18/3	1	No	O	NA	R (23SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1096 10961020		Injection site pain/ Soreness around the injection site	2	21SEP2020	18/3	1	No	O	NA	R (23SEP2020)	N/N	
>55/ C4591001 1096 10961024	MUSC	Flank pain/ Right Flank Pain#	2	10FEB2021	162/C	2	No	O	NA/TC	N	N/N	
	RENAL	Renal haematoma/ Right Kidney Hematoma#	2	12FEB2021	164/C	1	No	O	NA	N	N/N	
>55/ C4591001 1096 10961037	NERV	Headache/ Headache	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N	
>55/ C4591001 1096 10961038	GENRL	Injection site pain/ Injection Pain	1	20AUG2020	4/2	1	Yes		NA	R (21AUG2020)	N/N	
>55/ C4591001 1096 10961039	GENRL	Fatigue/ Fatigue	1	19AUG2020	3/2	1	Yes		NA	R (20AUG2020)	N/N	
>55/ C4591001 1096 10961044	INV	Hepatic enzyme increased/ Elevated Liver Enzymes	2	21SEP2020	12/22	3	No	O	NA	R (12OCT2020)	Y/N	
>55/ C4591001 1096 10961047	GENRL	Chills/ Chills	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	SKIN	Dermal cyst/ Left leg cyst (sebaceous)	2	14SEP2020	7/C	1	No	O	NA	N	N/N
>55/ C4591001 1096 10961056	NERV	Cerebrovascular accident/ Cerebrovascular accident#	4	22FEB2021	28/5	2	No	O	NA/TC	RS (26FEB2021)	Y/N
		Headache/ Headache#	4	22FEB2021	28/3	1	No	O	NA/TC	R (24FEB2021)	N/N
		Visual field defect/ Bilateral Peripheral Vision Loss#	4	22FEB2021	28/C	2	No	O	NA	N	N/N
	CONG	Atrial septal defect/ Patent Foramen Ovale#	4	23FEB2021	29/C	1	No	O	NA	N	N/N
	GENRL	Fatigue/ Fatigue#	4	23FEB2021	29/C	1	No	O	NA	N	N/N
	VASC	Hypertension/ Hypertension#	4	23FEB2021	29/4	2	No	O	NA	R (26FEB2021)	N/N
>55/ C4591001 1096 10961065	IMMUN	Seasonal allergy/ Seasonal allergies	2	22SEP2020	14/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1096 10961069	INJ&P	Upper limb fracture/ left wrist fracture(distal radius)#	2	13FEB2021	157/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1096 10961070	GENRL	Chills/ chills	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		Pyrexia/ fever	2	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1096 10961079	NERV	Lethargy/ lethargic	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
	EAR	Vertigo/ Vertigo	2	12SEP2020	3/41	1	Yes		NA	R (22OCT2020)	N/N
	GASTR	Dyspepsia/ Heart burn	2	12SEP2020	3/19	1	Yes		NA/TC	R (30SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1096 10961092	INFEC	Pyrexia/ Fever	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
		Sinusitis/ Sinus infection	2	22SEP2020	13/12	2	No	O	NA/TC	R (03OCT2020)	N/N
>55/ C4591001 1096 10961094	INJ&P	Skin laceration/ right hand laceration	1	05SEP2020	15/21	1	No	O	NA/TC	R (25SEP2020)	N/N
>55/ C4591001 1096 10961117	INFEC	Trichomoniasis/ trichomoniasis	1	10SEP2020	20/23	1	No	O	NA/TC	R (02OCT2020)	N/N
	NERV	Dizziness/ DIZZINESS	1	24AUG2020	1/2	1	Yes		NA	R (25AUG2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N
		Nausea/ NAUSEA	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ WORSENING HEADACHES	1	25AUG2020	2/4	1	Yes		NA	R (28AUG2020)	N/N
>55/ C4591001 1096 10961124	GENRL	Fatigue/ Fatigue	2	16SEP2020	2/2	1	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C4591001 1096 10961129	GENRL	Chills/ Chills	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
		Injection site erythema/ Injection site redness	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Injection site swelling/ Injection site swelling	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	2/3	1	Yes		NA/TC	R (18SEP2020)	N/N
	INFEC	Sinusitis/ Sinus infections	2	04OCT2020	20/13	2	No	O	NA/TC	R (16OCT2020)	N/N
>55/ C4591001 1096 10961133	MUSC	Arthralgia/ left knee pain	1	03SEP2020	10/C	2	No	O	NA/TC	N	N/N
	INJ&P	Meniscus injury/ torn meniscus left knee	1	15SEP2020	22/C	2	No	O	NA/TC	N	N/N
	INFEC	Abscess/ Superficial Abscess Left Knee	2	04DEC2020	78/11	2	No	O	NA	R (14DEC2020)	N/N
>55/ C4591001 1096 10961156	MUSC	Myalgia/ Muscle pain	2	20SEP2020	4/2	1	No	O	NA	R (21SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	INFEC	Urinary tract infection/ urinary tract infection#	2	12MAR2021	177/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1096 10961159	GENRL	Injection site pain/ Soreness at injection site*		28AUG2020	1/3	2	Yes		NA	R (30AUG2020)	N/N	
>55/ C4591001 1096 10961160	GASTR	Abdominal pain/ Abdominal pain	1	11SEP2020	15/7	2	No	O	NA	R (17SEP2020)	N/N	
	RESP	Nasal congestion/ Nasal congestion	1	17SEP2020	21/C	2	No	O	NA	N	N/N	
		Oropharyngeal pain/ Sore throat	1	17SEP2020	21/C	1	No	O	NA	N	N/N	
>55/ C4591001 1096 10961164	GENRL	Injection site pain/ INJECTION SITE SORENESS	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N	
>55/ C4591001 1096 10961166	GENRL	Pain/ generalized body aches	2	16SEP2020	1/4	1	Yes		NA	R (19SEP2020)	N/N	
	GENRL	Pyrexia/ fever	2	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N	
>55/ C4591001 1096 10961167	GENRL	Injection site pain/ injection site tenderness	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N	
	GENRL	Chills/ chills	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1096 10961181	GENRL	Pain/ GENERALIZED BODY ACHES	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		Pyrexia/ FEVER	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	INFECTION	Pneumonia/ Pneumonia#	4	18FEB2021	18/12	2	No	O	NA/TC	R (01MAR2021)	N/N
	RESP	Acute respiratory failure/ Acute Hypoxic Respiratory Failure#	4	23FEB2021	23/5	2	No	O	NA	R (27FEB2021)	Y/N
	INV	Troponin increased/ elevated troponin#	4	24FEB2021	24/15	2	No	O	NA	R (10MAR2021)	N/N
	CARD	Acute myocardial infarction/ Non-St-Elevation Myocardial Infarction#	4	26FEB2021	26/1	2	No	O	NA/TCN	R (26FEB2021)	Y/N
		Coronary artery disease/ Coronary Artery Disease#	4	26FEB2021	26/C	2	No	O	NA/TC	N	N/N
	CARD	Arteriospasm coronary/ Coronary Spasm#	4	08MAR2021	36/4	3	No	O	NA	R (11MAR2021)	Y/N
		Cardiovascular disorder/ Coronary Blood Stasis#	4	08MAR2021	36/5	3	No	O	NA/TC	R (12MAR2021)	Y/N
	GENRL	Fatigue/ Fatigue#	4	08MAR2021	36/C	2	No	O	NA	N	N/N
	Troponin increased/ worsening of elevated troponin to 55#	4	10MAR2021	38/C	2	No	O	NA	N	N/N	
>55/ C4591001 1096 10961182	GENRL	Injection site erythema/ Redness around injection site	1	29AUG2020	1/1	1	Yes		NA	R (29AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1096 10961184		Injection site pain/ Pain around the injection site	1	29AUG2020	1/1	2	Yes		NA	R (29AUG2020)	N/N
	GASTR	Glossodynia/ tongue soreness	2	19SEP2020	1/2	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Pain/ generalized body aches	2	20SEP2020	2/2	1	Yes		NA	R (21SEP2020)	N/N
	MUSC	Arthralgia/ LEFT SIDE HIP PAIN	2	25SEP2020	7/7	2	No	O	NA/TC	R (01OCT2020)	N/N
	MUSC	Back pain/ LOWER LEFT BACK PAIN	2	01OCT2020	13/9	2	No	O	NA/TC	R (09OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE SORENESS	2	19SEP2020	1/2	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Pyrexia/ FEVER	2	20SEP2020	2/2	2	Yes		NA	R (21SEP2020)	N/N
>55/ C4591001 1096 10961191	MUSC	Myalgia/ GENERALIZED MUSCLE ACHES	2	20SEP2020	2/2	1	Yes		NA	R (21SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	20SEP2020	2/2	2	Yes		NA	R (21SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE TENDERNESS IN LEFT ARM	1	30AUG2020	2/4	1	Yes		NA	R (02SEP2020)	N/N
>55/ C4591001	GASTR	Diarrhoea/ Diarrhea	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Injection site tenderness in left arm.	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ injection site soreness	2	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1096 10961192 >55/ C4591001 1096 10961201	GENRL	Injection site pain/ Injection site soreness	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	22SEP2020	2/3	1	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C4591001 1096 10961202	GASTR	Diarrhoea/ Diarrhea	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
	NERV	Headache/ Headache	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	03SEP2020	4/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	03SEP2020	4/5	2	Yes		NA	R (07SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	05SEP2020	6/2	2	Yes		NA	R (06SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	06SEP2020	7/2	1	Yes		NA	R (07SEP2020)	N/N
	GENRL	Chills/ Chills	1	06SEP2020	7/2	1	Yes		NA	R (07SEP2020)	N/N
	NERV	Headache/ Headache	1	06SEP2020	7/2	1	Yes		NA	R (07SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Fatigue/ Fatigue	2	30SEP2020	2/16	1	No	O	NA	R (15OCT2020)	N/N	
	BLOOD	Anaemia/ anemia	2	02NOV2020	35/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1096 10961204	GENRL	Injection site pain/ injection site soreness	2	21SEP2020	1/3	2	Yes		NA/TC	R (23SEP2020)	N/N	
>55/ C4591001 1096 10961224	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	2/3	2	Yes		NA	R (29JAN2021)	N/N	
>55/ C4591001 1096 10961232	GENRL	Injection site pruritus/ itchy around site injection	2	22SEP2020	1/8	1	Yes		NA	R (29SEP2020)	N/N	
>55/ C4591001 1096 10961241	GENRL	Chills/ chills	2	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N	
		Fatigue/ Fatigue	2	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N	
>55/ C4591001 1096 10961248	GENRL	Injection site erythema/ INJECTION SITE REDNESS	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N	
		Injection site pain/ INJECTION SITE TENDERNESS	1	04SEP2020	1/3	2	Yes		NA/TC	R (06SEP2020)	N/N	
		Injection site swelling/ INJECTION SITE SWELLING	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INV	Body temperature increased/ INCREASED BODY TEMPERATURE	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE TENDERNESS	2	25SEP2020	1/5	2	Yes		NA	R (29SEP2020)	N/N
		Pain/ GENERALIZED BODY ACHES	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ FEVER	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N
>55/ C4591001 1096 10961252	GENRL	Injection site pain/ Injection site soreness	1	04SEP2020	1/4	1	Yes		NA	R (07SEP2020)	N/N
	GENRL	Injection site erythema/ Injection site redness	1	05SEP2020	2/5	1	Yes		NA	R (09SEP2020)	N/N
>55/ C4591001 1096 10961260	GENRL	Injection site pain/ Injection site soreness	2	26SEP2020	1/4	2	Yes		NA	R (29SEP2020)	N/N
	INJ&P	Joint injury/ Left knee injury	2	26SEP2020	1/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1096 10961270	GENRL	Injection site pain/ INJECTION SITE SORENESS IN LEFT ARM	1	06SEP2020	2/2	2	Yes		NA	R (07SEP2020)	N/N
		Pain/ GENERALIZED BODY ACHES	1	06SEP2020	2/2	1	Yes		NA	R (07SEP2020)	N/N
		Pyrexia/ FEVER	1	06SEP2020	2/2	2	Yes		NA	R (07SEP2020)	N/N
	INV	Body temperature increased/ INCREASED BODY TEMPERATURE	1	06SEP2020	2/1	1	Yes		NA/TC	R (06SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1096 10961273	NERV	Headache/ HEADACHE	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N
	SKIN	Rash/ Rash, breasts	1	06SEP2020	2/2	1	Yes		NA	R (07SEP2020)	N/N
	GENRL	Chills/ Chills	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		Fatigue/ Fatigue	2	24SEP2020	1/3	2	Yes		NA	R (26SEP2020)	N/Y
		Injection site pain/ INJECTION SITE SORENESS IN LEFT ARM	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ Fever	2	24SEP2020	1/3	1	Yes		NA/TC	R (26SEP2020)	N/N
	MUSC	Myalgia/ Generalized muscle aches	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	25SEP2020	2/2	2	Yes		NA	R (26SEP2020)	N/N
		Injection site pain/ Injection site pain	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		Injection site swelling/ Injection site swelling	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ Fever	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
GENRL	Chills/ Chills	2	26SEP2020	3/1	2	Yes		NA	R (26SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	SKIN	Hyperhidrosis/ Sweating	2	26SEP2020	3/1	1	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ Intermittent Headaches	2	28SEP2020	5/13	1	Yes		NA/TC	R (10OCT2020)	N/N
>55/ C4591001 1096 10961281	GENRL	Injection site pain/ INJECTION SITE SORENESS	2	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N
	INFEC	Hordeolum/ left eye sty	2	07OCT2020	13/	1	No	O	NA/TC	R	N/N
>55/ C4591001 1096 10961283	NERV	Headache/ Headaches	1	06SEP2020	2/1	1	Yes		NA/TC	R (06SEP2020)	N/N
>55/ C4591001 1096 10961285	GENRL	Injection site pain/ Injection site soreness*		05SEP2020	1/2	2	Yes		NA/TC	R (06SEP2020)	N/N
>55/ C4591001 1096 10961295	GENRL	Fatigue/ fatigue	2	21OCT2020	23/2	1	No	O	NA/TC	R (22OCT2020)	N/N
		Pain/ generalized body aches due to shingrix vaccine	2	21OCT2020	23/2	1	No	O	NA/TC	R (22OCT2020)	N/N
>55/ C4591001 1096 10961300	GENRL	Injection site pain/ Injection site soreness	1	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N
	GENRL	Injection site pain/ Injection site soreness	2	29SEP2020	2/3	2	Yes		NA/TC	R (01OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1096 10961302	EAR	Deafness unilateral/ complete hearing loss left ear#	4	15JAN2021	3/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1096 10961308	GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	INV	Body temperature increased/ Increased body temperature	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ Generalized muscle aches	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
>55/ C4591001 1096 10961311	REPRO	Breast cyst/ benign cyst on left breast	2	20DEC2020	74/27	1	No	O	NA	R (15JAN2021)	N/N
>55/ C4591001 1096 10961329	NERV	Headache/ Headaches	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	INFEC	Herpes zoster/ Herpes Zoster	2	12NOV2020	38/C	1	No	O	NA	N	N/N
>55/ C4591001 1096 10961332	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1096 10961334	INJ&P	Bone contusion/ injury to right side rib (bruised)	1	28SEP2020	14/34	2	No	O	NA/TC	R (31OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1096 10961337	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N	
	RESP	Chronic obstructive pulmonary disease/ exacerbation of chronic obstructive pulmonary disease	2	24OCT2020	19/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1096 10961346	RESP	Dry throat/ dry throat	1	17SEP2020	2/1	1	No	O	NA	R (17SEP2020)	N/N	
>55/ C4591001 1096 10961352	INJ&P	Arthropod bite/ bug bite left shoulder#	3	20JAN2021	14/2	1	No	O	NA	R (21JAN2021)	N/N	
	SKIN	Erythema/ erythema 2 inches wide on left shoulder#	3	20JAN2021	14/2	1	No	O	NA	R (21JAN2021)	N/N	
>55/ C4591001 1096 10961355	INJ&P	Fall/ fall	2	31JAN2021	116/1	3	No	O	NA	R (31JAN2021)	N/N	
		Lower limb fracture/ Multiple lower extremity fractures	2	31JAN2021	116/C	3	No	O	NA/TC	N	Y/N	
	INFEC	Urinary tract infection/ urinary tract infection	2	05FEB2021	121/C	1	No	O	NA/TC	N	N/N	
	METAB	Hypokalaemia/ hypokalemia	2	05FEB2021	121/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001	NERV	Presyncope/ PRESYNCOPE	1	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/Y	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1096 10961356	GENRL	Fatigue/ Fatigue	1	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N	
		Injection site pain/ Injection site soreness	1	18SEP2020	2/3	2	Yes		NA	R (20SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site tenderness	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/Y	
>55/ C4591001 1096 10961364	GENRL	Fatigue/ Fatigue	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site soreness	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N	
>55/ C4591001 1097 10971006	BLOOD	Thrombocytosis/ thrombocytosis	2	09OCT2020	31/C	1	No	O	NA	N	N/N	
>55/ C4591001 1097 10971009	INJ&P	Fall/ Fall	2	04OCT2020	26/1	1	No	O	NA/TCN	R (04OCT2020)	N/N	
		Spinal fracture/ fractured transverse process	2	04OCT2020	26/C	2	No	O	NA/TC/TCN	RG	N/N	
	SKIN	Actinic keratosis/ Actinic Keratosis	2	13OCT2020	35/1	2	No	O	NA/TCN	R (13OCT2020)	N/N	
>55/ C4591001 1097 10971011	INFEC	Pneumonia/ Pneumonia	2	20SEP2020	12/16	3	No	O	NA/TC	R (05OCT2020)	Y/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1097 10971017	INJ&P	Skin laceration/ HEAD LACERATION	2	20SEP2020	12/10	2	No	O	NA/TCN	R (29SEP2020)	N/N
	INFEC	Urinary tract infection/ urinary tract infection	2	19SEP2020	5/44	3	No	O	NA/TC	R (01NOV2020)	N/N
>55/ C4591001 1097 10971019	GASTR	Retroperitoneal haematoma/ non traumatic retroperitoneal hematoma	2	13NOV2020	60/3	3	No	O	NA	R (15NOV2020)	Y/N
	GASTR	Duodenitis/ Duodenitis#	3	02FEB2021	19/14	2	No	O	NA/TC	R (15FEB2021)	N/N
>55/ C4591001 1097 10971021		Gastritis/ Gastritis#	3	02FEB2021	19/14	2	No	O	NA/TC	R (15FEB2021)	N/N
	INFEC	Candida infection/ Candida Infection#	3	02FEB2021	19/12	2	No	O	NA/TC	R (13FEB2021)	N/N
>55/ C4591001 1097 10971021	CARD	Tachycardia/ TACHYCARDIA AT REST (unspecified)	1	08SEP2020	16/	2	No	O	NA/TC/TCN	R	N/N
>55/ C4591001 1097 10971023	INFEC	Septic shock/ Septic Shock	2	16DEC2020	93/6	4	No	O	NA/TC/TCN/W	F (21DEC2020)	Y/N
>55/ C4591001 1097 10971024	NERV	Piriformis syndrome/ RIGHT PIRIFORMIS syndrome	1	05OCT2020	43/C	2	No	O	NA/TC/TCN	RG	N/N
>55/ C4591001	CARD	Acute myocardial infarction/ Non-STEMI	2	15SEP2020	2/1	3	No	O	NA/TC/TCN	R (15SEP2020)	Y/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1097 10971025 >55/ C4591001	NERV	Cerebrovascular accident/ CEREBROVASCULAR ACCIDENT#	4	24FEB2021	17/C	3	No	O	NA	N	Y/N	
1097 10971026 >55/ C4591001	SKIN	Actinic keratosis/ Actinic Keratosis#	3	28JAN2021	11/1	2	No	O	NA/TCN	R (28JAN2021)	N/N	
1097 10971027 >55/ C4591001	GASTR	Impaired gastric emptying/ Gastroparesis	2	02OCT2020	19/C	2	No	O	NA/TC	N	N/N	
1097 10971028	INJ&P	Corneal abrasion/ Bilateral Corneal Abrasion	2	02DEC2020	80/8	2	No	O	NA/TC	R (09DEC2020)	N/N	
	CARD	Cardiomegaly/ New onset Mild cardiomegaly#	2	09MAR2021	177/C	1	No	O	NA	N	N/N	
>55/ C4591001	INFEC	Urinary tract infection/ Acute Urinary Tract Infection	2	19OCT2020	35/6	2	No	O	NA/TC	R (24OCT2020)	N/N	
1097 10971031	MUSC	Arthralgia/ Worsening Chronic right hip pain	2	03NOV2020	50/15	3	No	O	NA/TCN	R (17NOV2020)	Y/N	
>55/ C4591001	MUSC	Polyarthritits/ inflammatory polyarthropathy	2	28OCT2020	44/13	2	No	O	NA/TC	R (09NOV2020)	N/N	
1097 10971039 >55/ C4591001	INFEC	Sinusitis/ SINUS INFECTION	1	15SEP2020	20/11	2	No	O	NA/TC	R (25SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1097 10971047 >55/ C4591001 1097 10971052	GASTR	Diarrhoea/ DIARRHEA	1	10SEP2020	15/36	2	No	CD	NA/TC	R (15OCT2020)	N/N
>55/ C4591001 1097 10971058	INFEC	Helicobacter infection/ H. PYLORI infection	1	10SEP2020	15/36	2	No	O	NA/TC	R (15OCT2020)	N/N
>55/ C4591001 1097 10971058	EYE	Cataract/ CATARACT RIGHT EYE	2	28SEP2020	11/	3	No	O	NA/TCN	R	N/N
>55/ C4591001 1097 10971060	INJ&P	Fall/ Fall	1	11SEP2020	15/1	2	No	O	NA/TC	R (11SEP2020)	N/N
>55/ C4591001 1097 10971061	GENRL	Ligament sprain/ Sprained Ankle	1	11SEP2020	15/8	2	No	O	NA/TC	R (18SEP2020)	N/N
>55/ C4591001 1097 10971061	GENRL	Pyrexia/ Fever 99.3#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1097 10971061	NERV	Uraemic encephalopathy/ Uremic encephalopathy	2	22OCT2020	36/4	3	No	O	NA/TC	RS (25OCT2020)	Y/N
>55/ C4591001 1097 10971064	RENAL	Acute kidney injury/ Acute kidney injury	2	22OCT2020	36/4	3	No	CD	NA/TC	RS (25OCT2020)	Y/N
>55/ C4591001 1097 10971064	CARD	Cardiac failure congestive/ congestive heart failure	2	22DEC2020	90/C	2	No	O	NA/TC	RG	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	CARD	Atrial fibrillation/ NEW ONSET ATRIAL FIB	2	04JAN2021	103/3	3	No	O	NA/TC	R (06JAN2021)	Y/N
	CARD	Atrial fibrillation/ Persistent Atrial Fibrillation#	2	21JAN2021	120/C	3	No	O	NA/TC/TCN	RG	Y/N
>55/ C4591001 1097 10971072	MUSC	Sjogren's syndrome/ Sjogren's Syndrome#	4	01MAR2021	19/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1097 10971082	GENRL	Injection site erythema/ Redness at injection site#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
		Injection site pain/ soreness at injection site#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
>55/ C4591001 1097 10971084	INFEC	Bacterial sepsis/ Sepsis Bacteremia	2	29SEP2020	7/13	3	No	O	NA/TC	R (11OCT2020)	Y/N
		Urinary tract infection/ Urinary Tract Infection	2	29SEP2020	7/13	3	No	O	NA/TC/TCN	R (11OCT2020)	Y/N
	INJ&P	Fall/ fall#	2	13FEB2021	144/1	1	No	O	NA	R (13FEB2021)	Y/N
	NERV	Dizziness/ dizziness#	2	13FEB2021	144/3	2	No	O	NA/TC	R (15FEB2021)	Y/N
>55/ C4591001 1097 10971087	INFEC	Tooth infection/ Dental Infection	2	19NOV2020	57/19	3	No	O	NA/TC	R (07DEC2020)	Y/N
>55/ C4591001	GENRL	Chills/ Chills	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1097 10971090		Pain/ Body Aches especially the legs	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N	
>55/ C4591001 1097 10971098	INFEC	Conjunctivitis/ CONJUNCTIVITIS	2	11JAN2021	109/4	2	No	O	NA/TC	R (14JAN2021)	N/N	
>55/ C4591001 1097 10971100	SKIN	Dermatitis contact/ CONTACT DERMATITIS TO FACE	2	02OCT2020	4/7	2	No	O	NA/TC	R (08OCT2020)	N/N	
	INJ&P	Venom poisoning/ POISONING DUE TO BROWN RECLUSE SPIDER VENOM	2	06OCT2020	8/38	2	No	O	NA/TCN	R (12NOV2020)	N/N	
>55/ C4591001 1097 10971102	RESP	Dyspnoea/ Intermittent shortness of breath#	4	11FEB2021	1/C	1	No	O	NA	N	N/N	
>55/ C4591001 1097 10971103	EAR	Vertigo positional/ BENIGN PAROXYMAL POSITIONAL VERTIGO	2	07DEC2020	71/3	2	No	O	NA/TCN	R (09DEC2020)	N/N	
>55/ C4591001 1097 10971115	GENRL	Pyrexia/ Post #2 Vaccine Fever	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N	
>55/ C4591001 1098 10981021	MUSC	Arthralgia/ Right Ankle sore(pain)	1	10SEP2020	22/2	1	No	O	NA	R (11SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1098 10981024	RESP	Dyspnoea/ Shortness of Breath	2	01OCT2020	8/7	1	No	O	NA	R (07OCT2020)	N/N
	CARD	Angina unstable/ Unstable Angina Pectoris Moderate	2	04OCT2020	11/2	1	No	O	NA/TC	R (05OCT2020)	N/N
	CARD	Cardiac failure congestive/ Diastolic Congestive Heart Failure with acute exacerbation	2	07OCT2020	14/3	1	No	O	NA	R (09OCT2020)	N/N
	GENRL	Chest pain/ ChestPain	2	07OCT2020	14/3	1	No	O	NA/TC/TCN	R (09OCT2020)	Y/N
	INFEC	Pneumonia/ Community Acquired Pneumonia	2	07OCT2020	14/3	1	No	O	NA	R (09OCT2020)	Y/N
	INJ&P	Fall/ fall	2	07OCT2020	14/1	1	No	O	NA/TC	R (07OCT2020)	N/N
	NERV	Dizziness/ Dizziness	2	07OCT2020	14/1	1	No	O	NA/TC	R (07OCT2020)	N/N
	RESP	Chronic obstructive pulmonary disease/ COPD with acute exacerbation	2	07OCT2020	14/3	1	No	O	NA/TC	R (09OCT2020)	N/N
>55/ C4591001 1098 10981133	GENRL	Pain/ Bodyache	2	02OCT2020	4/1	1	Yes		NA/TC	R (02OCT2020)	N/N
		Pyrexia/ Fever	2	02OCT2020	4/1	1	Yes		NA/TC	R (02OCT2020)	N/N
>55/ C4591001 1098 10981158	GENRL	Chills/ Chills	2	10OCT2020	6/1	1	Yes		NA/TC	R (10OCT2020)	N/N
		Pyrexia/ Fever	2	10OCT2020	6/1	1	Yes		NA/TC	R (10OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Muscle Aches	2	10OCT2020	6/1	1	Yes		NA/TC/TCN	R (10OCT2020)	N/N
>55/ C4591001 1098 10981209	INJ&P	Animal bite/ Catbite on Right index finger	1	13OCT2020	22/1	1	No	O	NA	R (13OCT2020)	N/N
>55/ C4591001 1098 10981257	GENRL	Chills/ Chills	1	16OCT2020	3/3	1	Yes		NA	R (18OCT2020)	N/N
>55/ C4591001 1101 11011002	GENRL	Pain/ generalized body aches#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
		Pyrexia/ low-grade fever#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
	NERV	Headache/ headache#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
>55/ C4591001 1101 11011006	GENRL	Injection site pain/ pain at injection site	1	02SEP2020	1/2	1	Yes		NA/TC	R (03SEP2020)	N/N
>55/ C4591001 1101 11011008	GENRL	Pyrexia/ fever	2	23SEP2020	2/6	1	Yes		NA	R (28SEP2020)	N/N
>55/ C4591001 1101 11011011	GENRL	Injection site pain/ injection site pain	1	03SEP2020	2/3	1	Yes		NA/TC	R (05SEP2020)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1101 11011017	GENRL	Injection site pain/ injection site pain#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
>55/ C4591001 1101 11011049	GENRL	Fatigue/ fatigue	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ injection site pain	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Injection site pain/ injection site pain	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
>55/ C4591001 1101 11011055	GASTR	Gastroesophageal reflux disease/ worsening GERD	2	30OCT2020	26/C	2	No	O	NA	N	N/N
		Hiatus hernia/ hiatal hernia	2	30OCT2020	26/C	2	No	O	NA	N	N/N
>55/ C4591001 1101 11011063	GENRL	Chills/ chills	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
		Pain/ body aches	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
		Pyrexia/ low-grade fever	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
>55/ C4591001	GASTR	Abdominal discomfort/ upset stomach	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1101 11011066		Diarrhoea/ diarrhea	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Injection site warmth/ warmth at injection site	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
	NERV	Dizziness/ lightheadedness	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
>55/ C4591001 1101 11011078	GENRL	Injection site pain/ injection site pain	2	07OCT2020	1/3	2	Yes		NA	R (09OCT2020)	N/Y
>55/ C4591001 1101 11011092	INFEC	Tinea pedis/ Tinea Pedis#	4	05FEB2021	2/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1101 11011102	GENRL	Injection site pain/ injection site pain#	3	02FEB2021	1/2	1	Yes		NA/TC	R (03FEB2021)	N/N
>55/ C4591001 1101 11011104	GENRL	Chills/ chills#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
		Injection site pain/ injection site pain#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
		Pyrexia/ low-grade fever#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
	MUSC	Myalgia/ general muscle aches#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
>55/ C4591001 1101 11011112	GENRL	Injection site bruising/ injection site bruising#	3	28JAN2021	1/8	2	Yes		NA	R (04FEB2021)	N/Y
>55/ C4591001 1107 11071014	RESP	Rhinorrhoea/ RHINORRHEA	1	05AUG2020	3/1	1	Yes		NA	R (05AUG2020)	N/N
>55/ C4591001 1107 11071023	INFEC	Eye infection/ LEFT EYE INFECTION	1	20AUG2020	18/7	1	No	O	NA/TC	R (26AUG2020)	N/N
>55/ C4591001 1107 11071035	GENRL	Chills/ CHILLS#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Chills/ CHILLS#	4	02MAR2021	1/3	1	Yes		NA	R (04MAR2021)	N/N
		Pain/ BODYACHES#	4	02MAR2021	1/3	1	Yes		NA	R (04MAR2021)	N/N
		Pyrexia/ FEVER#	4	02MAR2021	1/3	1	Yes		NA	R (04MAR2021)	N/N
	NERV	Headache/ HEADACHE#	4	02MAR2021	1/3	1	Yes		NA	R (04MAR2021)	N/N
>55/ C4591001 1107 11071037	REPRO	Benign prostatic hyperplasia/ BENIGN PROSTATIC HYPERPLASIA	2	01JAN2021	130/C	1	No	O	NA/TC	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1107 11071041	NEOPL	Basal cell carcinoma/ BASAL CELL CARCINOMA RIGHT SHOULDER	1	11AUG2020	7/8	1	No	O	NA/TCN	R (18AUG2020)	N/N	
>55/ C4591001 1107 11071044	HEPAT	Cholelithiasis/ CHOLELITHIASIS	2	11SEP2020	17/5	3	No	O	NA/TC/TCN	R (15SEP2020)	Y/N	
>55/ C4591001 1107 11071048	GASTR	Toothache/ TOOTH PAIN	2	21SEP2020	27/2	1	No	O	NA/TC	R (22SEP2020)	N/N	
>55/ C4591001 1107 11071061	INFEC	Conjunctivitis/ LEFT EYE CONJUNCTIVITIS	2	28AUG2020	2/7	1	No	O	NA/TC	R (03SEP2020)	N/N	
	INFEC	Conjunctivitis/ LEFT EYE CONJUNCTIVITIS	2	24SEP2020	29/	1	No	O	NA/TC	R	N/N	
>55/ C4591001 1107 11071085	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE (LEFT ARM)#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N	
		Injection site swelling/ SWELLING AT THE INJECTION SITE (LEFT ARM)#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N	
		Pain/ BODYACHES#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N	
>55/ C4591001 1107 11071090	EYE	Cataract/ BILATERAL CATARACTS	2	08SEP2020	8/C	2	No	O	NA	N	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1107 11071091	INJ&P	Arthropod bite/ INSECT BITE RIGHT ARM	1	15AUG2020	5/4	1	No	O	NA/TC	R (18AUG2020)	N/N	
>55/ C4591001 1107 11071116	RENAL	Nephrolithiasis/ RIGHT KIDNEY STONE#	2	25FEB2021	171/C	3	No	O	NA/TC/TCN	N	Y/N	
>55/ C4591001 1107 11071117	GENRL	Chills/ CHILLS	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N	
		Fatigue/ FATIGUE	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N	
		Injection site pain/ PAIN AT THE INJECTION SITE (LEFT ARM)	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N	
		Pyrexia/ FEVER	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N	
	MUSC	Myalgia/ MUSCLE PAIN (MYALGIAS)	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N	
	NERV	Headache/ HEADACHE	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N	
>55/ C4591001 1107 11071128	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
	NERV	Headache/ HEADACHE	2	08SEP2020	1/2	1	Yes		NA/TC	R (09SEP2020)	N/N	
>55/ C4591001	NERV	Headache/ HEADACHE	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1107 11071132	RESP	Oropharyngeal pain/ SORE THROAT	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N	
	GENRL	Chills/ CHILLS	2	08SEP2020	1/3	2	Yes		NA	R (10SEP2020)	N/N	
		Injection site pain/ PAIN AT THE INJECTION SITE (LEFT ARM)	2	08SEP2020	1/3	2	Yes		NA	R (10SEP2020)	N/N	
		Pyrexia/ FEVER	2	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N	
	NERV	Headache/ HEADACHE	2	08SEP2020	1/3	2	Yes		NA/TC	R (10SEP2020)	N/N	
>55/ C4591001 1107 11071133	MUSC	Myalgia/ MUSCLE PAIN (MYALGIAS)	2	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N	
	NERV	Headache/ HEADACHE	2	10SEP2020	2/4	1	Yes		NA/TC	R (13SEP2020)	N/N	
>55/ C4591001 1107 11071148	NERV	Dizziness postural/ POSTURAL CHANGE DIZZINESS	1	01SEP2020	13/3	1	No	O	NA	R (03SEP2020)	N/N	
>55/ C4591001 1107 11071149	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N	
>55/ C4591001 1107 11071150	NERV	Dizziness postural/ POSTURAL CHANGE DIZZINESS	1	21AUG2020	2/15	1	Yes		NA	R (04SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1107 11071153	GENRL	Chills/ CHILLS	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Injection site pain/ RIGHT ARM INJECTION SITE PAIN	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Injection site pain/ RIGHT ARM PAIN (INJECTION ARM)	2	11SEP2020	2/1	2	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1107 11071166	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE (LEFT ARM)	1	24AUG2020	1/5	1	Yes		NA/TC	R (28AUG2020)	N/N
>55/ C4591001 1107 11071167	EYE	Vision blurred/ BLURRY VISION	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N
	NERV	Dizziness/ DIZZINESS	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N
		Headache/ HEADACHE	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N
>55/ C4591001 1107 11071172	GENRL	Injection site pain/ LEFT ARM INJECTION PAIN	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1107 11071183	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE (LEFT ARM)	1	31AUG2020	1/4	1	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	RESP	Nasal congestion/ NASAL CONGESTION	1	01SEP2020	2/2	1	Yes		NA/TC	R (02SEP2020)	N/N	
	GENRL	Fatigue/ FATIGUE	1	02SEP2020	3/2	1	Yes		NA	R (03SEP2020)	N/N	
	MUSC	Myalgia/ MYALGIA (MUSCLE PAIN)	1	02SEP2020	3/2	1	Yes		NA	R (03SEP2020)	N/N	
>55/ C4591001 1107 11071187	RENAL	Nephrolithiasis/ LEFT KIDNEY STONE#	3	08FEB2021	13/10	2	No	O	NA/TC/TCN	R (17FEB2021)	N/N	
>55/ C4591001 1107 11071191	NEOPL	Papillary serous endometrial carcinoma/ UTERINE PAPILLARY SEROUS CARCINOMA	2	NOV2020	39/	3	No	O	NA/TC/TCN	R (30DEC2020)	Y/N	
	MUSC	Osteopenia/ OSTEOPENIA	2	DEC2020	69/C	1	No	O	NA/TC	N	N/N	
	INFEC	Catheter site infection/ LEFT ABDOMINAL PORT SITE INFECTION	2	12JAN2021	111/3	1	No	O	NA/TC	R (14JAN2021)	N/N	
	VASC	Hypertension/ HYPERTENSION#	4	MAR2021	22/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1107 11071196	INFEC	Diverticulitis/ DIVERTICULITIS	2	DEC2020	70/	3	No	O	NA/TC/TCN	R (22FEB2021)	Y/N	
>55/ C4591001 1107 11071197	INJ&P	Animal bite/ CAT BITE RIGHT LOWER LEG	2	23OCT2020	31/7	1	No	O	NA/TC	R (29OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1107 11071205	GENRL	Injection site pain/ PAIN AT INJECTION SITE (LEFT ARM)#	4	03MAR2021	2/1	1	Yes		NA	R (03MAR2021)	N/N
>55/ C4591001 1107 11071214	MUSC	Myalgia/ MYALGIA	2	06OCT2020	2/3	1	Yes		NA/TC	R (08OCT2020)	N/N
>55/ C4591001 1107 11071216	RENAL	Dysuria/ DYSURIA	1	21SEP2020	1/8	1	No	O	NA/TC	R (28SEP2020)	N/N
>55/ C4591001 1107 11071217	MUSC	Osteoarthritis/ LEFT HAND OSTEOARTHRITIS	1	29SEP2020	9/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1109 11091036	BLOOD	Lymphadenopathy/ SWOLLEN LYMPH NODES#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N
>55/ C4591001 1109 11091038	NERV	Headache/ HEADACHE	2	19AUG2020	2/2	3	Yes		NA/TC	R (20AUG2020)	N/N
>55/ C4591001 1109 11091049	MUSC	Back pain/ back pain	2	02SEP2020	15/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1109 11091074	INFEC	COVID-19 pneumonia/ Pneumonia COVID-19 illness	2	04DEC2020	107/18	4	No	O	NA/TC	R (21DEC2020)	Y/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N
>55/ C4591001 1109 11091079	GENRL	Fatigue/ fATIGUE#	4	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
>55/ C4591001 1109 11091084	MUSC	Arthralgia/ LEFT MIDDLE FINGER PIP TENDERNESS	1	01AUG2020	1/28	1	No	O	NA	R (28AUG2020)	N/N
	NEOPL	Malignant melanoma/ REGIONALLY ADVANCED MELANOMA OF THE RIGHT INGUINAL AREA	2	26NOV2020	98/C	4	No	O	NA/TC/TCN	N	Y/N
>55/ C4591001 1109 11091097	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1109 11091101	GENRL	Fatigue/ FATIGUE#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
		Pain/ BODY ACHES#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
		Pyrexia/ FEVER#	4	19FEB2021	2/C	1	Yes		NA	N	N/N
>55/ C4591001 1109 11091104	INV	Body temperature increased/ ELEVATED TEMPERATURE FOR 3 DAYS AFTER THE INJECTION	2	23AUG2020	1/4	1	Yes		NA/TC/TCN	R (26AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1109 11091107	GENRL	Injection site pain/ INJECTION SITE SORENESS	1	05AUG2020	3/3	1	Yes		NA	R (07AUG2020)	N/N	
	INV	Body temperature increased/ ELEVATED TEMPERATURE	1	05AUG2020	3/3	1	Yes		NA	R (07AUG2020)	N/N	
>55/ C4591001 1109 11091111	RESP	Cough/ COUGH	1	20AUG2020	18/16	1	No	O	NA	R (04SEP2020)	N/N	
	INFEC	Diverticulitis/ Diverticulitis flair-up	2	08NOV2020	78/6	4	No	O	NA/TC	R (13NOV2020)	Y/N	
>55/ C4591001 1109 11091113	GENRL	Fatigue/ FATIGUE#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	12MAR2021	30/2	1	Yes		NA	R (13MAR2021)	N/N	
>55/ C4591001 1109 11091119	GASTR	Nausea/ NAUSEA#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	
	NERV	Headache/ HEADACHE#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	
>55/ C4591001 1109 11091123	MUSC	Arthritis/ Arthritis Flare	2	17SEP2020	26/2	2	No	O	NA/TC	R (18SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1109 11091135	MUSC	Arthralgia/ Polyarthralgia	1	06AUG2020	4/1	1	No	O	NA	R (06AUG2020)	N/N
>55/ C4591001 1109 11091141	GENRL	Fatigue/ FATIGUE#	4	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001 1109 11091143	MUSC	Myalgia/ MYALGIA#	4	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
>55/ C4591001 1109 11091150	MUSC	Myalgia/ QUADRICEP MYALGIA	1	06AUG2020	3/4	1	No	O	NA	R (09AUG2020)	N/N
>55/ C4591001 1109 11091164	VASC	Deep vein thrombosis/ Deep Vein Thrombosis	2	07SEP2020	15/C	4	No	O	NA/TC	RG	Y/N
	GENRL	Chills/ CHILLS#	4	08MAR2021	1/1	1	Yes		NA	R (08MAR2021)	N/N
		Fatigue/ FATIGUE#	4	08MAR2021	1/1	1	Yes		NA	R (08MAR2021)	N/N
	MUSC	Myalgia/ MYALGIA#	4	08MAR2021	1/1	1	Yes		NA	R (08MAR2021)	N/N
>55/ C4591001 1109 11091175	GENRL	Chills/ CHILLS#	4	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1109 11091202	NERV	Injection site pain/ INJECTION SITE PAIN#	4	28JAN2021	2/7	1	Yes		NA	R (03FEB2021)	N/N	
		Headache/ HEADACHE#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N	
>55/ C4591001 1109 11091206	INJ&P	Fall/ FALL ON TENNIS COURT	2	18SEP2020	18/1	3	No	O	NA/TCN	R (18SEP2020)	N/N	
>55/ C4591001 1109 11091210	GASTR	Joint dislocation/ DISLOCATED LEFT SHOULDER	2	18SEP2020	18/1	3	No	O	NA/TCN	R (18SEP2020)	N/N	
		Mouth ulceration/ ASYMPTOMATIC MOUTH ULCER	1	24AUG2020	12/C	1	No	O	NA	RG	N/N	
>55/ C4591001 1109 11091233	NEOPL	Meningioma benign/ Meningioma of the Brain	2	05FEB2021	156/C	1	No	O	NA	N	N/N	
>55/ C4591001 1109 11091244	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE#	4	20JAN2021	3/4	1	Yes		NA	R (23JAN2021)	N/N	
>55/ C4591001	MUSC	Pyrexia/ FEVER#	4	20JAN2021	3/4	1	Yes		NA	R (23JAN2021)	N/N	
		Myalgia/ MUSCLE PAIN#	4	20JAN2021	3/4	1	Yes		NA	R (23JAN2021)	N/N	
>55/ C4591001	NERV	Cerebrovascular accident/ CVA	2	17NOV2020	69/50	3	No	O	NA/TC	RS (05JAN2021)	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1109 11091269	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N	
>55/ C4591001 1109 11091271	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N	
		Pyrexia/ FEVER 101.0#	4	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N	
	MUSC	Myalgia/ MYALGIA#	4	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N	
>55/ C4591001 1109 11091272	NERV	Headache/ HEADACHE#	4	11FEB2021	2/30	1	Yes		NA	R (12MAR2021)	N/N	
>55/ C4591001 1109 11091273	EYE	Cataract/ LEFT EYE CATARACT	1	31AUG2020	12/1	1	No	O	NA	R (31AUG2020)	N/N	
>55/ C4591001 1109 11091276	INFEC	Complicated appendicitis/ Acute appendicitis with necrosis	2	30SEP2020	22/3	4	No	O	NA/TC/TCN	R (02OCT2020)	Y/N	
>55/ C4591001 1109 11091280	MUSC	Myalgia/ MYALGIA#	3	08FEB2021	11/1	1	Yes		NA	R (08FEB2021)	N/N	
>55/ C4591001	GENRL	Chills/ CHILLS	1	22AUG2020	2/1	2	Yes		NA	R (22AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1109 11091281		Pyrexia/ FEVER	1	22AUG2020	2/1	2	Yes		NA	R (22AUG2020)	N/N	
>55/ C4591001 1109 11091284	RENAL	Hydronephrosis/ Acute Left Hydro Nephrosis	2	16NOV2020	63/38	3	No	O	NA/TC/TCN	R (23DEC2020)	Y/N	
	INFEC	Herpes zoster/ SHINGLES IOWER BACK	2	07JAN2021	115/16	2	No	O	NA/TC	R (22JAN2021)	N/N	
	SKIN	Dermatitis contact/ CONTACT DERMATITIS FROM THE CREAM USED TO TREAT SHINGLES	2	12FEB2021	151/14	2	No	O	NA/TC	R (25FEB2021)	N/N	
>55/ C4591001 1109 11091290	GASTR	Nausea/ NAUSEA#	4	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N	
	GENRL	Chills/ CHILLS#	4	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N	
	MUSC	Myalgia/ MYALGIA#	4	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N	
>55/ C4591001 1109 11091293	MUSC	Osteoarthritis/ Osteoarthritis right knee	1	02SEP2020	12/C	3	No	O	NA/TC/TCN	RG	N/N	
	GENRL	Pyrexia/ FEVER 100#	4	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N	
>55/ C4591001	GENRL	Pyrexia/ fever 101.0#	4	15FEB2021	1/1	2	Yes		NA	R (15FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1109 11091300 >55/ C4591001 1109 11091318	EAR	Vertigo/ Vertigo	1	24AUG2020	2/5	3	No	O	NA	R (28AUG2020)	N/N	
>55/ C4591001 1109 11091327	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N	
>55/ C4591001 1109 11091334	MUSC	Myalgia/ MYALGIA#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N	
>55/ C4591001 1109 11091351	GENRL	Chills/ CHILLS#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N	
>55/ C4591001 1109 11091374	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N	
>55/ C4591001 1109 11091374	INJ&P	Facial bones fracture/ FACIAL BONE FRACTURE	1	12SEP2020	15/C	3	No	O	NA/TC	RG	N/N	
		Fall/ Fall	1	12SEP2020	15/1	3	No	O	NA/TC	R (12SEP2020)	N/N	
		Skin laceration/ FACIAL LACERATIONS	1	12SEP2020	15/C	3	No	O	NA/TC	RG	N/N	
>55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1109 11091379	BLOOD	Coagulopathy/ COAGULATION DISORDER SECONDARY TO WARAFIN#	4	24FEB2021	6/3	1	No	CD	NA/TC	R (26FEB2021)	N/N	
>55/ C4591001 1109 11091387	MUSC	Osteoarthritis/ Worsening osteoarthritis of the right knee	2	14OCT2020	23/2	4	No	O	NA/TC/TCN	R (15OCT2020)	Y/N	
	VASC	Deep vein thrombosis/ Deep Vein Thrombosis (Right Leg)	2	20OCT2020	29/C	3	No	O	NA/TC	RG	N/N	
>55/ C4591001 1109 11091388	EAR	Ear pain/ Bilateral Ear Ache	1	18SEP2020	18/11	1	No	CD	NA/TC	R (28SEP2020)	N/N	
	GENRL	Injection site pruritus/ INJECTION SITE ITCHING#	4	05FEB2021	1/18	1	Yes		NA	R (22FEB2021)	N/N	
>55/ C4591001 1109 11091389	MUSC	Myalgia/ MUSCLE PAIN LEFT UPPER ARM	2	01NOV2020	42/C	1	No	O	NA	N	N/N	
>55/ C4591001 1109 11091390	MUSC	Myalgia/ MYALGIA#	4	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/N	
>55/ C4591001 1109 11091407	GENRL	Injection site pain/ INJECTION SITE PAIN#	3	24JAN2021	2/2	1	Yes		NA	R (25JAN2021)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1109 11091408	GENRL	Injection site pain/ Injection Site Pain Left Arm	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
>55/ C4591001 1109 11091421	GENRL	Fatigue/ FATIGUE#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
>55/ C4591001 1109 11091429	INJ&P	Foot fracture/ Fracture of fifth left metatarsal	2	25DEC2020	91/C	2	No	O	NA/TCN	RG	N/N
>55/ C4591001 1109 11091443	GENRL	Injection site bruising/ INJECTION SITE BRUSING LEFT ARM	1	08SEP2020	1/23	2	Yes		NA	R (30SEP2020)	N/N
>55/ C4591001 1109 11091445	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	06FEB2021	2/30	1	Yes		NA	R (07MAR2021)	N/N
>55/ C4591001 1109 11091452	MUSC	Myalgia/ Myalgia	2	10NOV2020	40/3	1	No	O	NA/TC	R (12NOV2020)	N/N
>55/ C4591001 1109 11091458	INJ&P	Corneal abrasion/ CORNEAL ABRATION#	3	24JAN2021	20/17	2	No	O	NA/TC	R (09FEB2021)	N/N
>55/ C4591001 1109 11091493	RESP	Cough/ Cough#	3	11MAR2021	14/C	1	No	O	NA/TC	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1109 11091503	GASTR	Abdominal pain upper/ ABDOMINAL PAIN RUQ	1	SEP2020	1/	3	No	O	P	R (30SEP2020)	N/N
>55/ C4591001 1109 11091537	GENRL	Injection site pain/ Injection Site Pain Left Arm	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C4591001 1109 11091538	NERV	Headache/ HEADACHE#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
	NERV	Headache/ HEADACHE#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
>55/ C4591001 1109 11091544	GENRL	Pyrexia/ FEVER#	4	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
>55/ C4591001 1109 11091558	RESP	Chronic obstructive pulmonary disease/ EXACERBATION OF COPD	2	06NOV2020	14/15	3	No	O	NA/TC	R (20NOV2020)	Y/N
	RESP	Chronic obstructive pulmonary disease/ RE-EXACERBATION OF COPD	2	30NOV2020	38/24	3	No	O	NA/TC	R (23DEC2020)	Y/N
>55/ C4591001 1110 11101004	MUSC	Back pain/ Lower Back Pain	2	01DEC2020	104/22	2	No	O	NA/TC	R (22DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Abdominal pain/ Abdominal Pain	2	05DEC2020	108/18	2	No	O	NA	R (22DEC2020)	N/N
	GENRL	Injection site pain/ Pain at site of Injection#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
>55/ C4591001 1110 11101016	GENRL	Injection site pain/ Soreness at site injection#	2	17DEC2020	119/2	1	Yes		NA	R (18DEC2020)	N/N
>55/ C4591001 1110 11101017	RENAL	Urinary retention/ URINARY RETENTION	2	08SEP2020	19/1	2	No	O	NA/TCN	R (08SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site/Left shoulder#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
>55/ C4591001 1110 11101026	MUSC	Myalgia/ Right Deltoid pain (post shingles vaccine injection)#	2	23FEB2021	184/4	1	No	O	NA	R (26FEB2021)	N/N
>55/ C4591001 1110 11101031	METAB	Diabetes mellitus inadequate control/ Uncontrolled Diabetes Mellitus Type 2	2	10NOV2020	78/4	3	No	O	NA/TC/TCN	R (13NOV2020)	Y/N
>55/ C4591001 1110 11101036	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	05OCT2020	42/C	1	No	O	NA/TC	N	N/N
	GENRL	Injection site pain/ Pain at Site of Injection Left Arm#	3	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
		Pyrexia/ Fever#	3	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1110 11101048	GENRL	Injection site pain/ Pain at injection site/Left arm#	3	22DEC2020	1/4	1	Yes		NA	R (25DEC2020)	N/N
	GENRL	Injection site pain/ Pain at site Injection site (left arm)#	4	11JAN2021	1/6	1	Yes		NA/TC	R (16JAN2021)	N/N
	NERV	Headache/ headache#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N
>55/ C4591001 1110 11101055	METAB	Vitamin D deficiency/ Vitamin D Deficiency	1	2020	1/C	2	No	O	NA/TC	N	N/N
	MUSC	Arthralgia/ Right Knee Pain	1	2020	1/	2	No	O	NA/TC	R (25FEB2021)	N/N
	HEPAT	Hepatic steatosis/ Fatty Liver	2	DEC2020	97/C	1	No	O	NA	N	N/N
	MUSC	Back pain/ Lower Back Pain	2	08DEC2020	104/34	2	No	O	NA/TC	R (10JAN2021)	N/N
>55/ C4591001 1110 11101071	INFEC	Tooth abscess/ molar abscess	1	15AUG2020	5/7	2	No	O	NA/TC	R (21AUG2020)	N/N
	NERV	Headache/ headache	1	16AUG2020	6/5	2	No	O	NA/TC/TCN	R (20AUG2020)	N/N
>55/ C4591001 1110 11101074	GASTR	Diarrhoea/ watery diarrhea	1	17AUG2020	6/1	1	No	O	NA	R (17AUG2020)	N/N
>55/ C4591001	MUSC	Osteoporosis/ Osteoporosis	2	OCT2020	30/C	1	No	O	NA/TC	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1110 11101079 >55/ C4591001 1110 11101087	GENRL	Injection site pain/ Pain at site of injection on the Right Arm#	3	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Injection site pain/ Pain at site of injection#	4	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Chills/ Chills#	4	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
		Fatigue/ Fatigue#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
>55/ C4591001 1110 11101088	GENRL	Chills/ Chills#	4	19JAN2021	1/1	1	Yes		NA	R (19JAN2021)	N/N
		Pyrexia/ Feeling of Feverishness#	4	19JAN2021	1/1	1	Yes		NA	R (19JAN2021)	N/N
	NERV	Headache/ Headache#	4	19JAN2021	1/1	1	Yes		NA	R (19JAN2021)	N/N
>55/ C4591001 1110 11101089	RENAL	Nephrolithiasis/ Nephrolithiasis#	4	15FEB2021	20/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1110 11101104	GASTR	Vomiting/ VOMIT	1	18AUG2020	1/1	1	No	O	NA	R (18AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Pain at the site of injection (left deltoid)#	3	25FEB2021	1/3	1	Yes		NA	R (27FEB2021)	N/N
>55/ C4591001 1110 11101108	INFEC	Ear infection/ Left ear canal infection.	2	27DEC2020	111/16	2	No	O	NA/TC	R (11JAN2021)	N/N
	PSYCH	Anxiety/ worsening Anxiety	2	07JAN2021	122/22	2	No	O	NA/TC	R (28JAN2021)	N/N
	GENRL	Injection site pain/ pain at the site of injection (left deltoid)#	3	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
>55/ C4591001 1110 11101112	INFEC	Cellulitis/ Left 4th toe cellulitis	2	JAN2021	116/	1	No	O	NA/TC	R	N/N
	GENRL	Injection site pain/ Pain at the site of injection (right deltoid)#	3	16FEB2021	1/3	1	Yes		NA	R (18FEB2021)	N/N
>55/ C4591001 1110 11101118	ENDO	Hypothyroidism/ Hypothyroidism	2	05NOV2020	59/C	2	No	O	NA/TC	N	N/N
		Oestrogen deficiency/ Hypoestrogenism	2	05NOV2020	59/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1110 11101119	INV	Body temperature increased/ Elevated temperature	1	28AUG2020	10/1	1	No	O	NA/TC	R (28AUG2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1110 11101128	GENRL	Injection site pain/ Pain at the site of injection (Left shoulder)#	3	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N	
		Injection site pain/ Pain at injection site on the left arm#	4	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N	
		Pain/ Generalized body aches.#	4	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N	
	MUSC	Pyrexia/ Fever (100.4 F)#	4	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N	
		Synovial cyst/ Worsening of Baker Cyst right knee#	4	FEB2021	7/	2	No	O	NA/TC/TCN	R (16FEB2021)	N/N	
		GASTR	Faeces soft/ WORSENING OF SOFT STOOL	1	09SEP2020	17/7	1	No	O	NA	R (15SEP2020)	N/N
			INJ&P	Tooth fracture/ Cracked Tooth#	4	17FEB2021	15/7	1	No	O	NA/TC/TCN	R (23FEB2021)
>55/ C4591001 1110 11101134	GENRL	Chills/ chills	1	01SEP2020	9/2	1	No	O	NA	R (02SEP2020)	N/N	
>55/ C4591001 1110 11101136	VASC	Hypertension/ hypertension	1	07SEP2020	14/C	1	No	O	NA/TC	N	N/N	
	INJ&P	Tooth fracture/ tooth fracture (molar)	2	29JAN2021	138/1	1	No	O	NA/TC/TCN	R (29JAN2021)	N/N	
	GENRL	Injection site pain/ pain at injection site#	3	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills#	3	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
		Pyrexia/ fever 100.1 degrees Fahrenheit#	3	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
	NERV	Headache/ headache#	3	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
>55/ C4591001 1110 11101137	INFEC	Sinusitis/ Sinus infection	2	15OCT2020	32/8	2	No	O	NA/TC	R (22OCT2020)	N/N
	GENRL	Pyrexia/ Fever 101 degrees Fahrenheit#	4	22JAN2021	2/3	1	Yes		NA/TC	R (24JAN2021)	N/N
	MUSC	Myalgia/ Muscle Pain#	4	22JAN2021	2/3	1	Yes		NA/TC	R (24JAN2021)	N/N
	NERV	Headache/ Headache#	4	22JAN2021	2/3	1	Yes		NA/TC	R (24JAN2021)	N/N
>55/ C4591001 1110 11101150	INJ&P	Limb injury/ avulsion flexor distal phalanx injury	2	14OCT2020	29/46	2	No	O	NA	R (28NOV2020)	N/N
>55/ C4591001 1110 11101152	MUSC	Myalgia/ muscle pain	1	04SEP2020	8/1	1	No	O	NA	R (04SEP2020)	N/N
>55/ C4591001 1110 11101160	GENRL	Chest pain/ Chest Pain	2	15DEC2020	86/2	3	No	O	NA/TC	R (16DEC2020)	Y/N
>55/ C4591001	GENRL	Chills/ Chills	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1110 11101166 >55/ C4591001	GENRL	Injection site pain/ Pain at site of injection (left deltoid)#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N	
1110 11101170 >55/ C4591001	MUSC	Back pain/ back pain radiate to right leg#	4	18FEB2021	10/C	2	No	O	NA/TC	N	N/N	
1110 11101171 >55/ C4591001	NERV	Transient ischaemic attack/ Transient Ischemic Attack	2	03NOV2020	44/4	3	No	O	NA/TC	R (06NOV2020)	Y/N	
1110 11101176 >55/ C4591001	GENRL	Chills/ Chills#	4	05JAN2021	2/1	1	Yes		NA	R (05JAN2021)	N/N	
1110 11101179		Fatigue/ Fatigue#	4	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N	
		Injection site pain/ Pain at site injection#	4	05JAN2021	2/4	1	Yes		NA	R (08JAN2021)	N/N	
	RESP	Cough/ Cough#	4	05JAN2021	2/1	1	Yes		NA	R (05JAN2021)	N/N	
>55/ C4591001	GENRL	Pain/ Body aches#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
1110 11101197 >55/ C4591001	MUSC	Arthralgia/ Bilateral knee pain#	4	08MAR2021	25/C	1	No	O	NA/TC	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1110 11101209 >55/ C4591001	GASTR	Dental caries/ Dental Cavity#	3	18JAN2021	15/9	1	No	O	NA/TC/TCN	R (26JAN2021)	N/N	
1110 11101215 >55/ C4591001	GASTR	Nausea/ Nausea#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	
1110 11101218	GENRL	Chills/ Chills#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	
		Injection site pain/ Pain at Site of Injection#	4	08FEB2021	1/C	1	Yes		NA	N	N/N	
		Pain/ Body Aches#	4	08FEB2021	1/2	2	Yes		NA	R (09FEB2021)	N/N	
		Pyrexia/ Fever#	4	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N	
	NERV	Headache/ Headache#	4	08FEB2021	1/2	2	Yes		NA	R (09FEB2021)	N/N	
>55/ C4591001	PSYCH	Depression/ Depression	2	18OCT2020	21/C	1	No	O	NA/TC	N	N/N	
1110 11101222 >55/ C4591001	NERV	Diabetic neuropathy/ diabetic peripheral neuropathy	1	15SEP2020	7/C	2	No	O	NA/TC	N	N/N	
1110 11101225 >55/ C4591001	GENRL	Chills/ chills#	3	04MAR2021	1/1	1	Yes		NA	R (04MAR2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1110 11101233		Pyrexia/ fever of 100.5 degrees Fahrenheit#	3	04MAR2021	1/1	1	Yes		NA/TC	R (04MAR2021)	N/N
>55/ C4591001 1110 11101245	MUSC	Plantar fasciitis/ Right foot plantar fasciitis recurrence	2	FEB2021	119/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1110 11101249	CARD	Ventricular extrasystoles/ Premature Ventricular Contraction	2	15OCT2020	11/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1110 11101251	GENRL	Injection site pain/ Pain at the Site of injection on the Left Arm#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
>55/ C4591001 1110 11101252	NERV	Tremor/ Hand Tremors	2	OCT2020	1/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1110 11101255	RESP	Asthma/ Asthma exacerbation	2	01MAR2021	148/4	2	No	O	NA/TC	R (04MAR2021)	N/N
>55/ C4591001 1110 11101259	GENRL	Injection site pain/ Pain at the Site of Injection on Left Arm#	3	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
>55/ C4591001	GENRL	Fatigue/ fatigue	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1110 11101272		Pyrexia/ fever	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
>55/ C4591001 1110 11101277	GENRL	Injection site pain/ Pain at site injection (Left Deltoid)#	3	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
>55/ C4591001 1110 11101280	INFEC	Herpes zoster/ Shingles	2	09DEC2020	58/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1110 11101288	GENRL	Pyrexia/ Fever	2	14OCT2020	2/1	2	Yes		NA/TC	R (14OCT2020)	N/N
>55/ C4591001 1110 11101289	GENRL	Fatigue/ fatigue#	3	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
>55/ C4591001 1110 11101291	GASTR	Injection site pain/ pain at injection site#	3	22FEB2021	1/5	1	Yes		NA	R (26FEB2021)	N/N
	GASTR	Diarrhoea/ loose stool	1	26SEP2020	5/1	1	No	O	NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ pain at the injection site left arm#	3	26FEB2021	2/1	1	Yes		NA	R (26FEB2021)	N/N
	GASTR	Hyperaesthesia teeth/ tooth sensitivity#	3	08MAR2021	12/C	1	No	O	NA/TC	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1110 11101302	NEOPL	Tonsil cancer/ tonsil cancer	2	15FEB2021	124/C	1	No	O	NA	N	Y/N	
	INJ&P	Procedural pain/ post op pain#	2	22FEB2021	131/15	3	No	O	NA/TC	R (08MAR2021)	Y/N	
>55/ C4591001 1110 11101303	METAB	Hyperlipidaemia/ Hyperlipidemia	2	30OCT2020	16/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1110 11101306	SKIN	Rash/ Skin Rash right forearm and left neck	1	02OCT2020	9/17	1	No	O	NA/TC	R (18OCT2020)	N/N	
	EYE	Ocular discomfort/ Eye Discomfort	2	16OCT2020	3/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1110 11101310	GENRL	Injection site pain/ soreness at site injection	2	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N	
	GENRL	Pain/ body aches	2	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N	
		Pyrexia/ Fever	2	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N	
	NERV	Headache/ headache	2	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N	
>55/ C4591001 1110 11101324	GENRL	Injection site pain/ Pain at The Site of Injection on the Left Arm#	3	05JAN2021	2/22	1	Yes		NA	R (26JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1110 11101332	MUSC	Arthralgia/ left shoulder pain#	4	21FEB2021	26/5	1	No	O	NA/TC	R (25FEB2021)	N/N
	VASC	Hypertension/ Hypertension	2	14DEC2020	53/C	1	No	O	NA/TC	N	N/N
	INJ&P	Hand fracture/ right hand 4th and 5th distal phalanges fractures#	3	04MAR2021	10/C	2	No	O	NA/TC/TCN	N	N/N
>55/ C4591001 1110 11101339		Skin laceration/ laceration of right 3rd finger#	3	04MAR2021	10/8	2	No	O	NA/TC/TCN	R (11MAR2021)	N/N
	GASTR	Diarrhoea/ Loose Stools	2	27OCT2020	2/4	1	Yes		NA	R (30OCT2020)	N/N
	MUSC	Trigger finger/ Trigger Finger/ Right ring finger	2	DEC2020	37/C	1	No	O	NA/TC/TCN	RG	N/N
>55/ C4591001 1110 11101351	GENRL	Injection site pain/ Pain at site of injection ( left Deltoid)#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
	MUSC	Trigger finger/ Trigger finger ( left hand third finger)#	3	JAN2021	1/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ pain at site injection	2	07NOV2020	2/2	1	Yes		NA	R (08NOV2020)	N/N
	INV	Body temperature increased/ elevated temperature	2	07NOV2020	2/2	1	Yes		NA/TC	R (08NOV2020)	N/N
	MUSC	Myalgia/ muscle pain	2	07NOV2020	2/2	1	Yes		NA	R (08NOV2020)	N/N
	NERV	Headache/ headache	2	07NOV2020	2/2	1	Yes		NA/TC	R (08NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1110 11101357†	GENRL	Injection site pain/ Pain at Site injection#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1110 11101359	GENRL	Injection site pain/ pain at injection site	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
	INFEC	Tooth abscess/ Tooth Abscess	1	20OCT2020	5/3	2	No	O	NA/TC/TCN	R (22OCT2020)	N/N
>55/ C4591001 1110 11101366	GENRL	Injection site pain/ Pain at site injection	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Pain at site Injection	2	11NOV2020	1/2	2	Yes		NA	R (12NOV2020)	N/N
	GASTR	Nausea/ Nausea	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Chills/ Chills	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		Fatigue/ Fatigue	2	12NOV2020	2/C	2	Yes		NA	N	N/N
	MUSC	Myalgia/ Muscle pain	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	2/1	2	Yes		NA	R (12NOV2020)	N/N
>55/ C4591001 1110 11101367	MUSC	Back pain/ lower back pain	1	17NOV2020	28/55	2	No	O	NA/TC	R (10JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1110 11101373†	INV	Blood glucose abnormal/ uncontrolled blood sugar (glucose)	2	20NOV2020	2/4	3	No	O	NA/TC	R (23NOV2020)	Y/N
	INV	Transaminases increased/ Transaminitis	2	04FEB2021	80/C	1	No	O	NA	N	N/N
>55/ C4591001 1110 11101376	MUSC	Muscle spasms/ Bilateral Lower Extremity Cramps	1	28OCT2020	1/1	1	No	O	NA/TC/TCN	R (28OCT2020)	N/N
>55/ C4591001 1111 11111008	NERV	Headache/ headache	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
	GASTR	Gastroesophageal reflux disease/ Exacerbation of acid reflux	2	12SEP2020	24/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1111 11111010	INFEC	Urosepsis/ Urosepsis#	3	11JAN2021	7/5	3	No	O	NA/TC	R (15JAN2021)	Y/N
>55/ C4591001	RENAL	Chronic kidney disease/ Acute kidney injury on chronic kidney disease stage III#	3	11JAN2021	7/5	2	No	O	NA/TCN	R (15JAN2021)	N/N
	RESP	Acute respiratory failure/ Acute hypoxic respiratory failure#	3	11JAN2021	7/5	3	No	O	NA/TCN	R (15JAN2021)	Y/N
>55/ C4591001	NEOPL	Non-small cell lung cancer stage III/ Nonsmall cell lung carcinoma stage 3#	4	25FEB2021	31/C	3	No	O	NA/TC	N	Y/N
	INFEC	Clostridium difficile infection/ clostridium difficile infection#	4	13MAR2021	47/C	2	No	O	NA/TC	N	Y/N
>55/ C4591001	INV	Blood glucose increased/ Increase glucose level	2	22AUG2020	2/27	1	No	O	NA	R (17SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1111 11111011	CARD	Palpitations/ Heart palpitations	2	26AUG2020	6/15	1	No	O	NA	R (09SEP2020)	N/N
	BLOOD	Lymphadenopathy/ Swollen lymph node (neck)	2	02DEC2020	104/8	2	No	O	NA/TC	R (09DEC2020)	N/N
	INFEC	Tooth infection/ Infected tooth bridge	2	02DEC2020	104/8	2	No	O	NA/TC	R (09DEC2020)	N/N
	BLOOD	Lymphadenopathy/ Swollen lymph node (neck)#	2	05FEB2021	169/8	2	No	O	NA/TC	R (12FEB2021)	N/N
	INFEC	Tooth infection/ Infected tooth bridge#	2	05FEB2021	169/8	2	No	O	NA/TC	R (12FEB2021)	N/N
>55/ C4591001 1111 11111013	GENRL	Chills/ Chills#	4	27JAN2021	2/2	2	Yes		NA	R (28JAN2021)	N/N
		Injection site pain/ Left sore arm pain @ injection site#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
		Pain/ Body aches#	4	27JAN2021	2/2	2	Yes		NA	R (28JAN2021)	N/N
		Pyrexia/ Fever#	4	27JAN2021	2/2	2	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1111 11111014	INJ&P	Road traffic accident/ Motor vehicle accident	2	11NOV2020	78/1	1	No	O	NA/TCN	R (11NOV2020)	N/N
	MUSC	Arthralgia/ Left shoulder pain	2	11NOV2020	78/47	1	No	O	NA/TCN	R (27DEC2020)	N/N
>55/ C4591001	CARD	Atrial fibrillation/ Atrial Fibrillation#	3	07JAN2021	3/2	1	No	O	NA	R (08JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1111 11111016	RESP	Pulmonary embolism/ Pulmonary emboli#	3	07JAN2021	3/2	3	No	O	NA/TC	R (08JAN2021)	Y/N
	VASC	Thrombosis/ Occlusive thrombus in the right calf#	3	07JAN2021	3/2	3	No	O	NA/TC	R (08JAN2021)	Y/N
>55/ C4591001 1111 11111020	EAR	Vertigo/ Vertigo	2	03SEP2020	9/5	1	No	O	NA	R (07SEP2020)	N/N
	GENRL	Chills/ Chills#	4	27JAN2021	2/3	1	Yes		NA/TCN	R (29JAN2021)	N/N
		Pain/ Body aches#	4	27JAN2021	2/3	2	Yes		NA/TCN	R (29JAN2021)	N/N
	NERV	Headache/ Headache#	4	27JAN2021	2/3	3	Yes		NA/TCN	R (29JAN2021)	N/N
>55/ C4591001 1111 11111033	GASTR	Nausea/ Nausea	2	30SEP2020	35/3	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	35/3	1	Yes		NA	R (02OCT2020)	N/N
		Injection site pain/ Left arm soreness at injection site	2	30SEP2020	35/3	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1111 11111034	GENRL	Pain/ Body aches	2	27AUG2020	2/1	1	Yes		NA	R (27AUG2020)	N/N
	INJ&P	Stress fracture/ Stress fracture (right foot)	2	26OCT2020	62/71	2	No	O	NA	R (04JAN2021)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1111 11111038	NEOPL	Malignant melanoma/ Melanoma (right temple)#	2	11FEB2021	170/13	1	No	O	NA/TC/TCN	R (23FEB2021)	N/N
>55/ C4591001 1111 11111041	MUSC	Arthritis/ Arthritis (right thumb)#	3	26FEB2021	8/1	1	No	O	NA	R (26FEB2021)	N/N
	SURG	Finger repair operation/ Repair (right thumb)#	3	26FEB2021	8/1	1	No	O	NA	R (26FEB2021)	N/N
>55/ C4591001 1111 11111044	MUSC	Pain in extremity/ Left sore arm	2	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
>55/ C4591001 1111 11111047	MUSC	Pain in extremity/ Sore arm pain (left)#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
>55/ C4591001 1111 11111055	MUSC	Neck pain/ neck pain	1	19AUG2020	14/27	2	No	O	NA	R (14SEP2020)	N/N
	INV	Blood potassium decreased/ Low potassium	2	OCT2020	36/C	1	No	O	NA	N	N/N
>55/ C4591001 1111 11111058	GASTR	Vomiting/ Vomiting#	4	27JAN2021	2/3	2	Yes		NA/TCN	R (29JAN2021)	N/N
	GENRL	Chills/ Chills#	4	27JAN2021	2/3	2	Yes		NA/TCN	R (29JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Pyrexia/ Fever#	4	27JAN2021	2/3	2	Yes		NA/TCN	R (29JAN2021)	N/N
	NERV	Headache/ Headache#	4	27JAN2021	2/3	2	Yes		NA/TCN	R (29JAN2021)	N/N
	SKIN	Hyperhidrosis/ Sweats#	4	27JAN2021	2/3	2	Yes		NA/TCN	R (29JAN2021)	N/N
>55/ C4591001 1111 11111084	SKIN	Rash/ Rash (legs, arms, and stomach)	1	16AUG2020	7/46	2	No	O	NA/TC	R (30SEP2020)	N/N
	INFEC	Sinusitis/ SINUS INFECTION	1	20AUG2020	11/4	1	No	O	NA/TC	R (23AUG2020)	N/N
	RESP	Cough/ COUGH	1	20AUG2020	11/4	1	No	O	NA/TC	R (23AUG2020)	N/N
>55/ C4591001 1111 11111085	IMMUN	Seasonal allergy/ Seasonal Rhinitis#	4	25FEB2021	21/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1111 11111091	INJ&P	Joint injury/ LATERAL LEFT KNEE INJURY	1	30AUG2020	20/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1111 11111092	GASTR	Tongue oedema/ Intermittent Angioedema (tongue)	2	01SEP2020	1/115	1	No	CD	NA	R (24DEC2020)	N/N
	SKIN	Angioedema/ Intermittent Angioedema (lips)	2	01SEP2020	1/115	1	No	CD	NA	R (24DEC2020)	N/N
	SKIN	Angioedema/ Angioedema (right side of face)#	2	29JAN2021	151/3	1	No	O	NA	R (31JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	SKIN	Angioedema/ Angioedema (left hand center palm to heel of hand)#	2	06FEB2021	159/2	1	No	O	NA	R (07FEB2021)	N/N
		Angioedema/ Angioedema (left sole of foot)#	2	06FEB2021	159/2	1	No	O	NA	R (07FEB2021)	N/N
	SKIN	Angioedema/ Angioedema (isolated around lips)#	2	20FEB2021	173/2	1	No	O	NA	R (21FEB2021)	N/N
	SKIN	Angioedema/ Angioedema (left side of jaw bone area)#	2	23FEB2021	176/3	1	No	O	NA	R (25FEB2021)	N/N
>55/ C4591001 1111 11111095	PSYCH	Mental disorder/ Undiagnosed Mental Disorder (not otherwise specified)	2	25SEP2020	25/C	2	No	O	NA	N	Y/N
>55/ C4591001 1111 11111103	GENRL	Oedema peripheral/ Lower extremity edema	2	OCT2020	32/	1	No	O	NA	R (27FEB2021)	N/N
	SKIN	Purpura/ Purpuric rash on lower extremity	2	OCT2020	32/	1	No	O	NA	R (27FEB2021)	N/N
	BLOOD	Anaemia/ Anemia	2	12OCT2020	43/C	1	No	O	NA/TC	N	N/N
	INV	Liver function test increased/ Elevated liver function tests	2	NOV2020	63/	2	No	O	NA	R (27FEB2021)	N/N
	RESP	Dyspnoea exertional/ Dyspnea on exertion#	2	FEB2021	155/	3	No	O	NA/TC	R (27FEB2021)	Y/N
	BLOOD	Splenic infarction/ Splenic infarcts#	2	16FEB2021	170/C	3	No	O	NA	N	N/N
	INFEC	Bacteraemia/ Bacteremia#	2	16FEB2021	170/12	3	No	O	NA/TC	R (27FEB2021)	Y/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1111 11111108	PSYCH	Endocarditis/ Endocarditis#	2	16FEB2021	170/12	2	No	O	NA/TC	R (27FEB2021)	Y/N
		Depression/ Exacerbation of depression	1	28AUG2020	15/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1111 11111109	INFEC	Pyelonephritis/ Pyelonephritis	2	28SEP2020	25/5	2	No	O	NA/TC	R (02OCT2020)	Y/N
>55/ C4591001 1111 11111110	MUSC	Pain in extremity/ Aches in the legs	1	14AUG2020	1/2	1	Yes		NA	R (15AUG2020)	N/N
>55/ C4591001 1111 11111125	NERV	Headache/ Worsening headache	1	14AUG2020	1/2	1	Yes		NA	R (15AUG2020)	N/N
	NERV	Headache/ Worsening headache	1	20AUG2020	7/2	1	Yes		NA	R (21AUG2020)	N/N
	NERV	Headache/ Worsening headache	2	05SEP2020	2/1	1	Yes		NA/TC	R (05SEP2020)	N/N
>55/ C4591001 1111 11111125	GENRL	Chills/ Chills	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1111 11111128	GENRL	Pain/ Body ache	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Fatigue/ Fatigue#	3	19FEB2021	1/6	1	Yes		NA/TCN	R (24FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Injection site pain/ Sore arm (Injection site pain)#	3	19FEB2021	1/6	1	Yes		NA/TCN	R (24FEB2021)	N/N
		Pyrexia/ Fever#	3	19FEB2021	1/3	2	Yes		NA/TCN	R (21FEB2021)	N/N
>55/ C4591001 1111 11111137	MUSC	Pain in extremity/ Right Sore Arm#	3	22JAN2021	1/1	2	Yes		NA/TC	R (22JAN2021)	N/N
>55/ C4591001 1111 11111140	INFEC	Urinary tract infection/ Urinary tract infection	2	07OCT2020	29/6	2	No	O	NA/TC	R (12OCT2020)	N/N
>55/ C4591001 1111 11111141	NEOPL	Basal cell carcinoma/ Basal cell skin cancer (right side of nose)#	2	MAR2021	169/C	2	No	O	NA/TCN	RG	N/N
>55/ C4591001 1111 11111147	GENRL	Chest pain/ Chest pain#	4	01FEB2021	22/1	1	No	O	NA/TC	R (01FEB2021)	N/N
>55/ C4591001 1111 11111154	GENRL	Injection site pain/ Left sore arm pain at injection site#	3	06FEB2021	2/3	2	Yes		NA	R (08FEB2021)	N/N
>55/ C4591001 1111 11111157	GENRL	Fatigue/ Fatigue#	4	27JAN2021	2/6	1	Yes		NA/TCN	R (01FEB2021)	N/N
		Injection site pain/ Sore arm pain at injection site#	4	27JAN2021	2/6	1	Yes		NA/TCN	R (01FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1111 11111175	GENRL	Injection site swelling/ Swelling at injection site#	4	27JAN2021	2/6	1	Yes		NA/TCN	R (01FEB2021)	N/N	
		Injection site pain/ Right sore arm at injection site#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N	
>55/ C4591001 1111 11111193	GASTR	Pancreatitis acute/ Acute Pancreatitis	1	19OCT2020	5/3	3	No	O	NA/TC	R (21OCT2020)	Y/N	
>55/ C4591001 1111 11111201	GENRL	Fatigue/ Fatigue#	4	02FEB2021	2/3	1	Yes		NA	R (04FEB2021)	N/N	
>55/ C4591001 1112 11121003	GENRL	Injection site pruritus/ Itching at injection site#	4	02FEB2021	2/4	1	Yes		NA/TCN	R (05FEB2021)	N/N	
		Injection site swelling/ Swelling at injection site#	4	02FEB2021	2/4	1	Yes		NA/TCN	R (05FEB2021)	N/N	
		Fatigue/ Fatigue#	3	12FEB2021	2/1	2	Yes		NA	R (12FEB2021)	N/N	
		Injection site pain/ Injection site pain#	3	12FEB2021	2/5	2	Yes		NA	R (16FEB2021)	N/N	
>55/ C4591001 1112 11121007	GENRL	Pyrexia/ Fever#	3	12FEB2021	2/1	2	Yes		NA/TC	R (12FEB2021)	N/N	
		Pyrexia/ Fever#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1112 11121029	SKIN	Rash/ Rash, scalp	2	09SEP2020	19/12	2	No	O	NA/TC	R (20SEP2020)	N/N	
>55/ C4591001 1112 11121034	IMMUN	Food allergy/ Allergic reaction to chocolate	1	12AUG2020	10/6	1	No	O	NA/TC	R (17AUG2020)	N/N	
>55/ C4591001 1112 11121043	INFEC	Tooth abscess/ Abscess tooth	2	17SEP2020	27/26	2	No	O	NA/TC	R (12OCT2020)	N/N	
>55/ C4591001 1112 11121079	MUSC	Arthralgia/ Joint pain, knees & ankles#	3	09JAN2021	3/8	2	Yes		NA/TC	R (16JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	29JAN2021	2/4	2	Yes		NA	R (01FEB2021)	N/N	
	MUSC	Arthralgia/ Joint pain (knees and ankles#)	4	29JAN2021	2/4	2	Yes		NA/TC	R (01FEB2021)	N/N	
>55/ C4591001 1112 11121086	VASC	Hypertension/ Hypertension	2	04DEC2020	96/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1112 11121089	GENRL	Injection site pain/ Injection site pain#	3	16DEC2020	1/3	2	Yes		NA/TC	R (18DEC2020)	N/N	
>55/ C4591001	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	2/2	2	Yes		NA/TC	R (18FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1112 11121116	MUSC	Arthralgia/ Joint pain, (hands/knees)#	4	17FEB2021	2/2	2	Yes		NA/TC	R (18FEB2021)	N/N
>55/ C4591001 1112 11121118	CARD	Tachycardia/ Tachycardia	1	12AUG2020	2/1	3	Yes		P/TC	R (12AUG2020)	N/N
	SKIN	Pruritus/ Generalized Pruritus	1	12AUG2020	2/1	3	Yes		NA/TC	R (12AUG2020)	N/N
>55/ C4591001 1112 11121131	MUSC	Myalgia/ Muscle aches, back and left arm	2	22SEP2020	13/4	1	No	O	NA	R (25SEP2020)	N/N
	MUSC	Intervertebral disc protrusion/ Herniated disc	2	26SEP2020	17/28	3	No	O	NA/TC/TCN	R (23OCT2020)	N/N
	VASC	Hypertension/ Worsening of Hypertension	2	05OCT2020	26/20	2	No	O	NA/TC	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/3	1	Yes		NA/TC	RS (19DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
>55/ C4591001 1112 11121133	GENRL	Injection site pain/ Injection site pain#	3	18DEC2020	1/3	2	Yes		NA/TC	R (20DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	09JAN2021	2/3	2	Yes		NA	R (11JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	09JAN2021	2/5	2	Yes		NA/TC	R (13JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Myalgia/ Muscle aches#	4	09JAN2021	2/3	2	Yes		NA/TC	R (11JAN2021)	N/N	
>55/ C4591001 1112 11121142	GENRL	Injection site pain/ Injection site pain#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/Y	
>55/ C4591001 1112 11121153	INFEC	Acute sinusitis/ Acute sinusitis	1	06SEP2020	18/4	2	No	O	NA/TC	R (09SEP2020)	N/N	
>55/ C4591001 1112 11121164	VASC	Hypertension/ Hypertension	2	04DEC2020	82/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1112 11121181	INFEC	Otitis externa/ Otitis externa, bilateral	1	31AUG2020	5/5	2	No	O	NA/TC	R (04SEP2020)	N/N	
>55/ C4591001 1112 11121195	GENRL	Injection site pain/ Injection site pain	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N	
>55/ C4591001 1112 11121202	GENRL	Fatigue/ Fatigue	1	03SEP2020	3/1	1	Yes		NA	R (03SEP2020)	N/N	
	MUSC	Myalgia/ Muscle aches	1	03SEP2020	3/1	1	Yes		NA/TC	R (03SEP2020)	N/N	
	INFEC	Sinusitis/ Rhinosinusitis	1	07SEP2020	7/6	1	No	O	NA/TC	R (12SEP2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1112 11121205	MUSC	Bursitis/ Trachanteric Bursitis	2	30SEP2020	9/17	2	No	O	NA/TC	R (16OCT2020)	N/N	
	METAB	Glucose tolerance impaired/ Pre-diabetes#	3	22DEC2020	6/C	2	No	O	NA/TC	N	N/N	
	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	2/1	1	Yes		NA/TC	R (02SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N	
	MUSC	Arthralgia/ Joint Pain, fingers	2	23SEP2020	2/1	2	Yes		NA/TC	R (23SEP2020)	N/N	
		Myalgia/ Muscle aches	2	23SEP2020	2/1	2	Yes		NA/TC	R (23SEP2020)	N/N	
	VASC	Hypertension/ Hypertension	2	NOV2020	41/C	2	No	O	NA/TC	N	N/N	
	>55/ C4591001 1112 11121209	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
	>55/ C4591001 1112 11121210	INJ&P	Eye injury/ Ocular Laceration, left eye#	2	13JAN2021	111/9	2	No	O	NA/TC	RS (21JAN2021)	N/N
	>55/ C4591001 1112 11121220	GASTR	Diarrhoea/ Diarrhea	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	25SEP2020	2/4	1	Yes		NA	R (28SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1112 11121223	MUSC	Arthralgia/ Joint pain, back, hips, knees, shoulders	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Injection site erythema/ Redness at injection site	1	04SEP2020	2/5	1	Yes		NA	R (08SEP2020)	N/N
>55/ C4591001 1112 11121227	INFEC	Injection site pain/ Injection site pain	1	04SEP2020	2/5	1	Yes		NA	R (08SEP2020)	N/N
		Paronychia/ Infected ingrown toenail, right big toe	1	14SEP2020	11/7	3	No	O	NA/TC	R (20SEP2020)	N/N
>55/ C4591001 1112 11121230	GENRL	Injection site pain/ Injection site pain, post vaccination	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
>55/ C4591001 1112 11121235	NERV	Headache/ Headache, post vaccination	1	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1112 11121236	GENRL	Injection site pain/ Injection site pain, post vaccination	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
>55/ C4591001	NERV	Headache/ Headache	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
	MUSC	Back pain/ Muscle Pain, back	1	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1112 11121241 >55/ C4591001	INJ&P	Meniscus injury/ Meniscus tear, left	1	16SEP2020	6/3	3	No	O	NA/TCN	R (18SEP2020)	N/N
1112 11121247 >55/ C4591001	GENRL	Chills/ Chills	1	06OCT2020	1/2	2	Yes		P/TC	R (07OCT2020)	N/N
1112 11121255		Pyrexia/ Fever	1	06OCT2020	1/2	2	Yes		P/TC	R (07OCT2020)	N/N
	MUSC	Myalgia/ Muscle Aches	1	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N
	NERV	Headache/ Headaches	1	06OCT2020	1/2	3	Yes		P/TC	R (07OCT2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
1112 11121274 >55/ C4591001	GENRL	Injection site pain/ Pain at injection	1	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
1112 11121276 >55/ C4591001	MUSC	Myalgia/ Myalgia	2	30OCT2020	2/1	2	Yes		NA/TC	R (30OCT2020)	N/N
1112 11121278	NERV	Headache/ Headache	2	30OCT2020	2/1	2	Yes		NA/TC	R (30OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1112 11121295	GENRL	Injection site pain/ Pain at the injection site	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
>55/ C4591001 1112 11121306	MUSC	Myalgia/ Muscle Aches	2	04NOV2020	2/1	1	Yes		NA	R (04NOV2020)	N/N
	NERV	Headache/ Headache	2	04NOV2020	2/1	1	Yes		NA	R (04NOV2020)	N/N
>55/ C4591001 1112 11121309	GENRL	Injection site pain/ Pain at the injection site, post vaccination	1	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C4591001 1112 11121312	GENRL	Injection site pain/ Injection site pain, post vaccination	1	15OCT2020	2/3	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
>55/ C4591001 1112 11121325	GENRL	Injection site pain/ Injection site pain#	4	06JAN2021	1/3	2	Yes		NA	R (08JAN2021)	N/N
	MUSC	Osteoporosis/ Osteoporosis, left hip#	4	10JAN2021	5/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1112 11121330	INFEC	Tonsillitis/ Tonsillitis#	4	05FEB2021	12/11	2	No	O	NA/TC	R (15FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1112 11121337	GASTR	Diarrhoea/ Diarrhea	1	22OCT2020	2/4	3	Yes		NA/TC/W	R (25OCT2020)	N/N	
		Nausea/ Nausea	1	22OCT2020	2/4	2	Yes		NA/TC	RG (25OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	22OCT2020	2/7	2	Yes		P	R (28OCT2020)	N/N	
	MUSC	Myalgia/ Muscle Aches	1	22OCT2020	2/7	2	Yes		NA/TC	R (28OCT2020)	N/N	
	NERV	Headache/ Headache	1	22OCT2020	2/7	2	Yes		NA/TC	R (28OCT2020)	N/N	
	GASTR	Vomiting/ Vomiting	1	25OCT2020	5/1	2	Yes		NA	R (25OCT2020)	N/N	
>55/ C4591001 1112 11121347	GASTR	Diarrhoea/ Diarrhea	2	12NOV2020	1/1	1	Yes		NA/TC	R (12NOV2020)	N/N	
	NERV	Headache/ Headache	2	12NOV2020	1/1	1	Yes		NA/TC	R (12NOV2020)	N/N	
>55/ C4591001 1112 11121348	MUSC	Myalgia/ Muscle Aches	2	14NOV2020	3/2	2	Yes		NA/TC	R (15NOV2020)	N/N	
	MUSC	Myalgia/ Myalgia#	4	07JAN2021	2/2	1	Yes		NA/TC	R (08JAN2021)	N/N	
	NERV	Headache/ Headache#	4	07JAN2021	2/2	1	Yes		NA/TC	R (08JAN2021)	N/N	
>55/ C4591001	CARD	Ventricular tachycardia/ Ventricular Tachycardia	2	11DEC2020	102/5	4	No	O	NA/TC/TCN	RS (15DEC2020)	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1114 11141006	METAB	Hypokalaemia/ Hypokalemia	2	12DEC2020	103/9	1	No	O	NA/TC/TCN	RS (20DEC2020)	N/N	
	BLOOD	Coagulopathy/ Blood coagulation disorder	2	07JAN2021	129/C	2	No	O	NA/TC/TCN	N	N/N	
	RESP	Pulmonary embolism/ pulmonary embolism	2	07JAN2021	129/4	2	No	O	NA/TC	R (10JAN2021)	N/N	
>55/ C4591001 1114 11141017	MUSC	Arthralgia/ Left Shoulder Pain#	3	08FEB2021	19/C	1	No	O	NA/TC	RG	N/N	
	GENRL	Chills/ CHILLS#	4	09MAR2021	2/2	1	Yes		NA	R (10MAR2021)	N/N	
>55/ C4591001 1114 11141019	GENRL	Injection site pain/ Injection Site Pain#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N	
	GENRL	Injection site pain/ Injection Site Pain#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N	
>55/ C4591001 1114 11141035	GENRL	Pain/ Generalized Achiness#	4	19FEB2021	1/4	1	Yes		NA	R (22FEB2021)	N/N	
>55/ C4591001 1114 11141036	INFEC	Herpes zoster/ Shingles Bilateral Back	2	25SEP2020	18/92	2	No	O	NA/TC	R (25DEC2020)	N/N	
>55/ C4591001	GENRL	Sudden cardiac death/ Sudden cardiac death	2	19OCT2020	42/1	4	No	O	NA/W	F (19OCT2020)	Y/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1114 11141050 >55/ C4591001	MUSC	Osteopenia/ Osteopenia	2	15DEC2020	98/C	1	No	CD	NA/TC	N	N/N
1114 11141055 >55/ C4591001	INFEC	Staphylococcal infection/ MRSA infection Right Stump	1	12SEP2020	20/27	2	No	O	NA/TC	R (08OCT2020)	Y/N
1114 11141080	INJ&P	Skin injury/ skin avulsion, left finger	1	12SEP2020	20/1	2	No	O	NA	R (12SEP2020)	N/N
	MUSC	Pain in extremity/ bilateral hand pain	1	12SEP2020	20/2	1	No	O	NA	R (13SEP2020)	N/N
	RENAL	Acute kidney injury/ acute kidney injury	1	12SEP2020	20/52	2	No	O	NA/TC	R (02NOV2020)	N/N
	CARD	Atrial fibrillation/ Atrial fibrillation	1	14SEP2020	22/C	2	No	O	NA	N	N/N
		Left ventricular hypertrophy/ Left Ventricular Hypertrophy	1	14SEP2020	22/C	1	No	O	NA	N	N/N
		Mitral valve incompetence/ mitral valve regurgitation	1	14SEP2020	22/C	1	No	O	NA	N	N/N
		Tricuspid valve incompetence/ Tricuspid regurgitation	1	14SEP2020	22/C	1	No	O	NA	N	N/N
	GENRL	Chest pain/ chest pain	1	14SEP2020	22/1	2	No	O	NA	R (14SEP2020)	N/N
	RESP	Pulmonary hypertension/ Pulmonary Hypertension	1	14SEP2020	22/C	1	No	O	NA	N	N/N
>55/ C4591001	GASTR	Constipation/ Constipation	2	27SEP2020	12/5	1	No	O	NA/TC/TCN	R (01OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1114 11141101	INFEC	Urinary tract infection/ urinary tract infection	2	13OCT2020	28/2	1	No	O	NA/TC/TCN	R (14OCT2020)	N/N
	GASTR	Nausea/ nausea#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ chills#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
		Pain/ Generalized achiness#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
>55/ C4591001 1114 11141102	GENRL	Peripheral swelling/ swollen toes Left foot	1	09SEP2020	15/103	1	No	O	NA/TC	R (20DEC2020)	N/N
>55/ C4591001 1114 11141110	GENRL	Chills/ CHILLS#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
		Pain/ ACHINESS#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
		Pyrexia/ FEVER#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
>55/ C4591001 1116 11161005	SKIN	Alopecia areata/ Intermittent Alopecia areata	2	01OCT2020	15/C	1	No	O	NA	N	N/N
>55/ C4591001 1116 11161016	GENRL	Injection site pain/ injection site soreness#	4	09FEB2021	2/3	1	Yes		NA	R (11FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1116 11161017	MUSC	Myalgia/ generalized muscle pain#	4	09FEB2021	2/3	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ headache#	4	09FEB2021	2/3	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Injection site pain/ injection site soreness#	4	09FEB2021	2/3	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Pain/ generalized body aches#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1116 11161030	NERV	Balance disorder/ loss of balance#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	INJ&P	Chest injury/ Traumatic Rib Injury	2	29OCT2020	43/20	1	No	O	NA	R (17NOV2020)	N/N
>55/ C4591001 1116 11161031	GASTR	Fall/ Fall	2	29OCT2020	43/1	1	No	O	NA	R (29OCT2020)	N/N
		Large intestine polyp/ Colon Polyp	2	02OCT2020	16/1	1	No	O	NA/TC/TCN	R (02OCT2020)	N/N
>55/ C4591001 1116 11161045	GASTR	Haemorrhoids/ External Hemorrhoids	2	OCT2020	14/	1	No	O	NA	R (27OCT2020)	N/N
	BLOOD	Anaemia/ Anemia	2	27OCT2020	40/C	3	No	O	NA/TC/TCN	RG	N/N
		Thrombocytopenia/ Thrombocytopenia	2	27OCT2020	40/16	1	No	O	NA	R (11NOV2020)	Y/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	VASC	Hypertension/ Hypertension	2	27OCT2020	40/C	1	No	O	NA/TC	N	N/N	
	CARD	Sinus bradycardia/ Sinus Bradycardia	2	28OCT2020	41/3	2	No	O	NA	R (30OCT2020)	N/N	
	GASTR	Hiatus hernia/ Hiatal Hernia#	2	09NOV2020	53/C	1	No	O	NA	N	N/N	
		Large intestine polyp/ Multiple Colon Polyps#	2	09NOV2020	53/1	1	No	O	NA	R (09NOV2020)	N/N	
	INFEC	Oesophageal candidiasis/ Candida Esophagitis#	2	10NOV2020	54/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1116 11161060	CARD	Coronary artery disease/ Coronary Artery Disease	2	05NOV2020	46/C	1	No	O	NA	N	N/N	
	CARD	Tachycardia/ Tachycardia per ECG	2	04JAN2021	106/1	1	No	O	NA/TC	R (04JAN2021)	N/N	
	INFEC	Urinary tract infection/ Urinary Tract Infection	2	04JAN2021	106/11	1	No	O	NA/TC	R (14JAN2021)	N/N	
>55/ C4591001 1116 11161061	GENRL	Pyrexia/ Fever#	4	10FEB2021	1/4	1	Yes		NA	R (13FEB2021)	N/N	
	NERV	Headache/ Headache#	4	10FEB2021	1/11	1	Yes		NA	R (20FEB2021)	N/N	
>55/ C4591001 1116 11161062	GENRL	Fatigue/ fatigue#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N	
	NERV	Headache/ Intermittent Headache#	3	13JAN2021	1/8	1	Yes		NA	R (20JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	4	05FEB2021	1/4	1	Yes		NA	R (08FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	06FEB2021	2/4	1	Yes		NA	R (09FEB2021)	N/N
		Injection site pain/ Injection site tenderness#	4	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N
	GENRL	Injection site erythema/ Erythema at injection site#	4	10FEB2021	6/3	1	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1116 11161067	GENRL	Injection site pain/ left arm, deltoid muscle, injection site pain#	4	04FEB2021	1/4	1	Yes		NA/TC/TCN	R (07FEB2021)	N/N
	GENRL	Chills/ chills#	4	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
		Pyrexia/ fever#	4	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
	NERV	Headache/ headache#	4	05FEB2021	2/3	1	Yes		NA	R (07FEB2021)	N/N
>55/ C4591001 1116 11161073	GENRL	Injection site pain/ Tenderness at injection site#	3	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1116 11161075	EAR	Tinnitus/ tinnitus	2	04OCT2020	13/C	1	No	O	NA	N	N/N
	INJ&P	Meniscus injury/ torn meniscus	2	13OCT2020	22/1	1	No	O	NA/TC	R (13OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1116 11161090	GENRL	Injection site pain/ injection site tenderness left arm#	2	22JAN2021	124/2	1	Yes		NA	R (23JAN2021)	N/N
>55/ C4591001 1116 11161096	GENRL	Injection site pain/ tenderness at injection site#	3	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/Y
>55/ C4591001 1116 11161109	GENRL	Injection site pain/ left arm tenderness at injection site left#	3	28JAN2021	1/7	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	18FEB2021	2/16	1	Yes		NA	R (05MAR2021)	N/N
		Pain/ generalized body aches#	4	18FEB2021	2/16	1	Yes		NA	R (05MAR2021)	N/N
	RESP	Upper respiratory tract congestion/ head congestion#	4	18FEB2021	2/16	1	Yes		NA	R (05MAR2021)	N/N
>55/ C4591001 1116 11161114	GASTR	Vomiting/ Vomiting	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1116 11161122	GENRL	Injection site pain/ Site tenderness at the injection site#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1116 11161123	GENRL	Pyrexia/ Fever 101.0 F#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
	MUSC	Myalgia/ generalized muscle aches#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Injection site pain/ Injection site tenderness left arm#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
>55/ C4591001 1116 11161131	BLOOD	Lymphadenopathy/ Left Axillary swollen lymph node	1	10SEP2020	7/5	2	Yes		NA	R (14SEP2020)	N/N
>55/ C4591001 1116 11161142	GENRL	Injection site pain/ Muscle Pain @ injection site	1	10SEP2020	7/5	2	Yes		NA	R (14SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	1	10SEP2020	7/5	2	Yes		NA	R (14SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain @ Chest Wall to Upper Back	1	10SEP2020	7/5	2	Yes		NA	R (14SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
MUSC	Arthralgia/ Generalized Joint Pain	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N	
MUSC	Myalgia/ Muscle Pain	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N	
NERV	Headache/ Headache	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N	
MUSC	Headache/ Headache	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N	
MUSC	Headache/ Headache	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N	
MUSC	Headache/ Headache	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1116 11161152	GENRL	Chills/ chills#	4	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
		Fatigue/ fatigue#	4	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
>55/ C4591001 1116 11161161	GASTR	Vomiting/ Vomiting	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Fatigue/ Fatigue/ Tiredness	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
>55/ C4591001 1116 11161163	INFEC	Furuncle/ Boil Left Hip Anteeior	2	16OCT2020	18/8	1	No	O	NA	R (23OCT2020)	N/N
>55/ C4591001 1116 11161170	GENRL	Injection site pain/ tenderness at the injection site Left arm#	3	27JAN2021	2/5	1	Yes		NA	R (31JAN2021)	N/N
>55/ C4591001 1116 11161181	GENRL	Injection site pain/ Tenderness at injection site#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
>55/ C4591001 1116 11161184	VASC	Hypertension/ Hypertension	2	27OCT2020	29/C	1	No	O	NA/TC/TCN	RG	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1116 11161198	INJ&P	Delayed recovery from anaesthesia/ slow to recover from anesthesia	2	02DEC2020	65/2	2	No	O	NA	R (03DEC2020)	Y/N	
	RESP	Pulmonary embolism/ PULMONARY EMBOLISM/ BLOOD CLOTS IN UPPER RIGHT LOBE	2	22DEC2020	85/1	3	No	O	NA/TC	RG (22DEC2020)	Y/N	
>55/ C4591001 1116 11161233	NERV	Carpal tunnel syndrome/ Carpal Tunnel Syndromw	2	19JAN2021	104/C	1	No	O	NA/TCN	N	N/N	
>55/ C4591001 1116 11161264	GENRL	Injection site pain/ tenderness at injection site- left deltoid#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N	
	GENRL	Pain/ generalized body aches#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N	
>55/ C4591001 1116 11161265	GENRL	Chills/ Chills#	3	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N	
		Pain/ generalized body aches#	3	24FEB2021	2/6	1	Yes		NA	R (01MAR2021)	N/N	
>55/ C4591001 1116 11161272	RESP	Asthma/ Worsening Asthma	2	12OCT2020	1/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1116 11161297	INFEC	Bronchitis/ Intermittent bronchitis	2	26OCT2020	11/5	1	No	O	NA/TC	R (30OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1116 11161311	GASTR	Rectal haemorrhage/ Rectal bleeding#	2	08FEB2021	110/1	2	No	O	NA	R (08FEB2021)	N/N
>55/ C4591001 1116 11161319	GASTR	Diarrhoea/ Diarrhea	1	26SEP2020	2/2	1	No	O	NA/TC	R (27SEP2020)	N/N
>55/ C4591001 1116 11161325	GENRL	Injection site pain/ Pain @ Injection Site(Left Deltoid)	2	28OCT2020	1/3	1	Yes		NA	R (30OCT2020)	N/Y
>55/ C4591001 1117 11171001	NEOPL	Lipoma/ FATTY TUMOR, FOOT, LEFT, WORSENING	2	28SEP2020	20/1	1	No	O	NA/TC/TCN	R (28SEP2020)	N/N
	INFEC	Sinusitis/ SINUSITIS	2	01OCT2020	23/14	1	No	O	NA/TC	R (14OCT2020)	N/N
	GASTR	Constipation/ CONSTIPATION	2	04OCT2020	26/7	2	No	O	NA/TC	R (10OCT2020)	N/N
		Gastrooesophageal reflux disease/ GERD EXACERBATION	2	04OCT2020	26/11	2	No	O	NA/TC	R (14OCT2020)	N/N
	VASC	Phlebolith/ PELVIC PHLEBOLITH	2	04OCT2020	26/32	1	No	O	NA	R (04NOV2020)	N/N
	GENRL	Injection site discomfort/ INJECTION SITE DISCOMFORT, RESIDUAL, LEFT ARM#	4	05FEB2021	1/C	1	Yes		NA/TC/TCN	RG	N/N
	SKIN	Alopecia/ HAIRLOSS, SCALP#	4	08FEB2021	4/C	1	No	O	NA	N	N/N



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>55/ C4591001 1117 11171003	MUSC	Back pain/ ACUTE EXACERBATION OF LOW BACK PAIN#	2	22FEB2021	168/C	3	No	O	NA/TC/TCN	RG	N/N	
>55/ C4591001 1117 11171006	INJ&P	Meniscus injury/ TORN MINISCUS, KNEE, RIGHT	2	01NOV2020	54/1	2	No	O	NA/TC/TCN	R (01NOV2020)	N/N	
>55/ C4591001 1117 11171007	HEPAT	Cholelithiasis/ GALL STONE	1	19AUG2020	3/83	2	No	O	NA/TCN	R (09NOV2020)	N/N	
	MUSC	Spondylitis/ ARTHRITIC CHANGES, LUMBAR SPINE	1	19AUG2020	3/C	1	No	O	NA	N	N/N	
	GASTR	Nausea/ NAUSEA	2	23SEP2020	16/2	1	No	CD	NA	R (24SEP2020)	N/N	
	GENRL	Chills/ CHILLS	2	23SEP2020	16/2	1	No	CD	NA	R (24SEP2020)	N/N	
	MUSC	Myalgia/ MYLAGIA	2	23SEP2020	16/2	1	No	CD	NA	R (24SEP2020)	N/N	
	SKIN	Dermal cyst/ RECURRENT SEBACEOUS CYST, UPPER BACK	2	01OCT2020	24/1	2	No	O	NA/TCN	R (01OCT2020)	N/N	
>55/ C4591001 1117 11171008	METAB	Hyperkalaemia/ Hyperkalemia	1	03SEP2020	18/C	1	No	O	NA	RG	N/N	
	MUSC	Tendonitis/ Right Hip Tendinitis	1	03SEP2020	18/8	2	No	O	NA/TC	R (10SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	PSYCH	Anxiety/ Worsening Anxiety	1	03SEP2020	18/36	1	No	O	NA/TC	R (08OCT2020)	N/N
	MUSC	Spinal osteoarthritis/ Osteoarthritis in Lower Back	1	04SEP2020	19/33	1	No	O	NA	R (06OCT2020)	N/N
>55/ C4591001 1117 11171012	INJ&P	Tooth fracture/ DENTAL FRACTURE, UPPER FRONT RIGHT#	3	23JAN2021	9/14	1	No	O	NA/TCN	R (05FEB2021)	N/N
>55/ C4591001 1117 11171013	INJ&P	Fall/ FALL	2	17SEP2020	9/1	1	No	O	NA/TCN	R (17SEP2020)	N/N
		Skin laceration/ LACERATION, FOREHEAD	2	17SEP2020	9/11	1	No	O	NA/TCN	R (27SEP2020)	N/N
>55/ C4591001 1117 11171018	VASC	Hypertension/ HYPERTENSION, WORSENING#	3	15JAN2021	3/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1117 11171020	GENRL	Swelling/ SWELLING, RIGHT SIDE OF HEAD#	4	08MAR2021	26/C	2	No	O	NA	RG	N/N
	INJ&P	Fall/ FALL#	4	08MAR2021	26/1	2	No	O	NA	R (08MAR2021)	N/N
		Ligament sprain/ SPRAIN, RIGHT ANKLE#	4	08MAR2021	26/C	2	No	O	NA/TCN	RG	N/N
>55/ C4591001 1117 11171024	GENRL	Temperature intolerance/ COLD INTOLERANCE	2	10SEP2020	2/C	1	No	O	NA	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	INFEC	Paronychia/ PARONYCHIA, HANDS, BILATERAL	2	10SEP2020	2/C	1	No	O	NA	N	N/N	
	MUSC	Muscle spasms/ CRAMP, LEG, UPPER, RIGHT	2	01OCT2020	23/6	1	No	O	NA	R (06OCT2020)	N/N	
	SKIN	Onychomadesis/ LOST FINGER NAILS, X4	2	07OCT2020	29/C	1	No	O	NA	N	N/N	
>55/ C4591001 1117 11171025	NERV	Aphasia/ APHASIA	2	30SEP2020	23/4	2	No	O	NA	R (03OCT2020)	N/N	
		Paraesthesia/ PARWSTHESIA, BACK AND ARMS, BILATERAL	2	30SEP2020	23/4	2	No	O	NA	R (03OCT2020)	N/N	
>55/ C4591001 1117 11171027	MUSC	Musculoskeletal stiffness/ NECK STIFFNESS	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N	
>55/ C4591001 1117 11171032	MUSC	Pain in extremity/ CALF PAIN, BILATERAL, WORSENING#	2	22FEB2021	167/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1117 11171040	VASC	Aortic arteriosclerosis/ CALCIFIED OBSTRUCTIVE PLAQUE, AORTIC ARCH#	3	26JAN2021	9/C	1	No	O	NA	N	N/N	
>55/ C4591001 1117 11171041	INJ&P	Tooth fracture/ DENTAL FRACTURE	2	07JAN2021	121/20	1	No	O	NA/TCN	R (26JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1117 11171042	Produ	Device connection issue/ LOOSE DENTAL FILLING	2	08OCT2020	25/1	1	No	O	NA/TCN	R (08OCT2020)	N/N	
	GENRL	Fatigue/ FATIGUE	2	12OCT2020	29/2	1	No	O	NA	R (13OCT2020)	N/N	
>55/ C4591001 1117 11171046	INJ&P	Muscle strain/ Muscle Strain, Lumbar	1	13SEP2020	21/2	1	No	O	NA	R (14SEP2020)	N/N	
>55/ C4591001 1117 11171047	CARD	Atrial fibrillation/ ATRIAL FIBRILLATION, EXACERBATION	2	15SEP2020	5/63	1	No	O	NA	R (16NOV2020)	N/N	
	RESP	Sleep apnoea syndrome/ SLEEP APNEA, OBSTRUCTIVE, MILD	2	22SEP2020	12/60	1	No	O	NA/TCN	R (20NOV2020)	N/N	
>55/ C4591001 1117 11171051	VASC	Hypertension/ HYPERTENSION, WORSENING#	2	18DEC2020	96/22	1	No	O	NA	R (08JAN2021)	N/N	
>55/ C4591001 1117 11171055	GASTR	Large intestine polyp/ COLON POLYP	2	DEC2020	77/	1	No	O	NA/TCN	R	N/N	
>55/ C4591001 1117 11171059	GASTR	Gastroesophageal reflux disease/ WORSENING GASTROESOPHAGIAL REFLUX	2	01OCT2020	14/10	1	No	O	NA/TC	R (10OCT2020)	N/N	
>55/ C4591001	INJ&P	Corneal abrasion/ CORNEA, SCRATCHED, RIGHT	1	11SEP2020	16/7	1	No	O	NA/TC	R (17SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1117 11171071	BLOOD	Lymph node pain/ SORE LYMPH NODES, NECK, RIGHT	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N	
>55/ C4591001 1117 11171079	CARD	Myocardial infarction/ MYOCARDIAL INFARCTION#	2	28JAN2021	136/2	3	No	O	NA/TC/TCN	R (29JAN2021)	Y/N	
>55/ C4591001 1117 11171081	NERV	Cervical radiculopathy/ C7 RADICULOPATHY#	2	11MAR2021	178/C	2	No	O	NA/TC/TCN	RG	N/N	
>55/ C4591001 1117 11171081	INV	Blood pressure increased/ ELEVATED BLOOD PRESSURE#	3	15JAN2021	1/22	1	Yes		NA	R (05FEB2021)	N/N	
>55/ C4591001 1117 11171086	CARD	Cardiac failure congestive/ CARDIAC FAILURE, CONGESTIVE#	2	14FEB2021	146/6	3	No	O	NA/TC	R (19FEB2021)	Y/N	
>55/ C4591001 1117 11171088	GENRL	Non-cardiac chest pain/ NON CARDIAC CHEST PAIN	2	14NOV2020	53/3	3	No	O	NA/TC/TCN	R (16NOV2020)	Y/N	
>55/ C4591001 1117 11171092	INJ&P	Tooth injury/ TOOTH, MECHANICAL TRAUMA, BACK MOLAR BILATERAL	2	22DEC2020	91/1	1	No	O	NA/TCN	R (22DEC2020)	N/N	
>55/ C4591001 1117 11171097	NERV	Periodic limb movement disorder/ INCREASED FREQUENCY PERIODIC LEG MOVEMENT	1	14SEP2020	11/18	1	No	O	NA/TC	R (01OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INJ&P	Ligament sprain/ SPRAIN, ANKLE, RIGHT	1	22SEP2020	19/16	1	No	O	NA/TC/TCN	R (07OCT2020)	N/N
	BLOOD	Iron deficiency anaemia/ IRON DEFICIENCY ANEMIA	2	07OCT2020	15/C	1	No	O	NA/TC/TCN	N	N/N
>55/ C4591001 1117 11171104	GASTR	Constipation/ CONSTIPATION, SEVERE#	3	18JAN2021	7/36	3	No	O	NA/TC	R (22FEB2021)	N/N
	RENAL	Urinary retention/ URINEARY RETENTION#	4	07FEB2021	6/16	1	No	O	NA/TC/TCN	R (22FEB2021)	N/N
>55/ C4591001 1117 11171110	VASC	Hypertension/ HYPERTENSION, WORSENING	1	12SEP2020	2/21	1	No	O	NA/TC	R (02OCT2020)	N/N
>55/ C4591001 1117 11171115	VASC	Hypertension/ HYPERTENSION, WORSENING	1	22SEP2020	9/10	1	No	O	NA/TC	R (01OCT2020)	N/N
	SKIN	Eczema/ ECZEMA, NECK, WORSENING	1	01OCT2020	18/8	1	No	O	NA/TC	R (08OCT2020)	N/N
>55/ C4591001 1117 11171122	NEOPL	Basal cell carcinoma/ BASAL CELL CARCINOMA, UPPER ARM, LEFT	2	20NOV2020	46/33	2	No	O	NA/TC/TCN	R (22DEC2020)	N/N
>55/ C4591001 1117 11171125	NERV	Headache/ HEADACHE	2	11NOV2020	29/2	1	No	O	NA/TC/TCN	R (12NOV2020)	N/N
>55/ C4591001	PSYCH	Anxiety/ WORSENING ANXIETY	1	22SEP2020	2/88	2	No	O	NA/TC	R (18DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1117 11171136 >55/ C4591001	INJ&P	Muscle strain/ THIGH MUSCLE, STRAIN, LEFT	1	11OCT2020	20/7	1	No	O	NA/TC	R (17OCT2020)	N/N
1117 11171141	INV	Thyroid function test abnormal/ ABNORMAL THYROID LABORATORY VALUES	2	NOV2020	20/C	1	No	O	NA	N	N/N
	GASTR	Small intestinal obstruction/ SMALL BOWEL OBSTRUCTION	2	27NOV2020	46/4	4	No	O	NA	R (30NOV2020)	Y/N
	HEPAT	Hepatic cyst/ HEPATIC CYST	2	27NOV2020	46/C	1	No	O	NA	N	N/N
		Hepatic steatosis/ HEPATIC STEATOSIS	2	27NOV2020	46/C	1	No	O	NA	N	N/N
	GASTR	Abdominal hernia/ INFRAUMBILICAL VENTRAL HERNIA	2	27DEC2020	76/C	1	No	O	NA	N	N/N
		Small intestinal obstruction/ SMALL BOWEL OBSTRUCTION	2	27DEC2020	76/4	3	No	O	NA/TC	R (30DEC2020)	Y/N
	SKIN	Actinic keratosis/ ACTINIC KERATOSIS, SCALP, WORSENING#	3	JAN2021	1/C	1	No	O	NA	N	N/N
	GENRL	Inflammation/ TOE INFLAMMATION, GREAT TOE, LEFT#	3	19JAN2021	6/8	2	No	O	NA/TC/TCN	R (26JAN2021)	N/N
	BLOOD	Lymphadenopathy/ SWOLLEN LYMPH NODES, RIGHT CERVICAL#	3	23JAN2021	10/5	1	No	O	NA/TCN	R (27JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1117 11171142	MUSC	Back pain/ LOW BACK PAIN	1	10OCT2020	19/5	1	No	O	NA	R (14OCT2020)	N/N	
>55/ C4591001 1117 11171146	GASTR	Hiatus hernia/ HIATAL HERNIA#	3	21JAN2021	3/C	1	No	O	NA	N	N/N	
	RESP	Pulmonary embolism/ PULMONARY EMBOLI#	3	21JAN2021	3/3	1	No	O	NA/TC	R (23JAN2021)	Y/N	
	VASC	Deep vein thrombosis/ DEEP VEIN THROMBOSIS, LOWER EXTREMITY, RIGHT#	3	21JAN2021	3/3	2	No	O	NA/TC	R (23JAN2021)	Y/N	
	EYE	Cataract/ CATARACTS, WORSENING CONDITION#	3	03FEB2021	16/C	1	No	O	NA	N	N/N	
>55/ C4591001 1117 11171151	MUSC	Neck pain/ WORSENING CERVICALGIA	1	30SEP2020	8/111	2	No	O	NA	R (18JAN2021)	N/N	
	PSYCH	Insomnia/ WORSENING INSOMNIA	1	30SEP2020	8/32	2	No	O	NA/TC	R (31OCT2020)	N/N	
	INFEC	Fungal skin infection/ FUNGUS, TOES, RIGHT (SKIN OF TOES)	2	OCT2020	1/C	1	No	O	NA/TC	RG	N/N	
		Onychomycosis/ FUNGUS, TOES, RIGHT (TOENAILS)	2	OCT2020	1/C	1	No	O	NA/TC	RG	N/N	
	INJ&P	Spinal fracture/ VERTEBRAL FRACTURE	2	06DEC2020	56/C	2	No	O	NA	RG	N/N	
>55/ C4591001	GENRL	Vessel puncture site haematoma/ HEMATOMA, PHLEBOTOMY SITE*		23SEP2020	1/16	1	No	O	NA	R (08OCT2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1117 11171152 >55/ C4591001 1117 11171155	SKIN	Dermatitis/ DERMATITIS, ARM, RIGHT, WORSENING	1	28SEP2020	6/59	1	No	O	NA/TC	R (25NOV2020)	N/N
>55/ C4591001 1117 11171160	MUSC	Osteoarthritis/ RIGHT KNEE OSTEOARTHRITIS, WORSENING	2	26OCT2020	13/2	2	No	O	NA/TCN	R (27OCT2020)	N/N
>55/ C4591001 1117 11171167	EAR	Vertigo/ VERTIGO	2	06NOV2020	24/4	3	No	O	NA/TC	R (09NOV2020)	Y/N
>55/ C4591001 1117 11171168	GASTR	Swollen tongue/ SWOLLEN TONGUE	2	04NOV2020	21/9	2	No	O	NA	R (12NOV2020)	N/N
>55/ C4591001 1117 11171182	MUSC	Arthralgia/ WORSENING KNEE PAIN, LEFT	1	06OCT2020	8/11	1	No	O	NA/TC	R (16OCT2020)	N/N
>55/ C4591001 1117 11171191	RENAL	Haematuria/ HEMATURIA	2	30NOV2020	34/3	2	No	O	NA/TC	R (02DEC2020)	N/N
>55/ C4591001	RENAL	Haematuria/ HEMATURIA	2	11DEC2020	45/2	2	No	O	NA/TC	R (12DEC2020)	N/N
>55/ C4591001	INFE	Fungal skin infection/ FUNGUS, TOE, RIGHT GREAT	1	26OCT2020	15/C	1	No	O	NA	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1117 11171193	SKIN	Urticaria papular/ PAPULAR UTICARIA, FOREARMS/THIGHS, BILATERAL	2	DEC2020	28/C	1	No	O	NA/TCN	RG	N/N	
>55/ C4591001 1118 11181005	INFEC	Tooth infection/ TOOTH INFECTION#	2	11FEB2021	165/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1118 11181006	GASTR	Diarrhoea/ loose bowels#	4	18FEB2021	7/1	1	No	O	NA	R (18FEB2021)	N/N	
>55/ C4591001 1118 11181013	VASC	Hypertension/ WORSENING OF HYPERTENSION	2	19JAN2021	141/C	3	No	O	NA/TC/TCN	RG	Y/N	
>55/ C4591001 1118 11181020	INFEC	Otitis externa/ Right ear otitis externa infection	2	24SEP2020	21/3	1	No	O	NA	R (26SEP2020)	N/N	
>55/ C4591001 1118 11181024	VASC	Pruritus/ GENERALIZED ITCHING	2	15JAN2021	134/C	1	No	O	NA	RG	N/N	
>55/ C4591001 1118 11181024	VASC	Hypertension/ WORSENING OF HYPERTENSION#	2	19FEB2021	169/C	1	No	CD	NA/TC	RG	N/N	
>55/ C4591001 1118 11181031	CARD	Angina pectoris/ cardiac chest pain	2	24NOV2020	82/3	2	No	O	NA/TC	R (26NOV2020)	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1118 11181038	MUSC	Tenosynovitis stenosaurs/ LEFT HALLUX STENOSING TENOSYNOVITIS	2	16NOV2020	74/75	1	No	O	NA/TC	R (29JAN2021)	N/N	
	MUSC	Intervertebral disc protrusion/ cervical herniated discs C5-C7#	2	29JAN2021	148/C	1	No	O	NA/TC	RG	N/N	
	RESP	Sleep apnoea syndrome/ sleep apnea#	2	01FEB2021	151/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1118 11181044	RESP	Pulmonary embolism/ bilateral pulmonary embolism	2	11NOV2020	65/C	3	No	O	NA/TC	RG	Y/N	
>55/ C4591001 1118 11181055	GASTR	Constipation/ constipation	2	01NOV2020	53/1	1	No	O	NA/TC	R (01NOV2020)	N/N	
>55/ C4591001 1118 11181057	INFEC	Diverticulitis/ Sigmoid diverticulitis	1	04SEP2020	18/15	3	No	O	NA/TC	R (18SEP2020)	Y/N	
>55/ C4591001 1118 11181058	HEPAT	Cholelithiasis/ cholelithiasis	1	02SEP2020	16/16	2	No	O	NA/TC	R (17SEP2020)	N/N	
>55/ C4591001 1118 11181067	INJ&P	Ligament sprain/ sprained left knee	2	09DEC2020	91/82	1	No	O	NA	R (28FEB2021)	N/N	
	RESP	Pharyngeal lesion/ oropharyngeal lesion	2	09DEC2020	91/82	2	No	O	NA	R (28FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1118 11181074	CARD	Bradycardia/ BRADYCARDIA	2	14SEP2020	4/51	2	No	O	NA/TC/TCN	RS (03NOV2020)	Y/N	
	METAB	Gout/ GOUT RIGHT FOOT	2	06OCT2020	26/C	1	No	CD	NA/TC	N	N/N	
>55/ C4591001 1118 11181077	INFEC	Urinary tract infection/ URINARY TRACT INFECTION#	3	25JAN2021	4/22	1	No	O	NA/TCN	R (15FEB2021)	N/N	
>55/ C4591001 1118 11181078	MUSC	Osteoarthritis/ WORSENING OF OSTEOARTHRITIS IN RIGHT KNEE	1	12SEP2020	24/34	1	No	O	NA	R (15OCT2020)	N/N	
	NERV	Tremor/ GENERALIZED TREMORS	2	01DEC2020	79/C	1	No	O	NA/TC/TCN	RG	N/N	
>55/ C4591001 1118 11181090	INFEC	Herpes zoster/ Shingles	1	30AUG2020	4/C	1	No	O	NA	N	N/N	
>55/ C4591001 1118 11181123	GASTR	Pancreatitis acute/ IDIOPATHIC ACUTE PANCREATITIS#	3	06FEB2021	18/7	3	No	O	NA	R (12FEB2021)	Y/N	
>55/ C4591001 1118 11181124	NEOPL	Squamous cell carcinoma/ squamous cell carcinoma of the upper left arm	1	2020	1/	2	No	O	NA	R (03NOV2020)	N/N	
	GENRL	Fatigue/ fatigue	1	24OCT2020	3/1	1	Yes		NA	R (24OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1120 11201002	NEOPL	Uterine leiomyoma/ fibroids	2	27DEC2020	131/31	2	No	O	NA/TC/TCN	R (26JAN2021)	Y/N	
>55/ C4591001 1120 11201008	INV	Blood glucose increased/ Elevated blood sugar	1	02AUG2020	4/35	1	Yes		NA	R (05SEP2020)	N/N	
	CARD	Atrial fibrillation/ atrial fibrillation	2	02SEP2020	15/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1120 11201010	GASTR	Abdominal pain upper/ RUQ Abdominal Pain#	4	03MAR2021	8/C	1	No	O	NA	N	N/N	
>55/ C4591001 1120 11201025	INJ&P	Tooth fracture/ Cracked Tooth	1	12AUG2020	10/30	2	No	CND	NA	R (10SEP2020)	N/N	
	RESP	Oropharyngeal pain/ Sore Throat	1	14AUG2020	12/8	2	No	CND	NA/TC	R (21AUG2020)	N/N	
>55/ C4591001 1120 11201036	INFEC	Herpes zoster/ Shingles herpes zoster	2	15DEC2020	112/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1120 11201050	CARD	Cardiac arrest/ Cardiac arrest	2	07NOV2020	73/1	4	No	O	NA/W	F (07NOV2020)	Y/N	
>55/ C4591001	INFEC	Ear infection/ right ear infection#	3	31DEC2020	14/13	1	No	CD	NA/TC	R (12JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1120 11201057 >55/ C4591001	NEOPL	Breast cancer/ breast cancer	2	05NOV2020	72/28	3	No	O	NA/TC	R (02DEC2020)	Y/N
1120 11201059 >55/ C4591001	INFEC	Otitis externa/ Otitis externa	1	20AUG2020	16/123	2	No	O	NA/TC/TCN	R (20DEC2020)	N/N
1120 11201060 >55/ C4591001	SKIN	Onycholysis/ Onycholysis#	2	15JAN2021	145/C	2	No	O	NA/TC	N	N/N
1120 11201070 >55/ C4591001	RESP	Cough/ cough	1	08AUG2020	4/7	2	No	O	NA/TC	R (14AUG2020)	N/N
1120 11201073 >55/ C4591001	INJ&P	Fall/ fall	2	18SEP2020	26/C	2	No	O	NA	N	N/N
1120 11201074		Skin abrasion/ GENERALIZED ABRASIONS	2	18SEP2020	26/C	2	No	O	NA/TC	N	N/N
	VASC	Haematoma/ HEMATOMA LEFT LATERAL THIGH	2	18SEP2020	26/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1120 11201090	PSYCH	Anxiety/ ANXIETY	2	29NOV2020	96/C	1	No	O	NA	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Dyspepsia/ DYSPEPSIA	2	18JAN2021	146/3	1	No	O	NA/TC	R (20JAN2021)	N/N
>55/ C4591001 1120 11201091	INJ&P	Contusion/ bruising bilateral arms	1	24AUG2020	19/C	1	No	O	NA/TC	RG	N/N
		Fall/ Fall	1	24AUG2020	19/1	1	No	O	NA/TC	R (24AUG2020)	N/N
>55/ C4591001 1120 11201114	INFEC	Mastitis/ mastitis#	3	30JAN2021	16/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1120 11201124	METAB	Hyperlipidaemia/ hyperlipidemia	2	08SEP2020	9/C	2	No	CD	NA/TC	N	N/N
>55/ C4591001 1120 11201127	GASTR	Diarrhoea/ Diarrhea	1	12AUG2020	2/3	3	Yes		P/TC/W	R (14AUG2020)	N/N
>55/ C4591001 1120 11201137	VASC	Hypertension/ worsening hypertension	1	02SEP2020	23/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1120 11201141	GASTR	Vomiting/ VOMITING	2	01OCT2020	30/1	1	No	O	NA	R (01OCT2020)	N/N
>55/ C4591001	RENAL	Nephrolithiasis/ nephrolithiasis	2	07SEP2020	6/12	2	No	O	NA	R (18SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1120 11201189	INV	Prostatic specific antigen increased/ elevated psa	2	16DEC2020	106/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1120 11201192	INJ&P	Facial bones fracture/ maxillary sinus fracture	2	27SEP2020	26/9	2	No	O	NA	R (05OCT2020)	N/N
		Fall/ mechanical fall	2	27SEP2020	26/1	2	No	O	NA/TCN	R (27SEP2020)	N/N
		Joint injury/ left wrist injury	2	27SEP2020	26/19	2	No	O	NA	R (15OCT2020)	N/N
		Joint injury/ right knee injury	2	27SEP2020	26/19	2	No	O	NA	R (15OCT2020)	N/N
		Skin abrasion/ abrasions	2	27SEP2020	26/19	1	No	O	NA	R (15OCT2020)	N/N
		Ulna fracture/ right ulna fracture	2	27SEP2020	26/19	2	No	O	NA/TC	R (15OCT2020)	N/N
	INFEC	Urinary tract infection/ urinary tract infection	2	17NOV2020	77/8	2	No	O	NA/TC	R (24NOV2020)	N/N
	MUSC	Arthralgia/ right knee pain#	4	22FEB2021	22/C	2	No	O	NA/TC	RG	N/N
	NERV	Cervical radiculopathy/ cervical radiculopathy#	4	01MAR2021	29/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1120 11201221	METAB	Hyperglycaemia/ hyperglycemia#	2	08FEB2021	154/C	2	No	O	NA/TC	UNK	N/N
	MUSC	Osteoarthritis/ worsening of osteoarthritis#	2	08FEB2021	154/C	2	No	O	NA/TC	N	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1120 11201226	SKIN	Diabetic foot/ diathetic ulcer on left small toe	2	20FEB2021	166/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1120 11201227	INJ&P	Arthropod sting/ Sting by a yellow jacket left ring finger	1	04SEP2020	18/8	2	No	O	NA/TC	R (11SEP2020)	N/N	
>55/ C4591001 1120 11201229	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	29DEC2020	111/7	2	No	O	NA/TC	R (04JAN2021)	N/N	
>55/ C4591001 1120 11201287	GENRL	Injection site pain/ Pain at injection site	2	12OCT2020	1/30	1	Yes		NA	R (10NOV2020)	N/Y	
>55/ C4591001 1120 11201316	EAR	Ear pain/ right ear pain	2	31DEC2020	60/10	1	No	O	NA/TC	R (09JAN2021)	N/N	
	MUSC	Temporomandibular joint syndrome/ temporomandibular joint syndrome#	2	11JAN2021	71/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1120 11201321	SKIN	Rash/ Rash right upper arm	2	25NOV2020	22/C	1	No	O	NA	N	N/N	
>55/ C4591001 1120 11201338	GENRL	Injection site bruising/ bruise at injection site	1	17OCT2020	2/25	1	Yes		NA	R (10NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1120 11201349	MUSC	Rotator cuff syndrome/ right torn rotator cuff	2	23FEB2021	107/C	2	No	O	NA	N	N/N	
>55/ C4591001 1120 11201350	SURG	Cardiac pacemaker replacement/ PACE MAKER BATTERY CHARGE	1	17NOV2020	29/1	1	No	O	NA	R (17NOV2020)	N/N	
	INFEC	Postoperative wound infection/ Postoperative wound infection to left upper chest	1	23NOV2020	35/43	1	No	O	NA/TC	R (04JAN2021)	Y/N	
	VASC	Haematoma/ HEMATOMA	1	23NOV2020	35/1	3	No	O	NA	RS (23NOV2020)	N/N	
	SURG	Wound drainage/ WOUND PUMP DRAINAGE	1	07DEC2020	49/C	1	No	O	NA	RG	N/N	
>55/ C4591001 1120 11201358	GENRL	Oedema peripheral/ BOTH LOWER EXTREMITY EDEMA	2	10NOV2020	1/C	1	No	O	NA	N	N/N	
>55/ C4591001 1120 11201360	NEOPL	Basal cell carcinoma/ BASAL CELL CARCINOMA RIGHT NOSTRIL	1	02NOV2020	13/9	2	No	O	NA/TCN	R (10NOV2020)	N/N	
>55/ C4591001 1120 11201399	GASTR	Pancreatitis/ Worsening of pancreatitis	2	28NOV2020	13/C	2	No	O	NA	N	N/N	
>55/ C4591001 1120 11201408	PSYCH	Depression/ worsening of depression	1	29OCT2020	2/18	2	Yes		NA	R (15NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1120 11201432	NEOPL	Pancreatic carcinoma/ Pancreatic cancer	2	04DEC2020	15/C	4	No	O	NA	N	Y/N	
>55/ C4591001 1121 11211021	GASTR	Diarrhoea/ Diarrhea	2	18SEP2020	3/1	1	Yes		NA	R (18SEP2020)	N/N	
>55/ C4591001 1121 11211077	GENRL	Injection site pain/ Injection site pain	1	22SEP2020	20/8	2	Yes		NA/TCN	R (29SEP2020)	N/N	
>55/ C4591001 1122 11221013	GENRL	Fatigue/ excessive fatigue	1	11SEP2020	4/3	1	Yes		NA	R (13SEP2020)	N/N	
	GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
		Pyrexia/ Fever 100.5 F	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
	MUSC	Pain in extremity/ left arm soreness	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
	NERV	Tremor/ trembling hands	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
>55/ C4591001 1122 11221015	GENRL	Fatigue/ fatigue#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N	
		Injection site swelling/ swelling at injection site#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/Y	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Pain in extremity/ right upper arm pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	NERV	Headache/ headache#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
>55/ C4591001 1122 11221018	GENRL	Injection site pain/ injection site pain left arm#	3	18DEC2020	2/3	1	Yes		NA	R (20DEC2020)	N/N
>55/ C4591001 1122 11221019	GENRL	Injection site pain/ Soreness in the upper arm around where injection was given#	3	23DEC2020	1/2	1	Yes		NA/TC	R (24DEC2020)	N/N
		Pain/ Generalized body aches#	3	23DEC2020	1/2	1	Yes		NA/TC	R (24DEC2020)	N/N
	NERV	Headache/ Headache#	3	23DEC2020	1/2	1	Yes		NA/TC	R (24DEC2020)	N/N
>55/ C4591001 1122 11221020	INFEC	Conjunctivitis/ right eye conjunctivitis#	3	19FEB2021	18/7	1	No	O	NA/TC	R (25FEB2021)	N/N
	GENRL	Injection site discomfort/ injection site discomfort#	4	23FEB2021	2/3	1	Yes		NA	R (25FEB2021)	N/N
>55/ C4591001 1122 11221021	GENRL	Fatigue/ Fatigue	1	11SEP2020	2/5	1	Yes		NA	R (15SEP2020)	N/N
		Pyrexia/ Feverish	1	11SEP2020	2/5	1	Yes		NA	R (15SEP2020)	N/N
	NERV	Tremor/ Shaky	1	11SEP2020	2/5	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Fatigue/ fatigue	2	02OCT2020	2/5	1	Yes		NA	R (06OCT2020)	N/N	
		Pyrexia/ feverish	2	02OCT2020	2/5	1	Yes		NA	R (06OCT2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	4	02FEB2021	1/3	1	Yes		NA/TC	R (04FEB2021)	N/N	
		Pyrexia/ fever#	4	02FEB2021	1/4	1	Yes		NA/TC	R (05FEB2021)	N/N	
	PSYCH	Insomnia/ trouble sleeping#	4	02FEB2021	1/4	1	Yes		NA/TC	R (05FEB2021)	N/N	
		Thinking abnormal/ foggy thought process#	4	02FEB2021	1/3	1	Yes		NA/TC	R (04FEB2021)	N/N	
>55/ C4591001 1122 11221029	GENRL	Injection site pain/ injection site soreness	2	02OCT2020	3/1	1	Yes		NA	R (02OCT2020)	N/N	
>55/ C4591001 1122 11221039	GENRL	Injection site pain/ soreness at injection site	2	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N	
	GENRL	Chills/ chills	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N	
		Pyrexia/ fever	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N	
	MUSC	Myalgia/ muscle aches	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N	
	NERV	Headache/ headache	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N	
>55/ C4591001	GASTR	Diarrhoea/ diarrhea#	4	09JAN2021	2/2	1	Yes		NA/TC	R (10JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1122 11221049		Nausea/ nausea#	4	09JAN2021	2/2	1	Yes		NA/TC	R (10JAN2021)	N/N	
	GENRL	Injection site pain/ injection site pain#	4	09JAN2021	2/2	1	Yes		NA/TC	R (10JAN2021)	N/N	
		Pain/ generalized body aches#	4	09JAN2021	2/2	1	Yes		NA/TC	R (10JAN2021)	N/N	
>55/ C4591001 1122 11221050	GENRL	Asthenia/ weakness	1	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N	
		Fatigue/ fatigue	1	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N	
>55/ C4591001 1122 11221057	GENRL	Non-cardiac chest pain/ non cardiac chest pain	1	21OCT2020	6/1	1	Yes		NA	R (21OCT2020)	N/N	
>55/ C4591001 1122 11221058	GENRL	Fatigue/ fatigue#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N	
		Injection site pain/ injection site pain left arm#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N	
	GENRL	Fatigue/ fatigue#	4	08JAN2021	2/2	1	Yes		NA/TC	R (09JAN2021)	N/N	
		Injection site pain/ injection site pain#	4	08JAN2021	2/2	1	Yes		NA/TC	R (09JAN2021)	N/N	
		Pyrexia/ fever#	4	08JAN2021	2/2	1	Yes		NA/TC	R (09JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1122 11221060	NERV	Headache/ headache#	4	08JAN2021	2/2	1	Yes		NA/TC	R (09JAN2021)	N/N
	GASTR	Diarrhoea/ diarrhea	1	22OCT2020	1/2	2	Yes		NA	R (23OCT2020)	N/N
	GENRL	Pain/ body aches	1	22OCT2020	1/2	2	Yes		NA	R (23OCT2020)	N/N
	NERV	Headache/ headache	1	22OCT2020	1/2	2	Yes		NA	R (23OCT2020)	N/N
	GENRL	Fatigue/ mild fatigue	2	11NOV2020	2/2	1	Yes		NA/TC	R (12NOV2020)	N/N
>55/ C4591001 1123 11231013		Pain/ mild body aches	2	11NOV2020	2/2	1	Yes		NA/TC	R (12NOV2020)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	06FEB2021	1/1	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1123 11231014	PSYCH	Depression/ Worsening of depression	2	06SEP2020	19/C	1	No	O	NA/TC	N	N/N
		Insomnia/ Worsening of insomnia	2	06SEP2020	19/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1123 11231015	EAR	Vertigo/ Vertigo	2	23NOV2020	97/23	1	No	O	NA/TC	R (15DEC2020)	N/N
	INFEC	Bronchitis/ Bronchitis#	2	08FEB2021	174/9	2	No	O	NA/TC/TCN	R (16FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1123 11231025	EYE	Conjunctival hyperaemia/ INTERMITTENT RIGHT EYE CONJUNCTIVE ERYTHEMA	1	24AUG2020	22/122	1	No	O	NA	R (23DEC2020)	N/N
>55/ C4591001 1123 11231039	INV	Blood pressure systolic increased/ Elevated systolic blood pressure*		05AUG2020	1/1	1	No	O	NA	R (05AUG2020)	N/N
>55/ C4591001 1123 11231040	EAR	Meniere's disease/ worsening meniere's disease episode#	3	28FEB2021	13/1	2	No	O	NA/TC	R (28FEB2021)	N/N
>55/ C4591001 1123 11231053	GENRL	Injection site pain/ Pain at injection site#	3	20FEB2021	3/2	1	No	O	NA	R (21FEB2021)	N/N
	INFEC	Tooth abscess/ Abscess tooth#	3	23FEB2021	6/9	2	No	O	NA/TC	R (03MAR2021)	N/N
>55/ C4591001 1123 11231066	GASTR	Vomiting/ Emesis	1	22AUG2020	12/1	1	No	O	NA	R (22AUG2020)	N/N
>55/ C4591001 1123 11231070	INJ&P	Radius fracture/ Left radius fracture	1	14AUG2020	4/C	1	No	O	NA/TC/TCN	RG	N/N
>55/ C4591001 1123 11231080	GASTR	Nausea/ nausea#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
>55/ C4591001 1123 11231089	PSYCH	Mood swings/ Mood instability	1	14AUG2020	2/165	1	No	O	NA	R (25JAN2021)	N/N
>55/ C4591001 1123 11231096	MUSC	Osteoarthritis/ Left hip osteoarthritis	2	SEP2020	1/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1123 11231126	GENRL	Injection site pain/ INJECTION SITE PAIN	2	09SEP2020	1/5	1	Yes		NA	R (13SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN	2	09SEP2020	1/5	1	Yes		NA	R (13SEP2020)	N/N
>55/ C4591001 1123 11231129	INJ&P	Ear canal abrasion/ EXTERNAL AUDITORY CANAL ABRASION	1	09SEP2020	22/1	1	No	O	NA	R (09SEP2020)	N/N
>55/ C4591001 1123 11231131	GENRL	Injection site pain/ Injection site pain left arm	1	19AUG2020	1/2	1	Yes		NA	R (20AUG2020)	N/N
>55/ C4591001 1123 11231147	GENRL	Injection site pain/ Injection site pain	2	14SEP2020	1/3	1	Yes		NA/TC	R (16SEP2020)	N/N
	MUSC	Myalgia/ Full body myalgia	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1123 11231149	NERV	Headache/ Headache	1	28AUG2020	5/2	1	Yes		NA	R (29AUG2020)	N/N
>55/ C4591001 1123 11231158	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Injection site pain	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Myalgia/ Full body myalgia	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1123 11231167	NERV	Headache/ Headache	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Pyrexia/ Fever	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
>55/ C4591001 1123 11231180	NERV	Sciatica/ Worsening of sciatic nerve pain	1	29AUG2020	4/19	1	No	O	NA/TC	R (16SEP2020)	N/N
	HEPAT	Biliary dyskinesia/ biliary dyskinesia	2	28DEC2020	106/14	1	No	O	NA/TCN	R (10JAN2021)	N/N
>55/ C4591001 1123 11231186	GENRL	Chills/ chills#	4	03MAR2021	2/2	1	Yes		NA	R (04MAR2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1123 11231198	MUSC	Myalgia/ myalgia#	4	03MAR2021	2/2	1	Yes		NA	R (04MAR2021)	N/N
	NERV	Headache/ Headache	1	27AUG2020	1/30	1	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Oedema peripheral/ Peripheral edema	1	29AUG2020	3/C	1	No	O	NA	N	N/N
	GASTR	Abdominal pain/ Abdominal pain	1	07SEP2020	12/26	1	No	O	NA	R (02OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	12SEP2020	17/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site erythema/ Redness at injection site	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	18SEP2020	1/15	1	Yes		NA	R (02OCT2020)	N/N
		Injection site swelling/ Swelling at injection site	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	19SEP2020	2/1	2	Yes		NA/TC	R (19SEP2020)	N/N
		Pyrexia/ FEVER	2	19SEP2020	2/1	2	Yes		NA/TC	R (19SEP2020)	N/N
	Arthralgia/ JOINT PAIN	2	19SEP2020	2/1	2	Yes		NA/TC	R (19SEP2020)	N/N	
	Myalgia/ FULL BODY MYALGIA	2	19SEP2020	2/7	2	Yes		NA/TC	R (25SEP2020)	N/N	
>55/ C4591001 1123 11231219	GENRL	Injection site pain/ Injection site pain	1	09SEP2020	1/4	1	Yes		NA/TC	R (12SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Dysgeusia/ Metallic taste in mouth	1	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N
	MUSC	Myalgia/ Left body myalgia	1	12SEP2020	4/5	1	Yes		NA/TC	R (16SEP2020)	N/N
>55/ C4591001 1123 11231226	CARD	Bradycardia/ Bradycardia	2	08DEC2020	69/21	1	No	CD	NA	R (28DEC2020)	N/N
>55/ C4591001 1123 11231231	GENRL	Chills/ Chills	2	30SEP2020	1/3	1	Yes		NA/TC	R (02OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	30SEP2020	1/3	1	Yes		NA/TC	R (02OCT2020)	N/N
>55/ C4591001 1123 11231241	METAB	Type 2 diabetes mellitus/ Worsening of Diabetes Type 2	2	25NOV2020	51/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1123 11231256	VASC	Deep vein thrombosis/ Deep Vein Thrombosis left leg	2	22NOV2020	49/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1123 11231259	GENRL	Injection site pain/ Pain at injection site	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
	GENRL	Chills/ Chills	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1123 11231274	GENRL	Fatigue/ fatigue#	4	03MAR2021	2/1	1	Yes		NA	R (03MAR2021)	N/N
	MUSC	Myalgia/ myalgia#	4	03MAR2021	2/1	1	Yes		NA	R (03MAR2021)	N/N
>55/ C4591001 1123 11231315	GENRL	Chills/ Chills#	4	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
		Injection site pain/ Pain at injection site#	4	20JAN2021	1/3	1	Yes		NA/TC	R (22JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
>55/ C4591001 1123 11231316	RESP	Hiccups/ Hiccups	1	09OCT2020	16/3	1	No	O	NA/TC	R (11OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	13OCT2020	1/5	1	Yes		NA	R (17OCT2020)	N/N
	NERV	Headache/ Headache	2	13OCT2020	1/5	1	Yes		NA/TC	R (17OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Chills/ Chills	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	15OCT2020	3/5	1	Yes		NA	R (19OCT2020)	N/N
	GENRL	Chills/ Chills	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1123 11231331	GENRL	Malaise/ Malaise	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
>55/ C4591001 1123 11231345	VASC	Hypertension/ Hypertension	2	24DEC2020	50/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1123 11231368	GENRL	Injection site pain/ Pain at injection site	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
		Injection site swelling/ Swelling at injection site	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C4591001 1123 11231406	RESP	Sleep apnoea syndrome/ Sleep apnea	1	OCT2020	1/C	2	No	O	NA/TCN	N	N/N
	GENRL	Chills/ Chills	2	04DEC2020	1/4	1	Yes		NA	R (07DEC2020)	N/N
		Fatigue/ Fatigue	2	04DEC2020	1/6	1	Yes		NA	R (09DEC2020)	N/N
		Pyrexia/ Fever	2	04DEC2020	1/4	1	Yes		NA	R (07DEC2020)	N/N
	MUSC	Myalgia/ Myalgia	2	04DEC2020	1/6	1	Yes		NA	R (09DEC2020)	N/N
	NERV	Headache/ Headache	2	04DEC2020	1/6	1	Yes		NA/TC	R (09DEC2020)	N/N
	GENRL	Injection site haemorrhage/ Left deltoid injection site ecchymosis	2	05DEC2020	2/8	1	Yes		NA	R (12DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1124 11241007	GASTR	Nausea/ Nausea	2	06DEC2020	3/2	1	Yes		NA	R (07DEC2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	08DEC2020	5/1	1	Yes		NA	R (08DEC2020)	N/N
	GENRL	Pain/ body aches#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
			Pyrexia/ fever#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)
>55/ C4591001 1124 11241029	NERV	Headache/ headache#	3	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	GENRL	Chills/ body chills#	3	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
			Fatigue/ fatigue#	3	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)
>55/ C4591001 1124 11241033	MUSC	Back pain/ lower back pain#	3	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
		Musculoskeletal stiffness/ neck stiffness#	3	07JAN2021	2/1	1	No	O	NA	R (07JAN2021)	N/N
	GASTR	Nausea/ Nausea	2	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	MUSC	Pain in extremity/ Painful fingers-Bilateral hands	2	02SEP2020	2/2	3	Yes		NA	R (03SEP2020)	N/N
		Pain in extremity/ Painful toes-Bilateral feet	2	02SEP2020	2/2	2	Yes		NA	R (03SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	SKIN	Skin discolouration/ Discolored fingers-Bilateral hands	2	02SEP2020	2/2	2	Yes		NA	R (03SEP2020)	N/N
		Skin discolouration/ Discolored toes-Bilateral feet	2	02SEP2020	2/2	2	Yes		NA	R (03SEP2020)	N/N
>55/ C4591001 1124 11241034	INFEC	Lyme disease/ lyme disease	2	17DEC2020	108/5	1	No	O	NA	R (21DEC2020)	N/N
>55/ C4591001 1124 11241037	GENRL	Pyrexia/ Fever	2	03SEP2020	2/2	2	Yes		NA/TC	R (04SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	03SEP2020	2/2	2	Yes		NA/TC	R (04SEP2020)	N/N
>55/ C4591001 1124 11241046	GENRL	Fatigue/ Fatigue	1	17AUG2020	1/2	2	Yes		NA/TC	R (18AUG2020)	N/N
		Injection site erythema/ Injection site erythema	1	17AUG2020	1/2	2	Yes		NA	R (18AUG2020)	N/N
	MUSC	Myalgia/ Myalgia	1	17AUG2020	1/2	2	Yes		NA/TC	R (18AUG2020)	N/N
>55/ C4591001 1124 11241048	INFEC	Conjunctivitis bacterial/ Bacterial conjunctivitis	1	06SEP2020	21/6	2	No	O	NA/TC	R (11SEP2020)	N/N
>55/ C4591001 1124 11241051	GENRL	Pyrexia/ Fever (102 degrees Fahrenheit)#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1124 11241056	GASTR	Gastroesophageal reflux disease/ Acid Reflux	2	06OCT2020	28/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1124 11241063	INJ&P	Limb fracture/ Fracture right third digit	2	05OCT2020	26/28	1	No	O	NA/TC	R (01NOV2020)	N/N	
>55/ C4591001 1124 11241070	GENRL	Chills/ Body Chills#	4	10MAR2021	2/1	1	Yes		NA	R (10MAR2021)	N/N	
>55/ C4591001 1124 11241074	GENRL	Chills/ Chills	1	21AUG2020	2/1	2	Yes		NA/TC	R (21AUG2020)	N/N	
	MUSC	Myalgia/ Body Aches/Myalgias	1	21AUG2020	2/1	2	Yes		NA/TC	R (21AUG2020)	N/N	
	SKIN	Hyperhidrosis/ Sweating	1	21AUG2020	2/1	2	Yes		NA/TC	R (21AUG2020)	N/N	
	GENRL	Chills/ Chills	2	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N	
		Pyrexia/ Fever	2	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N	
	SKIN	Hyperhidrosis/ Sweats	2	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N	
>55/ C4591001 1124 11241082	MUSC	Myalgia/ Muscle Aches (calves)	1	29AUG2020	6/3	1	No	O	NA	R (31AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1124 11241085	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/8	2	Yes		NA/TC	R (31AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	1/6	2	Yes		NA/TC	R (20SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	16SEP2020	2/1	2	Yes		NA	R (16SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	16SEP2020	2/1	2	Yes		NA/TC	R (16SEP2020)	N/N
>55/ C4591001 1124 11241091	GENRL	Injection site pruritus/ Injection site pruritus	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1124 11241107	INJ&P	Animal bite/ Right Hand Dog Bite	2	04OCT2020	18/8	1	No	O	NA/TC	R (11OCT2020)	N/N
>55/ C4591001 1124 11241110	GASTR	Diarrhoea/ Diarrhea/loose stool (1 episode)	1	02SEP2020	8/1	1	No	O	NA	R (02SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1124 11241114	IMMUN	Seasonal allergy/ Seasonal Allergies	1	30AUG2020	4/30	1	No	O	NA/TC	R (28SEP2020)	N/N
>55/ C4591001	GENRL	Pyrexia/ Fever	2	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1124 11241116	MUSC	Myalgia/ Myalgias	2	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C4591001 1124 11241119	GASTR	Abdominal pain/ abdominal pain#	3	05MAR2021	18/8	2	No	O	NA/TC	R (12MAR2021)	N/N
>55/ C4591001 1124 11241121	GENRL	Fatigue/ Fatigue	1	30AUG2020	4/1	2	Yes		NA	R (30AUG2020)	N/N
>55/ C4591001 1124 11241124	GENRL	Injection site pain/ Injection site pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
>55/ C4591001 1124 11241128	MUSC	Myalgia/ Myalgias	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
>55/ C4591001 1124 11241128	SKIN	Alopecia/ Hair loss	2	SEP2020	1/C	1	No	O	NA	N	N/N
>55/ C4591001 1124 11241140	INJ&P	Rib fracture/ Fractured Rib	1	22SEP2020	22/56	1	No	O	NA/TC	R (16NOV2020)	N/N
>55/ C4591001 1124 11241144	GENRL	Chills/ Chills	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1124 11241145	GENRL	Fatigue/ Fatigue	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		Injection site pain/ Injection site pain	2	24SEP2020	1/3	2	Yes		NA/TC	R (26SEP2020)	N/N
>55/ C4591001 1124 11241147	MUSC	Pyrexia/ Fever	2	24SEP2020	1/2	2	Yes		NA/TC	R (25SEP2020)	N/N
		Back pain/ Worsening back pain	2	21OCT2020	30/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1124 11241148	GENRL	Injection site pain/ Injection site soreness	1	02SEP2020	1/5	1	Yes		NA	R (06SEP2020)	N/N
		Injection site warmth/ Injection site warmth	1	02SEP2020	1/5	1	Yes		NA	R (06SEP2020)	N/N
	GASTR	Nausea/ Nausea	1	03SEP2020	2/4	1	Yes		NA	R (06SEP2020)	N/N
	NERV	Headache/ Headache	1	03SEP2020	2/5	1	Yes		NA/TC	R (07SEP2020)	N/N
	GENRL	Injection site warmth/ Injection site warmth	2	23SEP2020	1/5	1	Yes		NA	R (27SEP2020)	N/N
	MUSC	Musculoskeletal stiffness/ Left arm stiffness	2	23SEP2020	1/5	1	Yes		NA	R (27SEP2020)	N/N
		Pain in extremity/ Left arm soreness	2	23SEP2020	1/5	1	Yes		NA	R (27SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	2	24SEP2020	2/5	1	Yes		NA/TC	R (28SEP2020)	N/N
>55/ C4591001 1124 11241150	INV	Body temperature increased/ Elevated Body Temperature	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1124 11241151	MUSC	Back pain/ Mild Lower back pain	2	07OCT2020	17/26	1	No	O	NA	R (01NOV2020)	N/N
>55/ C4591001 1124 11241154	GENRL	Chills/ Chills	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
		Pyrexia/ Fever	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
>55/ C4591001 1124 11241156	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Pain/ BODY ACHES#	4	17FEB2021	8/1	1	Yes		NA	R (17FEB2021)	N/N
>55/ C4591001 1124 11241157	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		Injection site pain/ Injection site pain	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site erythema/ Injection site redness	2	04OCT2020	11/2	2	Yes		NA/TC	R (05OCT2020)	N/N
>55/ C4591001 1124 11241159	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	1/6	2	Yes		NA	R (08SEP2020)	N/N
>55/ C4591001 1124 11241160	INFEC	Urinary tract infection/ Urinary tract infection	2	09OCT2020	16/9	1	No	O	NA/TC	R (17OCT2020)	N/N
>55/ C4591001 1124 11241169	GENRL	Injection site pain/ injection site pain#	3	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
>55/ C4591001 1124 11241172	GENRL	Chills/ Chills	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		Pyrexia/ Fever	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ Worsening Headache	2	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N
>55/ C4591001 1124 11241182	GENRL	Injection site pain/ Injection site pain	1	08SEP2020	1/3	2	Yes		NA/TC	R (10SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1124 11241191	GENRL	Injection site pain/ Injection site pain	2	29SEP2020	1/3	1	Yes		NA/TC	R (01OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	2/3	2	Yes		NA	R (12SEP2020)	N/N	
	NERV	Headache/ Headache	1	11SEP2020	3/2	2	Yes		NA/TC	R (12SEP2020)	N/N	
	GENRL	Injection site erythema/ Injection Site Redness	1	12SEP2020	4/6	2	Yes		NA	R (17SEP2020)	N/N	
	EAR	Tinnitus/ Tinnitus	2	02OCT2020	4/2	1	No	O	NA	R (03OCT2020)	N/N	
	GENRL	Malaise/ Malaise	2	02OCT2020	4/2	1	Yes		NA	R (03OCT2020)	N/N	
	METAB	Hypercholesterolaemia/ hypercholesterolemia#	2	01MAR2021	154/C	1			NA/TC	RG	N/N	
	GENRL	Fatigue/ Fatigue	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N	
	NERV	Headache/ Worsening Headaches	2	30SEP2020	2/C	2	Yes		NA/TC	RG	N/N	
>55/ C4591001 1124 11241206	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/3	2	Yes		NA	R (12SEP2020)	N/N	
>55/ C4591001 1124 11241211	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/3	2	Yes		NA	R (12SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		Fatigue/ Fatigue	1	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ Headache	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
	MUSC	Bursitis/ Worsening bursitis of right hip	1	15SEP2020	6/128	2	No	O	NA/TC	R (20JAN2021)	N/N
	GENRL	Chills/ Chills	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
	NERV	Headache/ Headaches	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C4591001 1124 11241221	GENRL	Injection site pain/ Injection site soreness	2	02OCT2020	1/4	1	Yes		NA	R (05OCT2020)	N/N
>55/ C4591001 1125 11251016	NERV	Neuralgia/ Bilateral leg Nerve Pain	2	12JAN2021	134/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1125 11251041	INFEC	Cellulitis/ Cellulitis of Right Cheek	2	21SEP2020	18/13	1	No	O	NA/TC	R (03OCT2020)	N/N
>55/ C4591001 1125 11251048	CARD	Atrial fibrillation/ Atrial fibrillation	2	28JAN2021	142/C	2	No	O	NA/TC	RG	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1125 11251055	EAR	Vertigo/ Vertigo#	3	24FEB2021	10/9	1	No	O	NA/TC	R (04MAR2021)	N/N
	GENRL	Fatigue/ Fatigue	1	18AUG2020	1/3	1	Yes		NA	R (20AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	2/1	2	Yes		NA	R (19AUG2020)	N/N
	MUSC	Arthralgia/ joint pain	1	19AUG2020	2/1	1	No	O	NA	R (19AUG2020)	N/N
		Myalgia/ muscle pain	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	08SEP2020	1/1	2	Yes		NA	R (08SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1125 11251064	NERV	Sciatica/ Sciatica of Right Hip	2	15JAN2021	130/C	1	No	O	NA/TC	RG	N/N
	INFEC	Cellulitis/ Bilateral Lower Leg Cellulitis	2	29JAN2021	141/14	2	No	O	NA/TC	R (11FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain	1	24AUG2020	4/1	1	Yes		NA	R (24AUG2020)	N/N
>55/ C4591001 1125 11251066	GASTR	Gastric ulcer/ Gastric Ulcer	2	17SEP2020	7/169	2	No	O	NA/TC	R (04MAR2021)	N/N
>55/ C4591001 1125 11251070											

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1125 11251071	METAB	Vitamin D deficiency/ Vitamin D deficiency#	2	10FEB2021	155/C	1	No	O	NA/TC	N	N/N	
	VASC	Hypertension/ Hypertension#	2	10FEB2021	155/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1125 11251082	GENRL	Fatigue/ Fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	
>55/ C4591001 1125 11251085	VASC	Hypertension/ Hypertension	2	23DEC2020	101/59	1	No	O	NA/TC	R (19FEB2021)	N/N	
>55/ C4591001 1125 11251107	INJ&P	Muscle injury/ muscle sprain of lower back	1	12SEP2020	17/51	1	No	O	NA/TC	R (01NOV2020)	N/N	
>55/ C4591001 1125 11251118	MUSC	Bursitis/ Acute olecranon bursitis Left elbow	1	01SEP2020	6/C	2	No	O	NA	RG	N/N	
>55/ C4591001 1125 11251121	GASTR	Diarrhoea/ Diarrhea	1	01SEP2020	5/1	1	Yes		NA	R (01SEP2020)	N/N	
>55/ C4591001	ENDO	Hypogonadism/ hypogonadism	2	16OCT2020	24/C	2	No	O	NA/TC	N	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1125 11251129 >55/ C4591001	GENRL	Pain/ body aches	2	13OCT2020	19/1	1	No	O	NA	R (13OCT2020)	N/N
1125 11251147	INJ&P	Spinal compression fracture/ Compression fracture L4 vertebra	2	25OCT2020	31/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001	INFEC	COVID-19/ Covid-19	2	20JAN2021	121/26	3	No	O	NA/TC	R (14FEB2021)	Y/N
1125 11251154 >55/ C4591001	VASC	Hypertension/ Worsening of Hypertension	1	24SEP2020	22/15	2	No	O	NA/TC	R (08OCT2020)	N/N
1125 11251161 >55/ C4591001	INFEC	Chronic sinusitis/ Exacerbation of chronic Sinusitis	1	21SEP2020	14/5	2	No	O	NA/TC	R (25SEP2020)	N/N
1125 11251186 >55/ C4591001	INFEC	Acute sinusitis/ acute sinus infection	1	14SEP2020	7/10	1	No	O	NA/TC	R (23SEP2020)	N/N
1125 11251190 >55/ C4591001	GENRL	Chills/ Chills	1	28SEP2020	20/2	1	Yes		NA	R (29SEP2020)	N/N
1125 11251191		Pain/ bodyaches	1	28SEP2020	20/2	1	Yes		NA	R (29SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Pyrexia/ fever	1	28SEP2020	20/2	1	Yes		NA	R (29SEP2020)	N/N	
	MUSC	Exostosis/ Osteophyte to lateral left foot	2	14OCT2020	17/C	1	No	O	NA	N	N/N	
>55/ C4591001 1125 11251199	GASTR	Gastritis/ Gastritis	1	11SEP2020	2/1	1	No	O	NA	R (11SEP2020)	N/N	
>55/ C4591001 1125 11251209	INFEC	Onychomycosis/ Onychomycosis	2	19OCT2020	18/93	1	No	O	NA/TC	R (19JAN2021)	N/N	
	REPRO	Benign prostatic hyperplasia/ Benign prostatic hyperplasia#	3	01MAR2021	10/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1125 11251210	SKIN	Ecchymosis/ Ecchymosis	1	30SEP2020	20/8	1	No	O	NA	R (07OCT2020)	N/N	
>55/ C4591001 1125 11251211	NERV	Dizziness/ Dizziness	1	18SEP2020	8/15	1	Yes		NA/TC	R (02OCT2020)	N/N	
	MUSC	Back pain/ Acute low back pain	1	22JAN2021	134/46	2	No	O	NA/TC	R (08MAR2021)	N/N	
>55/ C4591001 1125 11251230	MUSC	Arthralgia/ joint pain	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N	
	MUSC	Arthralgia/ joint pain	1	23OCT2020	3/2	2	Yes		NA	R (24OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1126 11261004	GENRL	Fatigue/ Fatigue	1	24OCT2020	4/1	2	Yes		NA	R (24OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	1	24OCT2020	4/1	2	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	02FEB2021	1/5	2	Yes		NA/TC	R (06FEB2021)	N/N
		Pain/ Body aches#	4	02FEB2021	1/3	2	Yes		NA/TC	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	4	02FEB2021	1/3	1	Yes		NA/TC	R (04FEB2021)	N/N
	SKIN	Night sweats/ Sweating, nocturnal#	4	02FEB2021	1/1	1	Yes		NA	R (02FEB2021)	N/N
>55/ C4591001 1126 11261007	GENRL	Injection site pain/ Left upper arm injection site pain#	3	15JAN2021	1/3	1	Yes		NA	R (17JAN2021)	N/N
>55/ C4591001 1126 11261015	GENRL	Fatigue/ Fatigue#	4	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
	EYE	Cataract/ Bilateral Age Related combined form cataract	2	06JAN2021	126/C	1	No	O	NA/TCN	N	N/N
		Dry age-related macular degeneration/ Left nonexudative age related macular degeneration	2	06JAN2021	126/C	1	No	O	NA/TCN	N	N/N
		Dry eye/ Bilateral dry eye syndrome	2	06JAN2021	126/C	1	No	O	NA/TC/TCN	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1126 11261016	GENRL	Fatigue/ Fatigue#	3	27JAN2021	1/2	2	Yes		NA	R (28JAN2021)	N/N
		Injection site pain/ Pain, injection site#	3	27JAN2021	1/2	1	Yes		NA/TC	R (28JAN2021)	N/N
		Pain/ Body Aches#	3	27JAN2021	1/2	2	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Pain, Injection Site#	4	17FEB2021	1/1	1	Yes		NA	R (17FEB2021)	N/N
		Pain/ Body Aches#	4	17FEB2021	1/1	1	Yes		NA	R (17FEB2021)	N/N
	EAR	Vertigo/ Vertigo	2	12DEC2020	101/C	1	No	O	NA/TC/TCN	N	N/N
	EAR	Eustachian tube dysfunction/ Right Eustachian Tube Dysfunction	2	14DEC2020	103/32	2	No	O	NA/TC	R (14JAN2021)	N/N
	EAR	Tinnitus/ Tinnitus right ear#	3	11JAN2021	15/C	2	No	O	NA/TC	N	N/N
	EAR	Deafness neurosensory/ Asymmetric Bilateral Sensorineural Hearing Loss#	3	14JAN2021	18/C	2	No	O	NA	N	N/N
		Sudden hearing loss/ Right sudden hearing loss#	3	14JAN2021	18/C	2	No	O	NA/TC	N	N/N
	RENAL	Dysuria/ Dysuria#	4	25JAN2021	8/3	1	Yes		NA/TC	R (27JAN2021)	N/N
>55/ C4591001 1126 11261026	GENRL	Injection site pain/ Injection site pain#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection Site Pain#	4	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	05FEB2021	2/2	2	Yes		NA	R (06FEB2021)	N/N
	MUSC	Arthralgia/ Joint Pains#	4	05FEB2021	2/2	2	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1126 11261027	GENRL	Injection site pain/ Injection site pain#	3	16JAN2021	2/3	1	Yes		NA	R (18JAN2021)	N/N
	SKIN	Dry skin/ Worsening dry skin generalized#	3	25JAN2021	11/C	2	No	O	NA/TCN	N	N/N
	GENRL	Fatigue/ Fatigue#	4	05FEB2021	2/2	2	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1126 11261032	MUSC	Pain in extremity/ Left arm pain	1	18AUG2020	2/7	1	Yes		NA	R (24AUG2020)	N/N
>55/ C4591001 1126 11261036	GENRL	Fatigue/ Fatigue	1	19AUG2020	2/7	1	Yes		NA	R (25AUG2020)	N/N
	MUSC	Axillary mass/ Subcutaneous mass, right axilla	1	26AUG2020	9/34	1	No	O	NA	R (28SEP2020)	N/N
	GENRL	Fatigue/ Fatigue, Intermittent	2	15SEP2020	8/10	2	No	O	NA	R (24SEP2020)	N/N
	NEOPL	Basal cell carcinoma/ Basal cell carcinoma, left arm	2	15DEC2020	99/C	2	No	O	NA/TCN	N	N/N
	INJ&P	Fall/ Mechanical fall	2	17DEC2020	101/1	1	No	O	NA	R (17DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1126 11261038	VASC	Orthostatic hypotension/ Orthostatic Hypotension, Intermittent	2	17DEC2020	101/C	1	No	O	NA	N	N/N
	METAB	Dehydration/ Dehydration	2	22DEC2020	106/1	2	No	O	NA/TCN	R (22DEC2020)	N/N
	NERV	Dizziness/ Worsening dizziness	2	22DEC2020	106/2	2	No	O	NA/TCN	R (23DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Pain in extremity/ Left upper arm pain	1	18AUG2020	1/4	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
	NERV	Headache/ Headache	1	19AUG2020	2/1	1	Yes		NA/TC	R (19AUG2020)	N/N
	GENRL	Injection site pain/ Pain, Injection site	2	08SEP2020	1/4	2	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ Headache	2	09SEP2020	2/1	1	Yes		NA/TC	R (09SEP2020)	N/N
>55/ C4591001 1126 11261042	GENRL	Injection site pain/ Injection site pain#	3	23DEC2020	2/3	1	Yes		NA	R (25DEC2020)	N/N
GENRL	Injection site pain/ Pain, injection site#	4	11JAN2021	1/3	2	Yes		NA/TC	R (13JAN2021)	N/N	
GENRL	Pyrexia/ Fever#	4	12JAN2021	2/2	2	Yes		NA/TC	R (13JAN2021)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1126 11261049	MUSC	Trigger finger/ LEFT TRIGGER THUMB	2	19OCT2020	42/108	1	No	O	NA/TC/TCN	R (03FEB2021)	N/N	
		Trigger finger/ RIGHT TRIGGER THUMB	2	19OCT2020	42/108	1	No	O	NA/TC/TCN	R (03FEB2021)	N/N	
	MUSC	Rotator cuff syndrome/ TENDINITIS OF RIGHT ROTATOR CUFF	2	02NOV2020	56/94	1	No	O	NA/TC/TCN	R (03FEB2021)	N/N	
	GENRL	Injection site pain/ Pain, injection site#	3	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N	
	GENRL	Injection site pain/ Left upper arm injection site pain#	4	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N	
	INV	Alanine aminotransferase increased/ Elevated alanine transaminase level#	4	18FEB2021	16/C	2	No	O	NA	RG	N/N	
		Aspartate aminotransferase increased/ Elevated aspartate aminotransferase level#	4	18FEB2021	16/C	2	No	O	NA	RG	N/N	
>55/ C4591001 1126 11261051	GENRL	Chills/ Chills	2	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N	
		Injection site pain/ Injection Site Pain	2	11SEP2020	2/5	2	Yes		NA/TC	R (15SEP2020)	N/N	
		Pain/ Body Aches	2	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N	
	NERV	Headache/ Headache	2	11SEP2020	2/2	2	Yes		NA/TC	R (12SEP2020)	N/N	
>55/ C4591001	NERV	Headache/ Headache	2	01OCT2020	21/2	1	No	O	NA/TC	R (02OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1126 11261052	GENRL	Injection site pain/ Left upper arm injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N	
		Injection site pain/ Pain, injection site#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N	
	EAR	Eustachian tube dysfunction/ Bilateral eustachian tube dysfunction#	4	08MAR2021	19/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1126 11261054	GENRL	Chills/ Chills#	3	01FEB2021	1/1	1	Yes		NA	R (01FEB2021)	N/N	
		Fatigue/ Fatigue#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N	
		Injection site pain/ Left upper arm injection site pain#	3	01FEB2021	1/3	2	Yes		NA/TC	R (03FEB2021)	N/N	
>55/ C4591001 1126 11261057	INFEC	Diverticulitis/ WORSENING DIVERTICULITIS OF COLON	2	21NOV2020	54/13	2	No	O	NA/TC/TCN	R (03DEC2020)	N/N	
	GENRL	Injection site pain/ Left upper arm injection site pain#	3	15JAN2021	1/3	2	Yes		NA	R (17JAN2021)	N/N	
>55/ C4591001 1126 11261059	INFEC	Pustule/ Skin pustule right hip	1	05SEP2020	16/6	1	No	O	NA/TC/TCN	R (10SEP2020)	N/N	
	GENRL	Malaise/ Malaise	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Muscle Aches	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
>55/ C4591001 1126 11261065	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1126 11261066	GENRL	Malaise/ Malaise	2	15SEP2020	2/4	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Pain, injection site#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
		Injection site swelling/ Injection site swelling#	4	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
	MUSC	Arthralgia/ Joint aches#	4	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
	NERV	Headache/ Headache#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1126 11261067	MUSC	Pain in extremity/ Left upper arm pain	2	14SEP2020	1/3	2	Yes		NA	R (16SEP2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
		Fatigue/ Fatigue	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1126 11261069	MUSC	Myalgia/ Muscle aches	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ Headache	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Chills/ Chills#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N
	MUSC	Myalgia/ Generalized muscle aches#	3	30DEC2020	1/3	2	Yes		NA/TC	R (01JAN2021)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	4	19JAN2021	1/3	1	Yes		NA/TC	R (21JAN2021)	N/N
>55/ C4591001 1126 11261070	MUSC	Myalgia/ Muscle Aches#	4	20JAN2021	2/1	2	Yes		NA/TC	R (20JAN2021)	N/N
	MUSC	Pain in extremity/ Upper left arm pain	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N
	MUSC	Pain in extremity/ Upper left arm pain	2	15SEP2020	1/4	2	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001 1126 11261071	GENRL	Injection site pain/ Left upper arm injection site pain#	3	14JAN2021	1/4	2	Yes		NA/TC	R (17JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Chills/ Chills#	4	02FEB2021	1/2	2	Yes		NA	R (03FEB2021)	N/N
		Injection site pain/ Left upper arm injection site pain#	4	02FEB2021	1/3	1	Yes		NA/TC	R (04FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1126 11261072	GENRL	Pyrexia/ Fever#	4	02FEB2021	1/2	1	Yes		NA/TC	R (03FEB2021)	N/N	
		Malaise/ Malaise#	4	03FEB2021	2/1	2	Yes		NA	R (03FEB2021)	N/N	
		Fatigue/ Fatigue#	3	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N	
		Chills/ Chills#	4	02FEB2021	1/2	2	Yes		NA	R (03FEB2021)	N/N	
		Injection site pain/ Right upper arm injection site pain#	4	02FEB2021	1/3	2	Yes		NA/TC	R (04FEB2021)	N/N	
		Malaise/ Malaise#	4	02FEB2021	1/2	2	Yes		NA	R (03FEB2021)	N/N	
>55/ C4591001 1126 11261073	MUSC	Pyrexia/ Fever#	4	02FEB2021	1/2	2	Yes		NA/TC	R (03FEB2021)	N/N	
		Pain in extremity/ Left upper arm pain	2	14SEP2020	1/4	2	Yes		NA	R (17SEP2020)	N/N	
		Chills/ Chills	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N	
		Malaise/ Malaise	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N	
		Pyrexia/ Fever	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N	
>55/ C4591001	NERV	Headache/ Headache	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N	
		Injection site pain/ Pain, injection site	1	27AUG2020	2/4	1	Yes		NA	R (30AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1126 11261077	GENRL	Injection site erythema/ Injection site redness, left arm	2	16SEP2020	1/4	2	Yes		NA	R (19SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	29JAN2021	1/8	2	Yes		NA	R (05FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	30JAN2021	2/10	2	Yes		NA	R (08FEB2021)	N/N
	GENRL	Injection site erythema/ Injection site redness#	4	02FEB2021	5/5	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1126 11261079	INJ&P	Fall/ Mechanical fall	2	14NOV2020	60/1	2	No	O	NA	R (14NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N
	MUSC	Myalgia/ Muscle aches#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N
	NERV	Paraesthesia/ Tingling, generalized#	4	22JAN2021	1/1	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
>55/ C4591001 1126 11261084	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	1/11	1	Yes		NA	R (06SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1126 11261087	GENRL	Injection site pain/ Injection site pain	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
		Malaise/ Malaise	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1126 11261088	INV	Prostatic specific antigen increased/ Elevated Serum Prostate - Specific Antigen	1	28AUG2020	2/C	1	No	O	NA	N	N/N
>55/ C4591001 1126 11261089	GENRL	Injection site pain/ Left upper arm injection site pain#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Malaise/ Malaise#	4	10FEB2021	2/1	2	Yes		NA	R (10FEB2021)	N/N
		Pyrexia/ Fever#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
	MUSC	Pain in extremity/ Left upper arm pain	1	27AUG2020	1/3	1	Yes		NA/TC	R (29AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	28AUG2020	2/3	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ Fever	2	18SEP2020	1/2	1	Yes		NA/TC	R (19SEP2020)	N/N
MUSC	Myalgia/ Muscle aches	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Pain in extremity/ Left upper arm pain	2	19SEP2020	2/3	2	Yes		NA/TC	R (21SEP2020)	N/N
>55/ C4591001 1126 11261090	GENRL	Injection site pain/ Injection site pain	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
>55/ C4591001 1126 11261091	GENRL	Injection site pain/ Injection site pain#	3	29DEC2020	2/3	1	Yes		NA	R (31DEC2020)	N/N
		Malaise/ Malaise#	3	29DEC2020	2/3	1	Yes		NA	R (31DEC2020)	N/N
	SKIN	Rash/ Rash, back#	3	29DEC2020	2/3	1	Yes		NA/TC	R (31DEC2020)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	4	19JAN2021	1/3	2	Yes		NA	R (21JAN2021)	N/N
>55/ C4591001 1126 11261094	MUSC	Pain in extremity/ Left Upper Arm Pain	2	16SEP2020	1/4	2	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1126 11261095	MUSC	Arthralgia/ Right shoulder joint pain, worsening	2	15NOV2020	61/C	2	No	O	NA	RG	N/N
	INFEC	Herpes zoster/ Shingles	2	02DEC2020	78/7	2	No	O	NA/TC	R (08DEC2020)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	13FEB2021	2/1	2	Yes		NA	R (13FEB2021)	N/N
	EYE	Cataract/ Bilateral Cataracts#	4	12MAR2021	29/C	2	No	O	NA	N	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1126 11261097	GENRL	Injection site pain/ Left upper arm injection site pain#	3	14JAN2021	1/3	1	Yes		NA/TC	R (16JAN2021)	N/N
	GENRL	Chills/ Chills#	3	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Chills/ Chills#	4	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
		Fatigue/ Fatigue#	4	05FEB2021	2/2	2	Yes		NA	R (06FEB2021)	N/N
		Pyrexia/ Fever#	4	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1126 11261098	MUSC	Pain in extremity/ Left upper arm pain	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
>55/ C4591001 1126 11261100	GENRL	Injection site pain/ Inject site pain	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
>55/ C4591001 1126 11261102	GENRL	Mass/ Lump below left ear	1	31AUG2020	4/11	1	No	O	NA	R (10SEP2020)	N/N
	GENRL	Malaise/ Malaise	2	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N
		Pain/ Body aches	2	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Pyrexia/ Fever	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	SKIN	Pruritus/ Pruritus generalized	2	30NOV2020	74/64	2	No	O	NA/TC/TCN	R (01FEB2021)	N/N
		Rash/ Generalized body rash	2	30NOV2020	74/64	2	No	O	NA/TC/TCN	R (01FEB2021)	N/N
	GENRL	Injection site pain/ Pain, Injection Site#	2	20JAN2021	125/12	2	Yes		NA	R (31JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/4	2	Yes		NA	R (21FEB2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	18FEB2021	2/4	2	Yes		NA	R (21FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/4	2	Yes		NA	R (21FEB2021)	N/N
>55/ C4591001 1126 11261106	EYE	Dry eye/ Bilateral dry eye syndrome	2	15NOV2020	55/C	2	No	O	NA/TC	RG	N/N
	BLOOD	Iron deficiency anaemia/ Iron deficient anemia	2	13JAN2021	114/C	1	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	3	27JAN2021	1/3	2	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
>55/ C4591001 1126 11261107	MUSC	Arthralgia/ Left shoulder pain	2	22SEP2020	1/4	2	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ Right upper arm injection site pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1126 11261108	INFEC	Urinary tract infection/ Urinary tract infection#	3	25JAN2021	12/8	2	No	O	NA/TC	R (01FEB2021)	N/N
	GENRL	Injection site pain/ Right upper arm injection site pain#	4	04FEB2021	1/3	2	Yes		NA	R (06FEB2021)	N/N
	GENRL	Malaise/ Malaise#	4	05FEB2021	2/1	2	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1126 11261110	MUSC	Pain in extremity/ Left Upper Arm Pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	27SEP2020	7/1	1	Yes		NA	R (27SEP2020)	N/N
>55/ C4591001 1126 11261112	GENRL	Injection site pain/ Left Upper Arm Injection Site Pain#	3	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	30JAN2021	2/1	2	Yes		NA	R (30JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/2	2	Yes		NA	R (19FEB2021)	N/N
		Malaise/ Malaise#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
>55/ C4591001 1126 11261117	GENRL	Fatigue/ Fatigue#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1126 11261118	MUSC	Osteopenia/ Osteopenia	2	29DEC2020	97/C	1	No	O	NA/TC	N	N/N	
	EAR	Cerumen impaction/ Bilateral Cerumen Impaction#	3	11JAN2021	1/4	1	No	O	NA/TC/TCN	R (14JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	12JAN2021	2/3	1	Yes		NA	R (14JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	01FEB2021	1/3	2	Yes		NA/TC	R (03FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	02FEB2021	2/2	2	Yes		NA/TC	R (03FEB2021)	N/N	
		Malaise/ Malaise#	4	02FEB2021	2/2	1	Yes		NA/TC	R (03FEB2021)	N/N	
>55/ C4591001 1126 11261119	GENRL	Injection site pain/ Injection site pain	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
	GENRL	Malaise/ Malaise	2	27SEP2020	4/2	2	Yes		NA	R (28SEP2020)	N/N	
>55/ C4591001 1126 11261120	GENRL	Chills/ Chills	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/Y	
>55/ C4591001 1126 11261123	GENRL	Injection site pain/ INJECTION SITE PAIN	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N	
	GENRL	Injection site pain/ PAIN, INJECTION SITE	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1126 11261125	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site erythema/ INJECTION SITE REDNESS	2	25SEP2020	3/4	2	Yes		NA	R (28SEP2020)	N/N
	EAR	Tinnitus/ Tinnitus Left Ear	1	02SEP2020	1/C	2	No	O	NA	N	N/N
	GENRL	Injection site pain/ Pain, injection site#	3	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
	MUSC	Malaise/ Malaise	1	03SEP2020	1/2	2	Yes		NA/TC	R (04SEP2020)	N/N
	MUSC	Pain in extremity/ Left upper arm pain	1	03SEP2020	1/6	2	Yes		NA/TC	R (08SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Pain, Injection site	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N
MUSC	Myalgia/ Muscle aches, left arm	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N	
>55/ C4591001 1126 11261129	GENRL	Fatigue/ Fatigue	1	04SEP2020	2/3	1	Yes		NA	R (06SEP2020)	N/N

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>55/ C4591001 1126 11261130	GENRL	Injection site pain/ Injection site pain#	4	20JAN2021	2/3	1	Yes		NA	R (22JAN2021)	N/N
	NERV	Muscle spasticity/ Spasticity of bilateral lower extremities	2	01DEC2020	69/C	2	No	O	NA	N	N/N
	NEOPL	Neoplasm/ Neoplasm of uncertain behavior right flank#	3	29DEC2020	1/1	1	No	O	NA/TCN	R (29DEC2020)	N/N
	GENRL	Chills/ Chills#	4	21JAN2021	1/2	2	Yes		NA/TC	R (22JAN2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	21JAN2021	1/2	2	Yes		NA/TC	R (22JAN2021)	N/N
	NERV	Dizziness/ Dizziness#	4	21JAN2021	1/2	2	Yes		NA/TC	R (22JAN2021)	N/N
	NERV	Headache/ Headache#	4	21JAN2021	1/2	2	Yes		NA/TC	R (22JAN2021)	N/N
RENAL	Dysuria/ Dysuria#	4	08FEB2021	19/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1126 11261132	GENRL	Injection site pain/ Left upper arm injection site pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Left arm injection site pain#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Malaise/ Malaise#	4	03FEB2021	2/1	2	Yes		NA	R (03FEB2021)	N/N
	INJ&P	Skin abrasion/ Left nares abrasion (internal)#	4	16FEB2021	15/11	2	No	O	NA/TC	R (26FEB2021)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1126 11261133	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Chills/ Chills	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N
		Fatigue/ Fatigue	2	25SEP2020	2/4	2	Yes		NA/TC	R (28SEP2020)	N/N
		Injection site pain/ Injection site pain	2	25SEP2020	2/4	1	Yes		NA/TC	R (28SEP2020)	N/N
>55/ C4591001 1126 11261137	GENRL	Injection site pain/ Left upper arm injection site pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Left arm injection site pain#	4	02FEB2021	1/3	1	Yes		NA/TC	R (04FEB2021)	N/N
	GENRL	Malaise/ Malaise#	4	03FEB2021	2/2	2	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ Fever#	4	03FEB2021	2/1	1	Yes		NA/TC	R (03FEB2021)	N/N
>55/ C4591001 1126 11261138	NERV	Headache/ Headache#	4	03FEB2021	2/1	2	Yes		NA/TC	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Left upper arm injection site pain#	4	09FEB2021	1/3	1	Yes		NA/TC	R (11FEB2021)	N/N
		Pyrexia/ Fever#	4	09FEB2021	1/2	2	Yes		NA/TC	R (10FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Malaise/ Malaise#	4	10FEB2021	2/1	2	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1126 11261139	GENRL	Injection site pain/ Injection site pain	1	05SEP2020	2/7	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Left upper arm injection pain	2	23SEP2020	1/3	2	Yes		NA/TC	R (25SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	23SEP2020	1/2	2	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C4591001 1126 11261140	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	1/4	1	Yes		NA	R (07SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1126 11261146	GASTR	Nausea/ Nausea	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Malaise/ Malaise	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Pain/ Body aches	1	09SEP2020	2/1	1	Yes		NA/TC	R (09SEP2020)	N/N
	NERV	Headache/ Headache	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
	RENAL	Haematuria/ Hematuria	1	23SEP2020	16/4	2	No	O	NA/TC	R (26SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Fatigue/ Fatigue	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1126 11261152	INFEC	Hordeolum/ Stye right upper external eyelid	1	27SEP2020	19/3	1	No	O	NA/TCN	R (29SEP2020)	N/N
	GENRL	Injection site pain/ Left upper arm injection pain#	3	29DEC2020	1/3	2	Yes		NA	R (31DEC2020)	N/N
	GENRL	Injection site pain/ Left Upper Arm Injection Site Pain#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
>55/ C4591001 1126 11261153	GENRL	Injection site pain/ Pain, injection site	1	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1126 11261154	GENRL	Injection site pain/ Left upper arm injection site pain#	3	26JAN2021	1/2	2	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Pain, injection site#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
	MUSC	Groin pain/ Aches, bilateral groins#	4	19FEB2021	2/1	1	Yes		NA/TC	R (19FEB2021)	N/N
>55/ C4591001 1126 11261155	GENRL	Injection site pain/ Left upper arm injection site pain#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue#	4	09FEB2021	2/2	2	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1126 11261156	GENRL	Injection site pain/ Injection site pain	2	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N
>55/ C4591001 1126 11261159	MUSC	Myalgia/ Left upper arm muscle pain#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	16JAN2021	2/1	2	Yes		NA	R (16JAN2021)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	4	04FEB2021	1/3	2	Yes		NA	R (06FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
	MUSC	Myalgia/ Upper body muscle aches#	4	05FEB2021	2/1	2	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1126 11261160	NERV	Dizziness/ Light headedness	1	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/Y
	MUSC	Myalgia/ Muscle aches	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		Pain in extremity/ Left upper arm pain	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
>55/ C4591001 1126 11261162	GENRL	Fatigue/ Fatigue	1	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1126 11261163		Injection site pain/ Pain, Injection site	1	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N
	RESP	Throat irritation/ Throat Irritation	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Chills/ Chills	2	01OCT2020	1/3	2	Yes		NA	R (03OCT2020)	N/N
		Injection site pain/ Injection site pain	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
	MUSC	Back pain/ Lower back pain	2	30SEP2020	1/3	2	Yes		NA	R (02OCT2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	1/3	2	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1126 11261164	GENRL	Pain/ Body aches	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1126 11261167	VASC	Pyrexia/ Fever#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
		Flushing/ Facial flushing#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Pain, injection site#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1126 11261169	MUSC	Pain in extremity/ Left upper arm pain	1	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	02OCT2020	2/4	1	Yes		NA	R (05OCT2020)	N/N
		Injection site pruritus/ Injection site itchyess	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C4591001 1126 11261174	GENRL	Pain/ Body aches	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
		Injection site pain/ Injection site pain	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1126 11261175	GENRL	Injection site pain/ Pain, injection site	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ Injection site pain	2	30SEP2020	1/5	2	Yes		NA	R (04OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1126 11261176	GENRL	Chills/ Body chills*		11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ Pain, injection site*		11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Back pain/ Back pain	1	12SEP2020	2/1	3	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		Fatigue/ Fatigue	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	4	11FEB2021	1/3	2	Yes		NA	R (13FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	12FEB2021	2/2	2	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1126 11261179	NERV	Headache/ Headache	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
	RENAL	Nephrolithiasis/ Renal Calculus, worsening	2	09OCT2020	3/1	1	No	O	NA	R (09OCT2020)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	3	03FEB2021	1/3	2	Yes		NA	R (05FEB2021)	N/N
	NERV	Headache/ Headache#	3	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Malaise/ Malaise#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
	>55/ C4591001	GENRL	Injection site pain/ Pain, injection site	1	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1126 11261181 >55/ C4591001	GENRL	Injection site pain/ Left upper arm injection site pain#	3	28JAN2021	1/3	2	Yes		NA	R (30JAN2021)	N/N
1126 11261188 >55/ C4591001	GENRL	Injection site pain/ Left upper arm injection site pain#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
1127 11271006 >55/ C4591001	MUSC	Arthritis/ Arthritis in left thumb	2	03SEP2020	18/C	1	No	O	NA	N	N/N
1127 11271006	MUSC	Musculoskeletal pain/ Hip muscle pain bilateral exercise related	2	26SEP2020	41/C	1	No	O	NA	N	N/N
		Musculoskeletal pain/ knee muscle pain related to exercise	2	26SEP2020	41/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ injection site pain#	3	01FEB2021	1/5	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ injection side pain#	3	20FEB2021	20/7	1	Yes		NA	R (26FEB2021)	N/N
>55/ C4591001	INFEC	Cystitis/ Bladder infection	1	07AUG2020	10/13	1	No	O	NA/TC	R (19AUG2020)	N/N
1127 11271007	INFEC	Urinary tract infection/ urinary tract infection#	2	05FEB2021	172/C	1	No	CD	NA/TC	N	N/N
>55/ C4591001	INFEC	Fungal skin infection/ fungal infection right big toe#	2	03FEB2021	170/C	1	No	CD	NA	N	N/N
1127 11271018											

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1127 11271019	INJ&P	Fall/ fell off exercise bike	2	02SEP2020	16/1	1	No	O	NA	R (02SEP2020)	N/N	
	MUSC	Arthralgia/ pain left hip	2	02SEP2020	16/C	1	No	O	NA	N	N/N	
>55/ C4591001 1127 11271023	RESP	Asthma/ worsening of asthma	2	01OCT2020	45/C	1	No	O	NA/TC	N	N/N	
	NEOPL	Invasive ductal breast carcinoma/ Malignant invasive ductal carcinoma left breast	2	05NOV2020	80/C	3	No	O	NA	N	Y/N	
>55/ C4591001 1127 11271031	EAR	Ear pain/ earache	2	26SEP2020	39/4	1	No	O	NA	R (29SEP2020)	N/N	
>55/ C4591001 1127 11271034	SKIN	Dermatitis contact/ Poison ivy contact dermatitis	1	13AUG2020	14/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1127 11271041	NEOPL	Basal cell carcinoma/ Basal cell carcinoma, face	1	19AUG2020	20/C	2	No	O	NA	N	N/N	
>55/ C4591001 1127 11271046	INFEC	Urinary tract infection/ Urinary tract infection	2	12SEP2020	22/98	1	No	O	NA/TC	R (18DEC2020)	N/N	
	RENAL	Vesical fistula/ Fistula bladder	2	18DEC2020	119/C	2	No	O	NA/TC	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1127 11271061	INFEC	Sinusitis/ sinus infection	1	12AUG2020	8/10	1	No	O	NA/TC	R (21AUG2020)	N/N	
>55/ C4591001 1127 11271067	GENRL	Chills/ chills#	4	27FEB2021	1/3	2	Yes		NA	R (01MAR2021)	N/N	
	MUSC	Arthralgia/ generalized joint pain#	4	27FEB2021	1/3	2	Yes		NA	R (01MAR2021)	N/N	
>55/ C4591001 1127 11271089	INJ&P	Fall/ Fall	2	30AUG2020	1/1	1	No	O	NA	R (30AUG2020)	N/N	
		Fibula fracture/ right fibula fracture	2	30AUG2020	1/C	1	No	O	NA/TC/TCN	N	N/N	
>55/ C4591001 1128 11281009	CARD	Myocardial infarction/ Myocardial Infarction	2	27OCT2020	70/2	4	No	O	NA	R (28OCT2020)	Y/N	
	INFEC	Pneumonia/ Pneumonia	2	28OCT2020	71/32	4	No	O	NA/TC/W	F (28NOV2020)	Y/N	
>55/ C4591001 1128 11281014	INJ&P	Fall/ Fall	2	28AUG2020	2/24	2	No	O	NA/TCN	R (20SEP2020)	Y/N	
		Skin laceration/ FACIAL LACERATIONS	2	28AUG2020	2/1	2	No	O	NA	R (28AUG2020)	N/N	
>55/ C4591001	NERV	Dizziness/ Intermittent Dizziness	2	27OCT2020	68/C	2	No	O	NA	N	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1128 11281022 >55/ C4591001	GENRL	Chills/ Chills#	4	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N
1128 11281044 >55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN, RIGHT ARM#	3	08JAN2021	1/2	2	Yes		NA/TC	R (09JAN2021)	N/N
1128 11281051 >55/ C4591001	INJ&P	Chest injury/ Plueral Contusion	1	17AUG2020	13/29	2	No	O	NA/TC	R (14SEP2020)	N/N
1128 11281052 >55/ C4591001	INJ&P	Fall/ Fall Muscle strain/ Lower Back Strain	1	17AUG2020	13/1	2	No	O	NA	R (17AUG2020)	N/N
1128 11281053 >55/ C4591001	INJ&P	Muscle strain/ Lower Back Strain	1	22AUG2020	18/15	2	No	O	NA/TC	R (05SEP2020)	N/N
1128 11281058 >55/ C4591001	GENRL	Pain/ Body aches#	4	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
1128 11281084 >55/ C4591001	INV	Body temperature increased/ elevated body temperature (99.5F)#	4	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
1128 11281084 >55/ C4591001	GASTR	Diarrhoea/ Diarrhea	2	24SEP2020	23/1	1	No	O	NA	R (24SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1128 11281088	GENRL	Pyrexia/ Subjective Fever	2	12SEP2020	10/1	1	No	O	NA	R (12SEP2020)	N/N
	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	2	12SEP2020	10/1	1	No	O	NA	R (12SEP2020)	N/N
	GENRL	Pyrexia/ Subjective Fever	2	25SEP2020	23/1	1	No	O	NA	R (25SEP2020)	N/N
	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	2	25SEP2020	23/1	1	No	O	NA	R (25SEP2020)	N/N
>55/ C4591001 1128 11281097	GENRL	Chills/ Chills#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ Fever (102.0)#	4	03FEB2021	2/2	2	Yes		NA	R (04FEB2021)	N/N
	GASTR	Nausea/ Nausea#	4	04FEB2021	3/1	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1128 11281104	GENRL	Chills/ Chills#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ Injection site soreness, Left arm#	4	23FEB2021	2/4	1	Yes		NA	R (26FEB2021)	N/N
		Pain/ Body Aches#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
	NERV	Headache/ Headaches#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
>55/ C4591001	GENRL	Pyrexia/ Elevated Fever#	4	25JAN2021	1/C	1	Yes		NA	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1128 11281105	NERV	Headache/ Headache#	4	25JAN2021	1/C	1	Yes		NA/TC	RG	N/N	
>55/ C4591001 1128 11281121	GENRL	Pain/ Body Aches#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N	
		Pyrexia/ Fever#	4	02FEB2021	2/2	1	Yes		NA/TC	R (03FEB2021)	N/N	
	GENRL	Chills/ Chills#	4	03FEB2021	3/1	1	Yes		NA	R (03FEB2021)	N/N	
>55/ C4591001 1128 11281131	GENRL	Fatigue/ Fatigue#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N	
		Pyrexia/ Fever (101.4 F)#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N	
>55/ C4591001 1128 11281138	NEOPL	Oropharyngeal cancer recurrent/ Recurrence of Oropharyngeal Cancer, Left side	2	12NOV2020	64/C	3	No	O	NA/TC	N	Y/N	
>55/ C4591001 1128 11281141	CARD	Coronary artery disease/ Worsening of Coronary Artery Disease#	2	04JAN2021	117/1	3	No	O	NA/TCN	R (04JAN2021)	N/N	
	NERV	Restless legs syndrome/ Restless Leg Syndrome (bilateral)#	2	15JAN2021	128/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001	INFEC	Tooth abscess/ Abscessed Tooth	2	16SEP2020	9/18	1	No	O	NA/TC/TCN	R (03OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1128 11281142	REPRO	Prostatomegaly/ Enlarged Prostate	2	16NOV2020	70/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1128 11281150	PSYCH	Disorientation/ Disorientation	1	19AUG2020	1/2	2	Yes		NA	R (20AUG2020)	N/N
	GENRL	Chills/ Chill Episodes	1	20AUG2020	2/1	2	Yes		NA	R (20AUG2020)	N/N
	NERV	Somnolence/ Drowsyness	1	21AUG2020	3/2	2	Yes		NA	R (22AUG2020)	N/N
	NERV	Lethargy/ Lethargic	2	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N
>55/ C4591001 1128 11281158	INJ&P	Contusion/ HEAD CONTUSION#	4	08FEB2021	13/1	1	No	O	NA/TC	R (08FEB2021)	N/N
		Fall/ Fall#	4	08FEB2021	13/1	1	No	O	NA	R (08FEB2021)	N/N
>55/ C4591001 1128 11281160	GENRL	Injection site pain/ Injection Site Soreness, Left arm#	3	25JAN2021	1/4	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1128 11281179	GENRL	Fatigue/ Fatigue	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N
		Pain/ body aches	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Arthralgia/ sore left shoulder	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N	
	GENRL	Pain/ Body aches	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N	
		Pyrexia/ Fever	2	15SEP2020	2/2	2	Yes		NA/TC	R (16SEP2020)	N/N	
>55/ C4591001 1128 11281185	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	19SEP2020	4/5	2	No	O	NA/TC	R (23SEP2020)	N/N	
>55/ C4591001 1128 11281186	GENRL	Injection site pain/ Injection Site Soreness	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE (LEFT DELTOID) SORENESS#	3	21JAN2021	1/2	2	Yes		NA	R (22JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N	
	MUSC	Myalgia/ muscle pain#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N	
>55/ C4591001 1128 11281189	GENRL	Fatigue/ fatigue#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N	
	MUSC	Myalgia/ left deltoid soreness#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N	
>55/ C4591001 1128 11281191	GENRL	Chills/ Chills	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1128 11281192	GENRL	Injection site pain/ Injection Site Soreness, Left arm#	3	21JAN2021	1/2	1	Yes		NA/TC	R (22JAN2021)	N/N
	MUSC	Osteoarthritis/ worsening of right hip osteoarthritis#	4	23FEB2021	15/C	3	No	O	NA/TCN	RG	Y/N
>55/ C4591001 1128 11281206	GENRL	Chills/ Chills#	4	18JAN2021	1/3	1			NA/TC	R (20JAN2021)	N/N
		Fatigue/ Fatigue#	4	18JAN2021	1/3	1			NA/TC	R (20JAN2021)	N/N
		Injection site pain/ Left arm Injection Site Sornes#	4	18JAN2021	1/3	1			NA/TC	R (20JAN2021)	N/N
>55/ C4591001 1128 11281207	NEOPL	Basal cell carcinoma/ Skin, Left side Neck Basal Cell Carcinoma, Ulcerated	2	25SEP2020	12/C	2	No	O	NA	N	N/N
>55/ C4591001 1128 11281213	GENRL	Injection site pain/ INJECTION SITE SORENESS, LEFT ARM	1	27AUG2020	1/4	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE SORENESS, LEFT ARM	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C4591001 1128 11281214	GENRL	Injection site pain/ Injection Site Soreness left arm#	3	05JAN2021	1/2	1	Yes		NA/TC	R (06JAN2021)	N/N
	GENRL	Injection site pain/ Left arm soreness at injection site#	4	25JAN2021	1/2	1			NA/TC	R (26JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1128 11281215	MUSC	Pain/ Body Ache#	4	25JAN2021	1/2	1			NA/TC	R (26JAN2021)	N/N
		Musculoskeletal stiffness/ Slight Neck Stiffness#	4	25JAN2021	1/2	1			NA/TC	R (26JAN2021)	N/N
	GASTR	Nausea/ Nausea	2	18SEP2020	1/3	2	Yes		NA/TC	R (20SEP2020)	N/N
>55/ C4591001 1128 11281221	GENRL	Pyrexia/ Fever	2	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness, left arm	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Pain/ Body Aches	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
>55/ C4591001 1128 11281223	GENRL	Injection site pain/ Injection Site Soreness, left arm	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		Pain/ Body Aches	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Pyrexia/ low grade fever#	4	02FEB2021	1/2	1	Yes		NA/TC	R (03FEB2021)	N/N
>55/ C4591001 1128 11281226	GENRL	Pain/ body aches#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ INJECTION SITE SORENESS#	3	22JAN2021	2/3	1	Yes		NA/TC	R (24JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1128 11281233 >55/ C4591001 1128 11281242	GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1128 11281250	NEOPL	Breast cancer/ Breast Cancer	2	27DEC2020	89/C	3	No	O	NA	RG	Y/N
>55/ C4591001 1128 11281260	GENRL	Injection site pain/ Injection Site Soreness, Right arm#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
>55/ C4591001 1128 11281264	RESP	Oropharyngeal pain/ Sore Throat#	3	18JAN2021	7/3	1	Yes		NA	R (20JAN2021)	N/N
>55/ C4591001 1128 11281264	GENRL	Pain/ Body Aches	1	02SEP2020	1/3	1	Yes		NA/TC	R (04SEP2020)	N/N
>55/ C4591001 1128 11281266	GENRL	Pain/ Body Aches	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C4591001 1128 11281266	GENRL	Injection site pain/ Soreness to left deltoid, at injection site#	3	31DEC2020	2/2	1	Yes		NA	R (01JAN2021)	N/N
>55/ C4591001 1128 11281270	MUSC	Myalgia/ left deltoid pain#	3	28JAN2021	1/3	2	Yes		NA	R (30JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue#	3	29JAN2021	2/2	2	Yes		NA	R (30JAN2021)	N/N
>55/ C4591001 1128 11281273	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	1/3	1	Yes		NA/TC	R (04SEP2020)	N/Y
	NERV	Headache/ Headache	1	07SEP2020	6/2	1	No	O	NA/TC	R (08SEP2020)	N/N
>55/ C4591001 1128 11281277	GENRL	Fatigue/ Fatigue#	4	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ Headache#	4	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001 1128 11281278	GENRL	Fatigue/ fatigue	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
		Injection site pain/ Injection Site Pain, left arm	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	NERV	Headache/ Headache	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Pain/ body aches	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
	NEOPL	Squamous cell carcinoma of skin/ SQUAMOUS CELL CARCINOMA, RIGHT LATERAL TEMPLE	2	01OCT2020	9/5	2	No	O	NA	R (05OCT2020)	N/N
>55/ C4591001 1128 11281293	GENRL	Injection site pain/ injection site soreness	2	30SEP2020	2/5	1	Yes		NA	R (04OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1128 11281296	BLOOD	Anaemia/ anemia	2	23DEC2020	86/C	2	No	O	NA/TC	N	N/N
	INJ&P	Post-traumatic pain/ post traumatic pain	2	23DEC2020	86/11	2	No	O	NA/TC	R (02JAN2021)	Y/N
		Road traffic accident/ MOTOR VEHICLE ACCIDENT	2	23DEC2020	86/3	2	No	O	NA/TC/TCN	R (25DEC2020)	Y/N
	MUSC	Arthralgia/ severe right shoulder pain	2	23DEC2020	86/C	2	No	O	NA/TC	N	N/N
	NERV	Headache/ soreness to back of head	2	23DEC2020	86/3	2	No	O	NA/TC	R (25DEC2020)	N/N
>55/ C4591001 1128 11281298	GENRL	Injection site pain/ Soreness at injection site	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Pyrexia/ Subjective Fever	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
>55/ C4591001 1128 11281307	GENRL	Injection site pain/ Injection Site Soreness, Left arm#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness, Left arm#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	MUSC	Neck pain/ Neck pain#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001	GENRL	Fatigue/ Fatigue (Vaccine Reaction)	1	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1128 11281308		Injection site pain/ Injection site Left Arm Soreness (Vaccine Reaction)	1	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ Fatigue (vaccine reaction)	2	13OCT2020	1/2	2	Yes		NA	R (14OCT2020)	N/N
	GENRL	Injection site pain/ injection site Left Arm Soreness (Vaccine Reaction)	2	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
>55/ C4591001 1128 11281314	GENRL	Injection site pain/ Left Arm Injection Site Soreness	1	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Left Arm Injection Site Soreness	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
>55/ C4591001 1128 11281316	GENRL	Malaise/ GENERAL MALASIE#	4	28JAN2021	2/4	1	Yes		NA	R (31JAN2021)	N/N
		Pyrexia/ FEVER (101.5F)#	4	28JAN2021	2/2	1	Yes		NA/TC	R (29JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	28JAN2021	2/1	1	Yes		NA/TC	R (28JAN2021)	N/N
	EYE	Cataract/ BILATERAL CATARACTS#	4	03FEB2021	8/C	1	No	O	NA	RG	N/N
>55/ C4591001 1128 11281320	EAR	Vertigo/ Vertigo	2	08OCT2020	10/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1128 11281321	GENRL	Chills/ Chills	2	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
		Pain/ Body Aches	2	03OCT2020	2/2	2	Yes		NA/TC	R (04OCT2020)	N/N
		Pyrexia/ Fever	2	03OCT2020	2/2	2	Yes		NA/TC	R (04OCT2020)	N/N
	NERV	Headache/ Headache	2	03OCT2020	2/2	2	Yes		NA/TC	R (04OCT2020)	N/N
>55/ C4591001 1128 11281322	GENRL	Injection site pain/ INJECTION SITE SORENESS#	4	05FEB2021	1/4	1	Yes		NA	R (08FEB2021)	N/N
>55/ C4591001 1128 11281329	MUSC	Myalgia/ left deltoid pain#	3	18JAN2021	1/2	2	Yes		NA	R (19JAN2021)	N/N
>55/ C4591001 1128 11281336	NERV	Headache/ Headache	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1128 11281340	NERV	Headache/ HEADACHE	1	14SEP2020	4/1	1	Yes		NA/TC	R (14SEP2020)	N/N
	GENRL	Chills/ CHILLS#	4	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
		Fatigue/ FATIGUE#	4	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1128 11281344		Injection site pain/ INJECTION STIE (LEFT DELTOID) PAIN#	4	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
	MUSC	Myalgia/ MYALGIA#	4	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
	BLOOD	Lymph node pain/ bilateral submaxillary lymph node tenderness	1	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N
	GASTR	Diarrhoea/ loose stools	1	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N
	VASC	Flushing/ flushed face	1	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N
	BLOOD	Lymph node pain/ bilateral submaxillary lymph node tenderness	2	04OCT2020	2/2	1	Yes		NA	R (05OCT2020)	N/N
>55/ C4591001 1128 11281346	GASTR	Diarrhoea/ loose stools	2	04OCT2020	2/2	1	Yes		NA	R (05OCT2020)	N/N
	VASC	Flushing/ flushed face	2	04OCT2020	2/2	1	Yes		NA	R (05OCT2020)	N/N
	INFEC	Furuncle/ BOIL, TOP OF HEAD	2	05OCT2020	3/6	2	No	O	NA/TC	R (10OCT2020)	N/N
>55/ C4591001 1128 11281351	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	29OCT2020	27/10	2	No	O	NA/TC	R (07NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1128 11281353	GENRL	Malaise/ GENERAL MALAISE#	4	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1128 11281354	GENRL	Injection site pain/ Injection Site Soreness	2	08OCT2020	2/5	1	Yes		NA/TC	R (12OCT2020)	N/N
		Injection site pain/ Left Side of Neck to Injection Site Soreness	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N
		Pain/ Body Aches	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
		Pyrexia/ Subjective Fever	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	NERV	Headache/ Worsening of Headache	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
>55/ C4591001 1128 11281356	GENRL	Chills/ Chills	1	16SEP2020	3/2	1	Yes		NA	R (17SEP2020)	N/N
		Pain/ Body aches	1	16SEP2020	3/2	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ Fever	1	16SEP2020	3/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Chills/ Chills	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
>55/ C4591001 1128 11281371	GENRL	Injection site pain/ INJECTION SITE PAIN#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ FATIGUE#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
		Injection site pain/ INJECTION SITE PAIN#	4	19JAN2021	1/3	1	Yes		NA/TC	R (21JAN2021)	N/N
>55/ C4591001 1128 11281375	GENRL	Injection site pain/ Injection site soreness, left arm#	3	09FEB2021	1/5	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Chills/ Chills#	3	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
	SKIN	Urticaria/ Hives, whole body#	3	10FEB2021	2/4	2	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1128 11281380	GASTR	Diarrhoea/ Diarrhea	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
	SKIN	Rash/ Bilateral Armpit Rash	2	18OCT2020	11/6	1	No	O	NA/TC	R (23OCT2020)	N/N
>55/ C4591001 1128 11281383	GENRL	Fatigue/ FATIGUE	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Injection site pain/ LEFT ARM injection site PAIN	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Pain/ BODY ACHES	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
>55/ C4591001 1129 11291002	GENRL	Injection site pain/ left arm-injection site pain#	4	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1129 11291004	VASC	Hypertension/ hypertension	2	15JAN2021	151/C	2	No	O	NA/TC	N	N/N	
	NERV	Dizziness/ dizziness	2	16JAN2021	152/3	1	No	O	NA	R (18JAN2021)	N/N	
>55/ C4591001 1129 11291007	GENRL	Injection site pain/ left deltoid injection site soreness#	4	22JAN2021	1/4	1	Yes		NA	R (25JAN2021)	N/N	
>55/ C4591001 1129 11291008	SKIN	Dermatitis/ Back Dermatitis	1	12AUG2020	15/31	2	No	O	NA/TC	R (11SEP2020)	N/N	
>55/ C4591001 1129 11291009	PSYCH	Insomnia/ insomnia#	3	31DEC2020	8/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1129 11291011	GENRL	Injection site pain/ left deltoid muscle injection tenderness#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N	
	GASTR	Nausea/ nausea#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N	
	GENRL	Injection site pain/ left deltoid muscle injection site tenderness#	4	25JAN2021	1/4	2	Yes		NA/TC	R (28JAN2021)	N/N	
	NERV	Headache/ headache#	4	25JAN2021	1/2	2	Yes		NA/TC	R (26JAN2021)	N/N	
>55/ C4591001	INJ&P	Muscle injury/ muscle injury	2	30NOV2020	105/C	1	No	O	NA/TC	N	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1129 11291015 >55/ C4591001 1129 11291018	MUSC	Pain in extremity/ arm pain	2	30OCT2020	74/6	2	No	O	NA/TC	R (04NOV2020)	N/N
1129 11291018 >55/ C4591001 1129 11291024	MUSC	Pain in extremity/ arm pain	2	15DEC2020	120/2	1	No	O	NA	R (16DEC2020)	N/N
1129 11291024 >55/ C4591001 1129 11291026	GENRL	Fatigue/ fatigue#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
1129 11291026 >55/ C4591001 1129 11291027	PSYCH	Injection site pain/ left deltoid injection site tenderness#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
1129 11291027 >55/ C4591001 1129 11291027	PSYCH	Depression/ depression	2	28SEP2020	29/C	2	No	O	NA/TC	RG	N/N
1129 11291027 >55/ C4591001 1129 11291027	INJ&P	Fall/ fall	2	20DEC2020	112/1	2	No	O	NA/TC	R (20DEC2020)	N/N
1129 11291027 >55/ C4591001 1129 11291027	INJ&P	Fall/ fall	2	28DEC2020	120/1	2	No	O	NA	R (28DEC2020)	N/N
1129 11291027 >55/ C4591001 1129 11291027	INJ&P	Joint injury/ injured right hip strained tissue	2	28DEC2020	120/18	2	No	O	NA/TC	R (14JAN2021)	N/N
1129 11291027 >55/ C4591001 1129 11291027	GENRL	Injection site pain/ right deltoid muscle injection site tenderness#	3	31DEC2020	1/4	1	Yes		NA	R (03JAN2021)	N/N
1129 11291027 >55/ C4591001 1129 11291027	GENRL	Pain/ body aches#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Pyrexia/ fever#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
>55/ C4591001 1129 11291028	METAB	Type 2 diabetes mellitus/ Worsened type 2 diabetes	2	08SEP2020	21/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1129 11291031	INFEC	Urinary tract infection/ urinary tract infection#	4	05FEB2021	12/8	1	No	O	NA/TC/TCN	R (12FEB2021)	N/N
>55/ C4591001 1129 11291032	GASTR	Vomiting/ vomiting#	4	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Chills/ chills#	4	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N
		Fatigue/ fatigue#	4	25JAN2021	1/1	3	Yes		NA	R (25JAN2021)	N/N
		Pain/ generalized body ache#	4	25JAN2021	1/7	3	Yes		NA	R (31JAN2021)	N/N
		Pyrexia/ mild fever#	4	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N
	MUSC	Osteoarthritis/ worsened degenerative joint disease left shoulder#	4	16FEB2021	23/2	3	No	O	NA/TC/TCN	R (17FEB2021)	Y/N
>55/ C4591001 1129 11291035	GENRL	Swelling/ bilateral transient neck tissue swelling	1	03AUG2020	1/2	1	Yes		NA	R (04AUG2020)	N/N
	METAB	Diabetes mellitus/ worsening diabetes mellitus#	4	24FEB2021	31/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	VASC	Hypertension/ worsening hypertension#	4	24FEB2021	31/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1129 11291037	NEOPL	Squamous cell carcinoma of head and neck/ Metastatic Squamous Cell Carcinoma of head and neck	2	30NOV2020	99/C	3	No	O	NA/TC	RG	Y/N	
>55/ C4591001 1129 11291038	INJ&P	Fall/ fall	2	12NOV2020	81/1	2	No	O	NA	R (12NOV2020)	N/N	
		Jaw fracture/ fracture jaw right side	2	12NOV2020	81/13	3	No	O	NA	R (24NOV2020)	N/N	
		Tooth fracture/ broken tooth left upper incisor	2	12NOV2020	81/C	2	No	O	NA	RG	N/N	
	NERV	Syncope/ syncopal episode	2	12NOV2020	81/1	3	No	O	NA	R (12NOV2020)	N/N	
>55/ C4591001 1129 11291044	INFEC	Cellulitis/ left arm cellulitis	2	17SEP2020	24/32	2	No	O	NA	R (18OCT2020)	N/N	
>55/ C4591001 1129 11291046	NERV	Intracranial aneurysm/ Aneurysm x3 Mid lateral Cranial Artery#	2	22JAN2021	152/19	3	No	O	NA/TC/TCN	R (09FEB2021)	Y/N	
		Vocal cord paralysis/ right vocal cord paralysis#	2	22JAN2021	152/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1129 11291057	INJ&P	Limb injury/ right great toe avulsion injury	1	14AUG2020	8/48	1	No	O	NA/TC	R (30SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Nausea/ nausea#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Chills/ chills#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
		Fatigue/ fatigue#	4	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
	NERV	Headache/ worsening headache#	4	26JAN2021	1/2	2	Yes		NA	R (27JAN2021)	N/N
	GASTR	Diarrhoea/ diarrhea#	4	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Pyrexia/ fever#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	SKIN	Skin lesion/ skin lesion uncertain etiology tip of nose less than 0.5cm#	4	01FEB2021	7/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1129 11291059	BLOOD	Lymphadenopathy/ Left supraclavicular adenopathy	2	31AUG2020	4/C	1	Yes		NA/TCN	RG	N/N
	VASC	Hypertension/ worsening hypertension#	2	01JAN2021	127/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1129 11291067	GENRL	Injection site pain/ left deltoid muscle injection site tenderness#	3	01FEB2021	1/4	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Malaise/ Malaise#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
		Pain/ Generalized Body Aches#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1129 11291074	EAR	Vertigo/ Worsened Vertigo	1	21AUG2020	12/4	3	No	O	NA	R (24AUG2020)	Y/N	
	EYE	Diplopia/ double vision	1	21AUG2020	12/2	3	No	O	NA	R (22AUG2020)	Y/N	
>55/ C4591001 1129 11291075	INJ&P	Skin abrasion/ Abrasion left middle toe	2	18SEP2020	19/46	2	No	O	NA/TC	R (02NOV2020)	N/N	
	INFEC	Herpes virus infection/ worsened recurrent herpetic lesion, gluteal area	2	21OCT2020	52/13	1	No	O	NA	R (02NOV2020)	N/N	
	GASTR	Gastroesophageal reflux disease/ GERD#	4	16FEB2021	15/C	2	No	O	NA/TC	N	N/N	
	RENAL	Hypertonic bladder/ overactive bladder#	4	26FEB2021	25/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1129 11291084	GENRL	Fatigue/ fatigue#	4	25JAN2021	1/2	1	Yes		NA/TCN	RS (26JAN2021)	N/N	
>55/ C4591001 1129 11291085	GENRL	Fatigue/ fatigue#	4	08JAN2021	1/2	1	Yes		NA/TCN	R (09JAN2021)	N/N	
	MUSC	Pain in extremity/ left are soreness#	4	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N	
>55/ C4591001 1129 11291086	INV	Intraocular pressure increased/ worsened increased intraocular pressure#	2	19JAN2021	142/C	2	No	O	NA/TC	N	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NEOPL	Basal cell carcinoma/ basal cell skin cancer-left lower leg#	2	02FEB2021	156/C	2	No	O	NA/TCN	N	N/N
	EYE	Macular oedema/ macular edema-right eye#	2	16FEB2021	170/5	2	No	O	NA/TC	R (20FEB2021)	N/N
>55/ C4591001 1129 11291090	ENDO	Hypothyroidism/ Hypothyroidism-Subject was prescribed Levothyroxine 50 po qd on 18sep2020	2	18SEP2020	19/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1129 11291091	GENRL	Fatigue/ mild fatigue#	2	01DEC2020	2/2	1	Yes		NA	R (02DEC2020)	N/N
		Injection site pain/ injection pain#	2	01DEC2020	2/2	1	Yes		NA	R (02DEC2020)	N/N
>55/ C4591001 1129 11291095	MUSC	Osteoarthritis/ worsened left knee degenerative joint disease	2	05OCT2020	36/2	3	No	O	NA	R (06OCT2020)	Y/N
>55/ C4591001 1129 11291100	PSYCH	Depression/ worsening depression	2	03DEC2020	95/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1129 11291105	GENRL	Pain/ generalized body aches#	4	27JAN2021	1/2	2	Yes		NA/TC	R (28JAN2021)	N/N
	NERV	Dizziness/ dizziness#	4	27JAN2021	1/2	2	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001	GASTR	Abdominal distension/ intermittent bloating	1	18AUG2020	2/14	1	No	O	NA	R (31AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1129 11291108		Flatulence/ intermittent flatulence	1	18AUG2020	2/14	1	No	O	NA	R (31AUG2020)	N/N
>55/ C4591001 1129 11291111	INFEC	Eye infection/ right eye-infection#	4	01MAR2021	29/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1129 11291113	MUSC	Back pain/ worsening back pain	2	26SEP2020	19/38	2	No	O	NA/TC	R (02NOV2020)	N/N
	GENRL	Injection site pain/ left deltoid injection site pain#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1129 11291114	CARD	Mitral valve prolapse/ Mitral Valve prolapse	2	06OCT2020	29/C	1	No	O	NA	N	N/N
>55/ C4591001 1129 11291118	VASC	Hypertension/ worsened hypertension#	4	16FEB2021	22/9	1	No	O	NA/TC	R (24FEB2021)	N/N
>55/ C4591001 1129 11291122	INJ&P	Ankle fracture/ right ankle fracture#	4	19FEB2021	26/C	2	No	O	NA/TCN	RG	N/N
>55/ C4591001 1129 11291123	RENAL	Urinary retention/ Urinary retention with emergency catheter	1	04SEP2020	18/36	2	No	O	NA/TCN	R (09OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1129 11291127	INFEC	Sepsis/ Sepsis#	2	16JAN2021	131/11	3	No	O	NA/TC/TCN	R (26JAN2021)	Y/N	
	MUSC	Back pain/ intermittent lower back pain#	2	16JAN2021	131/1	2	No	O	NA/TC	R (16JAN2021)	N/N	
		Neck pain/ neck pain#	2	16JAN2021	131/11	1	No	O	NA/TC	R (26JAN2021)	N/N	
	BLOOD	Pancytopenia/ Pancytopenia#	2	20JAN2021	135/C	3	No	O	NA	RG	Y/N	
		Splenomegaly/ Splenomegaly#	2	20JAN2021	135/C	1	No	O	NA	N	N/N	
	GASTR	Pancreatic calcification/ Pancreatic Calculus#	2	20JAN2021	135/C	1	No	O	NA	N	N/N	
	VASC	Hypertension/ worsened hypertension#	2	20JAN2021	135/C	1	No	O	NA/TC	RG	N/N	
	GASTR	Gastritis erosive/ erosive gastropathy#	2	22JAN2021	137/C	2	No	O	NA/TC	RG	N/N	
HEPAT	Cholelithiasis/ Gallstones#	2	22JAN2021	137/C	1	No	O	NA	N	N/N		
>55/ C4591001 1129 11291132	GASTR	Diarrhoea/ diarrhea	2	24SEP2020	11/1	1	No	O	NA	R (24SEP2020)	N/N	
	NERV	Headache/ headache	2	05OCT2020	22/4	1	No	O	NA	R (08OCT2020)	N/N	
>55/ C4591001 1129 11291134	GENRL	Injection site pain/ soreness at injection site-left arm#	4	26JAN2021	1/3	1	Yes		NA/TC	R (28JAN2021)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1129 11291138	MUSC	Myalgia/ generalized muscle soreness#	4	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
	INFEC	Osteomyelitis/ osteomyelitis distal phalanx right 3rd toe	1	31AUG2020	7/27	3	No	O	NA/TC	R (26SEP2020)	Y/N
	EYE	Retinal detachment/ detached left retina	2	26OCT2020	42/3	2	No	O	NA/TC/TCN	R (28OCT2020)	N/N
>55/ C4591001 1129 11291139	MUSC	Myalgia/ Left Deltoid Tenderness	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
>55/ C4591001 1129 11291150	SKIN	Erythema/ Left deltoid erythema	1	25AUG2020	1/2	2	Yes		NA	R (26AUG2020)	N/N
	GENRL	Fatigue/ fatigue	1	15SEP2020	22/2	2	Yes		NA	R (16SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	1	15SEP2020	22/2	2	Yes		NA/TC	R (16SEP2020)	N/N
		Myalgia/ Muscle pain	1	15SEP2020	22/2	2	Yes		NA/TC	R (16SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N
	INFEC	Urinary tract infection/ Urinary tract infection	2	31OCT2020	47/9	2	No	O	NA/TC	R (08NOV2020)	N/N
	GENRL	Chills/ chills#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	Fatigue/ fatigue#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1129 11291161	MUSC	Rotator cuff syndrome/ left rotator cuff tear	2	21NOV2020	61/C	1	No	O	NA	RG	N/N	
	CARD	Coronary artery disease/ worsening coronary artery disease	2	01DEC2020	71/49	3	No	O	NA/TC/TCN	R (18JAN2021)	Y/N	
	GENRL	Chills/ chills#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N	
		Pyrexia/ mild fever#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N	
	MUSC	Muscular weakness/ muscle weakness#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N	
		Myalgia/ myalgia#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N	
>55/ C4591001 1129 11291166	CARD	Myocardial infarction/ myocardial infarction#	2	03FEB2021	129/1	4	No	O	NA/W	F (03FEB2021)	Y/N	
>55/ C4591001 1129 11291173	GENRL	Asthenia/ weakness	2	04NOV2020	31/1	2	No	O	NA/TCN	R (04NOV2020)	N/N	
	SKIN	Hyperhidrosis/ diaphoresis	2	04NOV2020	31/1	2	No	O	NA/TCN	R (04NOV2020)	N/N	
>55/ C4591001 1129 11291175	INFEC	Urinary tract infection/ urinary tract infection	2	23OCT2020	19/13	2	No	O	NA/TC	R (04NOV2020)	N/N	
>55/ C4591001	GENRL	Injection site pain/ left arm (deltoid muscle) injection site tenderness#	3	05JAN2021	1/2	2	Yes		NA/TC	R (06JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1129 11291176	GENRL	Injection site pain/ left arm (deltoid muscle) injection site tenderness#	4	25JAN2021	1/2	2	Yes		NA/TC	R (26JAN2021)	N/N
>55/ C4591001 1129 11291180	GASTR	Salivary gland enlargement/ left salivary gland enlargement#	2	10JAN2021	98/8	1	No	O	NA	R (17JAN2021)	N/N
>55/ C4591001 1129 11291183	MUSC	Arthralgia/ left shoulder soreness	1	18SEP2020	4/2	2	Yes		NA/TC	R (19SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	06OCT2020	1/10	1	Yes		NA	R (15OCT2020)	N/N
	MUSC	Arthralgia/ bilateral shoulder pain	2	06OCT2020	1/10	2	Yes		NA/TC	R (15OCT2020)	N/N
		Myalgia/ bilateral upper extremity muscle pain	2	06OCT2020	1/10	2	Yes		NA/TC	R (15OCT2020)	N/N
	GENRL	Chills/ chills#	4	15FEB2021	1/2	2	Yes		NA	R (16FEB2021)	N/N
	NERV	Headache/ headache#	4	15FEB2021	1/3	2	Yes		NA	R (17FEB2021)	N/N
	RENAL	Urinary tract obstruction/ Urinary Obstruction#	4	09MAR2021	23/2	3	No	O	NA/TCN	R (10MAR2021)	Y/N
	REPRO	Benign prostatic hyperplasia/ Worsened BPH#	4	09MAR2021	23/C	2	No	O	NA/TC	N	N/N
>55/ C4591001	GASTR	Nausea/ Nausea#	4	23FEB2021	2/1	3	Yes		NA	R (23FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1129 11291186	NERV	Dysgeusia/ Dysgeusia#	4	24FEB2021	3/C	1	Yes		NA	N	N/N
		Parosmia/ Hyperosmia#	4	24FEB2021	3/C	1	Yes		NA	N	N/N
>55/ C4591001 1129 11291188	GENRL	Injection site pain/ left arm injection site muscle pain	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1129 11291191	INJ&P	Arthropod bite/ let lower leg insect bite	1	09OCT2020	19/3	1	No	O	NA/TC	R (11OCT2020)	N/N
	SKIN	Urticaria/ allergic urticaria-bilateral hands	1	11OCT2020	21/C	1	No	O	NA/TC	RG	N/N
		Urticaria/ allergic urticaria-bilateral legs	1	11OCT2020	21/C	1	No	O	NA/TC/TCN	RG	N/N
>55/ C4591001 1129 11291194	METAB	Hypercholesterolaemia/ worsening hypercholesterolemia#	2	25JAN2021	106/C	2	No	O	NA/TC	N	N/N
	GENRL	Injection site pain/ left deltoid muscle site injection soreness#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1129 11291200	GENRL	Fatigue/ fatigue#	4	12JAN2021	1/2	1	Yes		NA/TCN	R (13JAN2021)	N/N
	NERV	Headache/ headache#	4	12JAN2021	1/2	1	Yes		NA/TCN	R (13JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1129 11291204	GASTR	Nausea/ nausea#	3	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Injection site erythema/ left deltoid-redness at injection site#	3	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ left deltoid-tenderness at injection site#	3	06JAN2021	1/3	1	Yes		NA/TC	R (08JAN2021)	N/N
	NERV	Headache/ headache#	3	06JAN2021	1/1	1	Yes		NA/TC	R (06JAN2021)	N/N
	GASTR	Nausea/ nausea#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ left deltoid muscle tenderness at injection site#	4	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
	NERV	Headache/ headache#	4	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
>55/ C4591001 1129 11291206	NERV	Dizziness/ Intermittent dizziness	1	02OCT2020	5/C	1	No	O	NA	N	N/N
>55/ C4591001 1129 11291207	GENRL	Chills/ chills	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
		Pyrexia/ fever	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
>55/ C4591001 1129 11291214	MUSC	Myalgia/ left deltoid muscle tenderness	2	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1129 11291217	METAB	Type 2 diabetes mellitus/ type 2 diabetes mellitus	2	28OCT2020	2/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1129 11291219	MUSC	Osteoarthritis/ worsened osteoarthritis#	4	15FEB2021	14/3	1	No	O	NA	R (17FEB2021)	N/N	
>55/ C4591001 1129 11291221	INJ&P	Tendon rupture/ Ruptured left bicep tendon#	4	22FEB2021	22/C	3	No	O	NA/TC/TCN	N	N/N	
	MUSC	Rotator cuff syndrome/ right rotator cuff tear#	4	22FEB2021	22/C	3	No	O	NA/TC	N	N/N	
	GASTR	Constipation/ constipation#	4	24FEB2021	24/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1129 11291222	GENRL	Chills/ chills	2	03NOV2020	1/3	2	Yes		NA/TC	R (05NOV2020)	N/N	
	MUSC	Arthralgia/ joint pain-generalized	2	03NOV2020	1/3	2	Yes		NA/TC	R (05NOV2020)	N/N	
		Myalgia/ muscle pain	2	03NOV2020	1/3	2	Yes		NA/TC	R (05NOV2020)	N/N	
	EAR	Tinnitus/ tinnitus-left ear	2	29NOV2020	27/C	1	Yes		NA	N	N/N	
>55/ C4591001 1129 11291231	MUSC	Pain in extremity/ Arm Soreness#	3	02FEB2021	1/3	1	Yes		NA/TC/TCN	R (04FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1129 11291232	INFEC	Urinary tract infection/ urinary tract infection	1	01NOV2020	19/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1129 11291233	GENRL	Injection site erythema/ injection site redness#	4	13JAN2021	1/6	1	Yes		NA	R (18JAN2021)	N/N	
	GENRL	Chills/ chills#	4	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N	
>55/ C4591001 1129 11291236	GENRL	Injection site pain/ left deltoid muscle injection site tenderness#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N	
	GENRL	Injection site erythema/ left deltoid-erythema at injection site#	3	13JAN2021	23/3	1	Yes		NA	R (15JAN2021)	N/N	
		Injection site swelling/ left deltoid-swelling at injection site#	3	13JAN2021	23/3	1	Yes		NA	R (15JAN2021)	N/N	
>55/ C4591001 1129 11291237	INJ&P	Thermal burn/ burn on left arm#	2	07JAN2021	63/C	1	No	O	NA	RG	N/N	
>55/ C4591001 1129 11291243	GENRL	Injection site pain/ left deltoid muscle injection site tenderness#	3	19JAN2021	2/1	2	Yes		NA/TC	R (19JAN2021)	N/N	
	GENRL	Pain/ generalized body aches#	4	09FEB2021	2/2	2	Yes		NA/TC	R (10FEB2021)	N/N	
		Pyrexia/ fever#	4	09FEB2021	2/2	2	Yes		NA/TC	R (10FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1129 11291246	INJ&P	Joint injury/ left knee strain	1	06NOV2020	14/7	1	No	O	NA/TC	R (12NOV2020)	N/N
	INJ&P	Muscle rupture/ right calf muscle tear#	2	18JAN2021	67/11	1	No	O	NA/TC	R (28JAN2021)	N/N
	GENRL	Injection site pain/ left arm injection site pain#	3	03FEB2021	2/1	2	Yes		NA/TC	R (03FEB2021)	N/N
>55/ C4591001 1130 11301004	GENRL	Pain/ generalized body aches#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1130 11301007	METAB	Gout/ worsening gout#	3	08FEB2021	19/29	1	No	O	NA/TC	R (08MAR2021)	N/N
	GENRL	Pain/ body aches#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1130 11301009	RENAL	Dysuria/ Dysuria	1	01SEP2020	7/50	1	No	O	NA	R (20OCT2020)	N/N
>55/ C4591001 1130 11301010	NEOPL	Rectal cancer/ Worsening of Rectal Cancer#	4	16FEB2021	1/C	2	No	O	NA/TC	N	N/N
	GASTR	Nausea/ Nausea related to Folfiri treatment#	4	10MAR2021	23/C	3	No	O	NA/TC	N	N/N
		Vomiting/ Vomiting related to Folfiri treatment#	4	10MAR2021	23/C	3	No	O	NA	N	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1130 11301018	NERV	Syncope/ Syncope episode#	4	10MAR2021	23/1	3	No	O	NA/TC	R (10MAR2021)	N/N
	VASC	Hypertension/ Acute Hypertension#	4	11MAR2021	24/1	3	No	O	NA/TC	R (11MAR2021)	N/N
	GENRL	Fatigue/ Extreme fatigue#	4	18FEB2021	1/4	2	Yes		NA	R (21FEB2021)	N/N
	GENRL	Chills/ Chills#	4	19FEB2021	2/1	2	Yes		NA	R (19FEB2021)	N/N
	MUSC	Arthralgia/ Joint Pain - generalized#	4	19FEB2021	2/3	2	Yes		NA	R (21FEB2021)	N/N
		Myalgia/ Muscle soreness#	4	19FEB2021	2/3	2	Yes		NA	R (21FEB2021)	N/N
	NERV	Headache/ Headache#	4	19FEB2021	2/3	2	Yes		NA	R (21FEB2021)	N/N
>55/ C4591001 1130 11301019	VASC	Peripheral coldness/ Icy Cold Hands#	4	19FEB2021	2/1	2	Yes		NA	R (19FEB2021)	N/N
	GASTR	Colitis microscopic/ collageous colitis	2	09DEC2020	78/C	2	No	O	NA	N	N/N
>55/ C4591001 1130 11301031	GENRL	Injection site rash/ Rash - injection site#	4	09FEB2021	1/11	1	Yes		NA	R (19FEB2021)	N/N
	SKIN	Rash/ Rash- various places on body#	4	09FEB2021	1/11	1	Yes		NA	R (19FEB2021)	N/N
	INFEC	Urinary tract infection/ Urinary Tract Infection#	4	07MAR2021	27/C	1	No	O	NA/TC	RG	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1130 11301039	NERV	Transient ischaemic attack/ Transient Ischemic Attack#	4	07MAR2021	27/1	2	No	O	NA/TC	R (07MAR2021)	Y/N
	GASTR	Colitis microscopic/ worsening microscopic colitis	1	11SEP2020	9/61	2	No	O	NA/TC	R (10NOV2020)	N/N
	INV	Blood pressure increased/ Worsened Acute Blood Pressure Elevation	2	04OCT2020	5/1	2	No	O	NA	R (04OCT2020)	N/N
>55/ C4591001 1130 11301040	MUSC	Back pain/ Acute Back Pain	2	04OCT2020	5/1	2	No	O	NA	R (04OCT2020)	N/N
	GENRL	Chills/ chills#	4	18FEB2021	1/3	1	Yes		NA/TC	R (20FEB2021)	N/N
		Fatigue/ Fatigue#	4	18FEB2021	1/3	1	Yes		NA/TC	R (20FEB2021)	N/N
		Pain/ body aches#	4	18FEB2021	1/3	1	Yes		NA/TC	R (20FEB2021)	N/N
	MUSC	Pain in extremity/ Arm soreness#	4	18FEB2021	1/3	1	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ Headache (pressure behind the eyes)#	4	18FEB2021	1/3	1	Yes		NA/TC	R (20FEB2021)	N/N
>55/ C4591001 1130 11301050	NERV	Thoracic radiculopathy/ thoracic radiculopathy	2	25DEC2020	88/23	1	No	O	NA	R (16JAN2021)	N/N
	INFEC	Genital herpes/ worsening genital herpes	2	11JAN2021	105/9	2	No	O	NA/TC	R (19JAN2021)	N/N
	GASTR	Nausea/ Nausea#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
		Crying/ Crying Uncontrollably#	3	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/Y
		Fatigue/ Fatigue#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
		Myalgia/ Muscle Pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ Headache#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ extraordinary fatigue#	4	18FEB2021	1/3	2	Yes		NA/TC	R (20FEB2021)	N/N
	GASTR	Nausea/ Terrible nausea#	4	19FEB2021	2/2	2	Yes		NA	R (20FEB2021)	N/N
	MUSC	Arthralgia/ Generalized joint aches#	4	19FEB2021	2/2	2	Yes		NA/TC	R (20FEB2021)	N/N
		Myalgia/ Muscle Aches#	4	19FEB2021	2/2	2	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	4	19FEB2021	2/2	2	Yes		NA/TC	R (20FEB2021)	N/N
>55/ C4591001 1130 11301057	GENRL	Injection site pain/ Injection Site Pain#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
		Pain/ Body aches#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1130 11301060	NERV	Headache/ Headache#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	RENAL	Urinary hesitation/ Urinary Hesitancy#	4	03FEB2021	2/1	1	Yes		NA/TC	R (03FEB2021)	N/N
	RESP	Oropharyngeal pain/ Sore throat	2	12OCT2020	15/96	2	No	O	NA	R (15JAN2021)	N/N
	GASTR	Abdominal pain upper/ Right Upper Quadrant Epigastric Pain#	4	16FEB2021	8/10	2	No	O	NA/TC	R (25FEB2021)	N/N
	GASTR	Coeliac artery aneurysm/ celiac artery aneurysm	2	06NOV2020	37/C	1	No	O	NA/TC	N	N/N
	VASC	Arteriosclerosis/ atherosclerosis	2	06NOV2020	37/C	1	No	O	NA/TC	N	N/N
	GENRL	Pain/ body aches#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ Muscle pain#	4	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Chills/ Intermittent chills#	4	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001	GENRL	Pyrexia/ fever#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Chills/ chills#	3	23FEB2021	21/C	1	Yes		NA	RG	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1130 11301067	MUSC	Myalgia/ full body muscle aches#	3	23FEB2021	21/C	1	Yes		NA	RG	N/N
	NERV	Headache/ headache#	3	23FEB2021	21/C	1	Yes		NA	RG	N/N
>55/ C4591001 1130 11301098	GENRL	Chills/ Chills#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
		Fatigue/ Fatigue#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ Injection Site Tenderness#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
		Pain/ Generalized achiness#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Mild pain at injection site - left arm#	4	17FEB2021	2/C	1	Yes		NA/TC	RG	N/N
		Injection site swelling/ Mild arm swelling at injection site - left arm#	4	17FEB2021	2/C	1	Yes		NA/TC	RG	N/N
		Pain/ Generalized body aches#	4	17FEB2021	2/C	1	Yes		NA/TC	RG	N/N
>55/ C4591001 1131 11311001	MUSC	Intervertebral disc protrusion/ lumbar disc herniation#	3	14FEB2021	11/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001	GASTR	Dyspepsia/ nausea/ dyspepsia	1	14AUG2020	2/33	1	Yes		NA/TC	R (15SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1131 11311008 >55/ C4591001	GENRL	Fatigue/ fatigue#	3	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
1131 11311013 >55/ C4591001	RESP	Pulmonary embolism/ Pulmonary Embolism#	2	02MAR2021	175/C	3	No	O	NA	N	Y/N
1131 11311021	VASC	Aortic aneurysm/ Aortic Aneurysm#	2	02MAR2021	175/C	3	No	O	NA	N	Y/N
		Deep vein thrombosis/ Deep Vein Thrombosis#	2	02MAR2021	175/C	3	No	O	NA	N	Y/N
>55/ C4591001	GENRL	Chills/ chills	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
1131 11311023	NERV	Headache/ headache	2	08SEP2020	1/2	1	Yes		NA/TC	R (09SEP2020)	N/N
	RESP	Epistaxis/ epistaxis	2	10OCT2020	33/1	1	No	O	NA/TCN	R (10OCT2020)	N/N
>55/ C4591001	GENRL	Chills/ chills	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
1131 11311034	GENRL	Injection site pain/ injection site pain	2	11SEP2020	2/5	1	Yes		NA/TC	R (15SEP2020)	N/N
		Pyrexia/ fever	2	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1131 11311040	MUSC	Back pain/ low back pain	2	11SEP2020	2/8	1	Yes		NA/TC	R (18SEP2020)	N/N
		Musculoskeletal discomfort/ hip discomfort	2	11SEP2020	2/8	1	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ headache	2	09SEP2020	2/1	2	Yes		NA	R (09SEP2020)	N/N
>55/ C4591001 1131 11311043	GENRL	Chills/ chills#	3	04FEB2021	1/2	2	Yes		NA	R (05FEB2021)	N/N
	GASTR	Toothache/ dental pain	2	10OCT2020	30/C	2	No	O	NA/TCN	N	N/N
>55/ C4591001 1131 11311044	GASTR	Gastritis/ exacerbation of gastritis	2	27OCT2020	47/8	1	No	O	NA/TC	R (03NOV2020)	N/N
	GASTR	Abdominal distension/ abdominal bloating	1	26AUG2020	8/6	1	No	O	NA/TC	R (31AUG2020)	N/N
>55/ C4591001 1131 11311056	GASTR	Nausea/ nausea	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
>55/ C4591001 1131 11311057	MUSC	Dupuytren's contracture/ Dupuytren's Contracture, left fifth digit	2	22SEP2020	12/C	1	No	O	NA	N	N/N
		Dupuytren's contracture/ Dupuytren's Contracture, right fifth digit	2	22SEP2020	12/10	2	No	O	NA/TCN	R (01OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INFEC	Herpes zoster/ shingles multidermatomal	2	30SEP2020	20/50	2	No	O	NA/TC	R (18NOV2020)	N/N
	INFEC	Postoperative wound infection/ Postoperative wound infection at right hand, 5th digi	2	07OCT2020	27/18	2	No	O	NA/TC	R (24OCT2020)	N/N
>55/ C4591001 1131 11311059	MUSC	Spinal stenosis/ Spinal Stenosis diagnosed	1	27AUG2020	8/C	2	No	O	NA/TCN	N	N/N
>55/ C4591001 1131 11311067	VASC	Peripheral artery stenosis/ Right femoral artery stenosis	2	19NOV2020	70/	3	No	O	NA/TCN	R	Y/N
>55/ C4591001 1131 11311084	INJ&P	Limb injury/ left shoulder strain	2	21JAN2021	130/C	1	No	O	NA/TC/TCN	RG	N/N
	GENRL	Injection site pain/ soreness at injection site#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N
	INFEC	Fungal skin infection/ fungal rash under breast#	4	03MAR2021	15/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1131 11311088	GENRL	Injection site pain/ pain at injection site	2	15SEP2020	1/4	1	Yes		NA/TC	R (18SEP2020)	N/N
	MUSC	Arthralgia/ increasing joint pain	2	SEP2020	1/C	2	No	O	NA/TC	N	N/N
	INJ&P	Muscle strain/ muscle strain	2	23SEP2020	9/9	2	No	O	NA	R (01OCT2020)	N/N
	MUSC	Pain in extremity/ left forearm pain	2	23SEP2020	9/C	2	No	O	NA/TC	N	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1131 11311095	BLOOD	Lymphadenopathy/ swollen axillary lymph nodes	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Malaise/ malaise	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	NERV	Headache/ headache	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
	MUSC	Myalgia/ generalized myalgia	2	02OCT2020	4/1	2	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1131 11311100	GENRL	Chills/ chills#	3	02FEB2021	2/2	2	Yes		NA	R (03FEB2021)	N/N
		Fatigue/ fatigue#	3	02FEB2021	2/3	2	Yes		NA	R (04FEB2021)	N/N
		Pain/ body aches#	3	02FEB2021	2/2	2	Yes		NA/TC	R (03FEB2021)	N/N
>55/ C4591001 1131 11311110	MUSC	Back pain/ low back pain	1	15SEP2020	16/10	1	No	O	NA/TC	R (24SEP2020)	N/N
>55/ C4591001 1131 11311114	GENRL	Injection site pain/ injection site arm pain	2	24SEP2020	1/5	1	Yes		NA	R (28SEP2020)	N/N
>55/ C4591001 1131 11311115	GENRL	Fatigue/ fatigue#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Injection site pain/ injection site pain#	3	09FEB2021	2/3	2	Yes		NA/TC	R (11FEB2021)	N/N
	MUSC	Myalgia/ muscle aches#	4	01MAR2021	1/C	2	Yes		NA/TC	RG	N/N
	GASTR	Diarrhoea/ diarrhea#	4	02MAR2021	2/2	2	Yes		NA/TC	R (03MAR2021)	N/N
		Nausea/ nausea#	4	02MAR2021	2/3	1	Yes		NA/TC	R (04MAR2021)	N/N
	GENRL	Fatigue/ fatigue#	4	02MAR2021	2/3	2	Yes		NA	R (04MAR2021)	N/N
		Malaise/ malaise#	4	02MAR2021	2/3	2	Yes		NA	R (04MAR2021)	N/N
>55/ C4591001 1131 11311125	SKIN	Rash/ rash on both arms and legs	1	13SEP2020	12/19	1	No	O	NA/TC	R (01OCT2020)	N/N
>55/ C4591001 1131 11311130	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1131 11311137	GENRL	Pain/ Body aches	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
>55/ C4591001 1131 11311140	MUSC	Myalgia/ muscle pain	2	24SEP2020	1/5	2	Yes		NA/TC	R (28SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1131 11311145	NERV	Headache/ headache	2	24SEP2020	1/5	2	Yes		NA/TC	R (28SEP2020)	N/N
	MUSC	Arthralgia/ generalized joint pain	2	25SEP2020	2/34	2	Yes		NA/TC	R (28OCT2020)	N/N
	NEOPL	Breast cancer/ Breast Cancer, Right Breast	2	08DEC2020	76/C	2	No	O	NA/TCN	N	Y/N
	GENRL	Asthenia/ generalized weakness, intermittent	1	SEP2020	1/C	2	No	CD	NA	N	N/N
	INJ&P	Fall/ Frequent falls	1	SEP2020	1/C	2	No	CD	NA	N	N/N
		Skin abrasion/ abrasion of right forearm	1	SEP2020	1/C	1	No	CD	NA	N	N/N
	NERV	Paraesthesia/ tingling of bilateral limbs, intermittent	1	SEP2020	1/C	1	No	CD	NA	N	N/N
	CARD	Atrial fibrillation/ Atrial fibrillation with rapid ventricular response	1	08OCT2020	31/6	2	No	O	NA/TC	R (13OCT2020)	N/N
	METAB	Hypovolaemia/ hypovolemia	1	08OCT2020	31/6	2	No	O	NA/TC	R (13OCT2020)	N/N
	NERV	Syncope/ Syncope	1	08OCT2020	31/6	3	No	O	NA/TC	R (13OCT2020)	Y/N
	RENAL	Acute kidney injury/ acute kidney injury	1	08OCT2020	31/6	2	No	O	NA/TC	R (13OCT2020)	N/N
	METAB	Hypovolaemia/ hypovolemia	1	18OCT2020	41/8	2	No	O	NA	R (25OCT2020)	N/N
RENAL	Acute kidney injury/ acute kidney injury	1	18OCT2020	41/8	2	No	O	NA/TC	R (25OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1131 11311149	SKIN	Diabetic foot/ diabetic foot ulcer, right foot	1	18OCT2020	41/C	2	No	O	NA/TC	N	N/N
	VASC	Orthostatic hypotension/ Hypotension, orthostatic	1	18OCT2020	41/8	3	No	O	NA/TC	R (25OCT2020)	Y/N
	NEOPL	Basal cell carcinoma/ basal cell carcinoma (right fore arm, left temple)	1	09SEP2020	2/1	1	No	O	NA/TCN	R (09SEP2020)	N/N
	GENRL	Chills/ chills	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	29SEP2020	1/3	2	Yes		NA	R (01OCT2020)	N/N
>55/ C4591001 1131 11311150	GENRL	Pyrexia/ low grade temperature injection	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
	NERV	Headache/ headache	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
	PSYCH	Irritability/ irritable mood	2	04OCT2020	7/23	2	Yes		NA	R (26OCT2020)	N/N
	GENRL	Injection site pain/ muscle pain at injection site#	3	03FEB2021	1/2	2	Yes		NA	R (04FEB2021)	N/N
	CARD	Atrioventricular block complete/ complete heart block	2	08DEC2020	71/12	4	No	O	NA/TC/TCN	RS (19DEC2020)	Y/N
>55/ C4591001 1131 11311151	GENRL	Bradycardia/ symptomatic bradycardia	2	08DEC2020	71/12	2	No	O	NA/TCN	R (19DEC2020)	N/N
	CARD	Cardiomegaly/ mild cardiomegaly	2	17DEC2020	80/C	1	No	CND	NA	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	METAB	Hypokalaemia/ hypokalemia	2	17DEC2020	80/2	1	No	CD	NA/TC/TCN	R (18DEC2020)	N/N
	VASC	Hypertensive urgency/ hypertensive urgency	2	17DEC2020	80/3	2	No	O	NA/TC	R (19DEC2020)	N/N
>55/ C4591001 1131 11311154	GENRL	Non-cardiac chest pain/ non-cardiac chest pain	2	26OCT2020	29/1	3	No	O	NA/TC	R (26OCT2020)	N/N
>55/ C4591001 1131 11311156	MUSC	Arthralgia/ joint pain in hands	1	17SEP2020	9/92	2	Yes		NA	R (17DEC2020)	N/N
>55/ C4591001 1131 11311163	EYE	Blepharitis/ left eye blepharitis	1	28SEP2020	19/8	1	No	O	NA/TC	R (05OCT2020)	N/N
>55/ C4591001 1131 11311166	GENRL	Fatigue/ fatigue#	3	03FEB2021	2/1	2	Yes		NA	R (03FEB2021)	N/N
	MUSC	Flank pain/ left flank pain#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
>55/ C4591001 1131 11311168	MUSC	Myalgia/ muscle aches	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
>55/ C4591001 1131 11311180	GENRL	Axillary pain/ left axillary pain	2	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Fatigue/ fatigue	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		Injection site pain/ injection site pain, left deltoid	2	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N
	SKIN	Rash/ rash on trunk	2	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N
>55/ C4591001 1131 11311185	MUSC	Myalgia/ left lower abdomen muscle pain	1	06OCT2020	20/5	1	No	O	NA/TC	R (10OCT2020)	N/N
>55/ C4591001 1131 11311188	GENRL	Injection site pain/ injection site pain	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
	INV	Body temperature increased/ temperature elevation	2	08OCT2020	1/2	1	Yes		NA/TCN	R (09OCT2020)	N/N
>55/ C4591001 1131 11311195	GENRL	Fatigue/ fatigue	2	10OCT2020	2/2	2	Yes		NA	R (11OCT2020)	N/N
>55/ C4591001 1131 11311204	VASC	Injection site pain/ injection site pain Aortic stenosis/ Worsening Aortic Stenosis#	2	10OCT2020	2/2	2	Yes		NA	R (11OCT2020)	N/N
			3	05FEB2021	16/9	3	No	O	NA	R (13FEB2021)	Y/N
	CARD	Cardio-respiratory arrest/ Cardiopulmonary Arrest#	3	15FEB2021	26/1	4	No	O	NA/W	F (15FEB2021)	Y/N
>55/ C4591001	GENRL	Injection site pain/ arm soreness at injection site	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1131 11311206	MUSC	Myalgia/ generalized muscle pain	2	16OCT2020	2/3	2	Yes		NA/TC	R (18OCT2020)	N/N	
>55/ C4591001 1131 11311208	GASTR	Vomiting/ vomiting#	4	21JAN2021	2/1	2	Yes		NA	R (21JAN2021)	N/N	
	GENRL	Chills/ chills#	4	21JAN2021	2/2	2	Yes		NA	R (22JAN2021)	N/N	
	MUSC	Arthralgia/ joint pain (generalized)#	4	21JAN2021	2/2	3	Yes		NA/TC/TCN	R (22JAN2021)	N/N	
	NERV	Headache/ headache#	4	21JAN2021	2/2	2	Yes		NA/TC	R (22JAN2021)	N/N	
>55/ C4591001 1131 11311211	GENRL	Injection site pain/ pain at injection site	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N	
	MUSC	Myalgia/ generalized myalgia	2	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/N	
	INV	Body temperature increased/ elevated temperature	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N	
>55/ C4591001 1131 11311213	MUSC	Myalgia/ right upper posterior thigh muscle pain	1	05OCT2020	12/C	1	No	O	NA	RG	N/N	
	INJ&P	Contusion/ bruising left knee	2	01NOV2020	20/C	1	No	O	NA/TC	RG	N/N	
		Contusion/ right arm with bruises	2	01NOV2020	20/C	2	No	O	NA	RG	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1131 11311214	GENRL	Fall/ fall	2	01NOV2020	20/1	2	No	O	NA	RS (01NOV2020)	N/N
		Skin abrasion/ abrasion right arm	2	01NOV2020	20/C	2	No	O	NA/TC	RG	N/N
		Chills/ chills	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
		Injection site pain/ injection site/arm pain	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
>55/ C4591001 1131 11311216	MUSC	Myalgia/ muscle pain	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	EAR	Vertigo/ reoccurrence of vertigo	1	04OCT2020	11/3	1	No	O	NA	R (06OCT2020)	N/N
	EAR	Vertigo/ reoccurrence of vertigo	2	12NOV2020	29/1	1	No	O	NA	R (12NOV2020)	N/N
>55/ C4591001 1131 11311222	INJ&P	Post procedural haematoma/ Post-op Hematoma	2	30DEC2020	77/2	3	No	O	NA	R (31DEC2020)	Y/N
	GENRL	Injection site pain/ injection site pain#	3	19FEB2021	2/6	2	Yes		NA/TC	R (24FEB2021)	N/N
	CONG	Heart disease congenital/ congenital heart anomaly	2	02NOV2020	18/14	4	No	O	NA/TC/TCN	R (15NOV2020)	Y/N
	INJ&P	Anaemia postoperative/ post surgery anemia	2	11NOV2020	27/2	1	No	O	NA/TCN	R (12NOV2020)	N/N
>55/ C4591001	MUSC	Myalgia/ myalgia	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1131 11311223	NERV	Lethargy/ lethargy	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
>55/ C4591001 1131 11311225	EYE	Vitreous floaters/ Floater in left eye	1	11OCT2020	17/C	1	No	O	NA	N	N/N
	GASTR	Nausea/ nausea#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N
>55/ C4591001 1131 11311227	GENRL	Swelling face/ left side facial swelling	1	18OCT2020	21/2	2	No	O	NA/TC	R (19OCT2020)	N/N
	INJ&P	Arthropod sting/ bee sting	1	18OCT2020	21/1	2	No	O	NA/TC	R (18OCT2020)	N/N
	SKIN	Urticaria/ hives, upper torso	1	18OCT2020	21/1	2	No	O	NA/TC	R (18OCT2020)	N/N
>55/ C4591001 1131 11311235	GENRL	Injection site pain/ right arm pain at injection site	1	09OCT2020	1/4	1	Yes		NA	R (12OCT2020)	N/N
>55/ C4591001 1131 11311237	GENRL	Fatigue/ fatigue	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		Injection site pain/ Injection site pain	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache	1	26OCT2020	15/C	1	No	O	NA/TC	RG	N/N
	RESP	Sinus congestion/ sinus congestion	1	26OCT2020	15/C	1	No	O	NA	N	N/N
>55/ C4591001 1131 11311238	GASTR	Nausea/ nausea	1	13OCT2020	1/32	1	Yes		NA	R (13NOV2020)	N/Y
	VASC	Hypertension/ worsening of hypertension	1	14OCT2020	2/17	1	No	O	NA/TC	R (30OCT2020)	N/N
>55/ C4591001 1131 11311245	GENRL	Injection site bruising/ bruising at injection site	1	15OCT2020	1/11	1	No	O	NA	R (25OCT2020)	N/N
	INFEC	Urinary tract infection/ urinary tract infection	1	03NOV2020	20/8	2	No	O	NA/TC	R (10NOV2020)	N/N
>55/ C4591001 1131 11311249	GENRL	Pyrexia/ low grade temperature elevation	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Chills/ chills	2	12NOV2020	1/3	3	Yes		NA	R (14NOV2020)	N/N
		Fatigue/ fatigue	2	12NOV2020	1/3	3	Yes		NA	R (14NOV2020)	N/N
		Pyrexia/ low grade temperature elevation	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ myalgia	2	12NOV2020	1/3	3	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ headache	2	12NOV2020	1/3	2	Yes		NA	R (14NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1131 11311255	GENRL	Chills/ chills#	4	01MAR2021	1/3	2	Yes		NA/TC	R (03MAR2021)	N/N
		Injection site pain/ injection site pain#	4	01MAR2021	1/C	2	Yes		NA/TC	RG	N/N
		Pyrexia/ low grade temperature elevation#	4	01MAR2021	1/3	1	Yes		NA/TC	R (03MAR2021)	N/N
	MUSC	Myalgia/ muscle pain - generalized#	4	01MAR2021	1/3	2	Yes		NA/TC	R (03MAR2021)	N/N
>55/ C4591001 1131 11311259	GENRL	Chills/ chills	2	18NOV2020	2/1	1	Yes		NA	R (18NOV2020)	N/N
		Pyrexia/ fever 100.7	2	18NOV2020	2/2	1	Yes		NA/TC	R (19NOV2020)	N/N
	NERV	Headache/ headache	2	18NOV2020	2/7	1	Yes		NA/TC	R (24NOV2020)	N/N
	NERV	Headache/ headache	2	24NOV2020	8/1	1	Yes		NA/TC	R (24NOV2020)	N/N
>55/ C4591001 1131 11311262	GENRL	Injection site pain/ injection site pain	1	30OCT2020	1/4	2	Yes		NA	R (02NOV2020)	N/N
	GENRL	Fatigue/ fatigue	1	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N
	GENRL	Injection site bruising/ bruise at injection site	2	20NOV2020	1/15	2	No	O	NA	R (04DEC2020)	N/N
	GASTR	Nausea/ nausea	2	21NOV2020	2/2	1	Yes		NA	R (22NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills	2	21NOV2020	2/1	2	Yes		NA	R (21NOV2020)	N/N
		Fatigue/ fatigue	2	21NOV2020	2/2	2	Yes		NA	R (22NOV2020)	N/N
	MUSC	Myalgia/ myalgia	2	21NOV2020	2/2	2	Yes		NA	R (22NOV2020)	N/N
	NERV	Dizziness/ dizziness	2	21NOV2020	2/2	2	Yes		NA	R (22NOV2020)	N/N
		Headache/ headache	2	21NOV2020	2/4	2	Yes		NA	R (24NOV2020)	N/N
>55/ C4591001 1133 11331006	PSYCH	Bipolar disorder/ Worsening Bipolar Disorder	2	24AUG2020	4/12	3	No	O	NA/TC/TCN	R (04SEP2020)	Y/N
	INFEC	Urinary tract infection/ Urinary tract infection	2	05OCT2020	46/10	3	No	O	NA	R (14OCT2020)	Y/N
	NERV	Syncope/ Syncope	2	05OCT2020	46/1	3	No	O	NA/TC	R (05OCT2020)	N/N
>55/ C4591001 1133 11331031	GENRL	Pain/ body aches	2	21AUG2020	1/8	1	Yes		NA/TCN	R (28AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	28AUG2020	8/4	1	Yes		NA	R (31AUG2020)	N/N
		Injection site erythema/ Redness at the injection site	2	28AUG2020	8/4	2	Yes		NA/TC	R (31AUG2020)	N/N
		Injection site pain/ Injection site pain	2	28AUG2020	8/4	2	Yes		NA/TC	R (31AUG2020)	N/N
		Injection site swelling/ Swelling at the injection site	2	28AUG2020	8/4	2	Yes		NA/TC	R (31AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1133 11331075	GENRL	Pain/ Body Aches	2	28AUG2020	8/4	1	Yes		NA	R (31AUG2020)	N/N	
		Injection site swelling/ INJECTION SITE SWELLING	2	04SEP2020	8/4	1	Yes		NA	R (07SEP2020)	N/N	
	SKIN	Pain/ right upper deltoid pain	2	04SEP2020	8/4	1	Yes		NA	R (07SEP2020)	N/N	
Erythema/ right upper deltoid redness		2	04SEP2020	8/4	1	Yes		NA	R (07SEP2020)	N/N		
>55/ C4591001 1133 11331085	EAR	Vertigo/ VERTIGO	1	28AUG2020	22/1	2	No	O	NA/TC	R (28AUG2020)	N/N	
>55/ C4591001 1133 11331147	GASTR	Pancreatitis acute/ Acute Pancreatitis#	3	21JAN2021	18/2	2	No	O	NA/TC	R (22JAN2021)	Y/N	
	INFEC	Asymptomatic bacteriuria/ Asyntomatic Bacteriuria#	3	22JAN2021	19/1	2	No	O	NA/TC	R (22JAN2021)	N/N	
>55/ C4591001 1133 11331148	GENRL	Pain/ BODY ACHES#	3	09JAN2021	2/1	2	Yes		NA/TC	R (09JAN2021)	N/N	
>55/ C4591001 1133 11331169	RESP	Cough/ DRY COUGH	2	12SEP2020	9/8	2	No	O	NA/TC	R (19SEP2020)	N/N	
		Upper-airway cough syndrome/ POST NASAL DRIP	2	12SEP2020	9/8	2	No	O	NA/TC	R (19SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1133 11331176	NERV	Tension headache/ tension headache	2	29SEP2020	26/2	2	No	O	NA/TC	R (30SEP2020)	N/N
>55/ C4591001 1133 11331199	GENRL	Chills/ Chills	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N
>55/ C4591001 1133 11331220	GENRL	Pyrexia/ fever	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Arthralgia/ joint pain	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1133 11331227	INJ&P	Fall/ Fall	1	09SEP2020	17/1	2	No	O	NA/TC	R (09SEP2020)	N/N
		Foot fracture/ left hallux fracture (first toe)	1	09SEP2020	17/42	2	No	O	NA/TC/TCN	R (20OCT2020)	N/N
>55/ C4591001 1133 11331233	GASTR	Diarrhoea/ DIARRHEA#	3	23JAN2021	2/5	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ SORENESS AT INJECTION SITE#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
	GASTR	Nausea/ NAUSEA#	3	24JAN2021	3/2	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Chills/ CHILLS#	3	26JAN2021	5/2	1	Yes		NA	R (27JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1133 11331237	GENRL	Injection site pain/ PAIN INJECTION SITE (LEFT ARM)	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1133 11331244	GENRL	Pain/ Body Ache	1	07SEP2020	13/1	2	No	O	NA/TC	R (07SEP2020)	N/N
>55/ C4591001 1133 11331251	GENRL	Chills/ Chills	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		Injection site discomfort/ Discomfort at injection site	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		Pain/ body aches	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Arthralgia/ joint pain	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001 1133 11331279	GENRL	Fatigue/ FATIGUE	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
>55/ C4591001 1133 11331281	GENRL	Fatigue/ TIREDNESS	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ chills	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1133 11331290	NERV	Fatigue/ tiredness	2	18SEP2020	1/6	1	Yes		NA/TCN	R (23SEP2020)	N/N
		Pain/ body aches	2	18SEP2020	1/4	2	Yes		NA/TC/TCN	R (21SEP2020)	N/N
		Headache/ headches	2	18SEP2020	1/2	2	Yes		NA/TC/TCN	R (19SEP2020)	N/N
	GENRL	Malaise/ Malaise	1	29AUG2020	3/3	2	Yes		NA/TC	R (31AUG2020)	N/N
	NERV	Headache/ Headache	1	29AUG2020	3/3	2	Yes		NA/TC	R (31AUG2020)	N/N
	GENRL	Chills/ CHILLS	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	NERV	Pain/ BODY ACHES	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1133 11331302	NERV	Headache/ HEADACHE	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Pain/ Body ache	1	27AUG2020	1/7	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	18SEP2020	1/5	1	Yes		NA/TCN	R (22SEP2020)	N/N
>55/ C4591001 1133 11331312	INFEC	Pain/ BODY ACHES	2	18SEP2020	1/5	2	Yes		NA/TC/TCN	R (22SEP2020)	N/N
		Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION (URI)	2	01OCT2020	14/5	1	No	O	NA	R (05OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1133 11331343	MUSC	Myalgia/ MUSCLE ACHE	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C4591001 1133 11331344	PSYCH	Anxiety disorder/ Worsening of Anxiety Disorder	1	08SEP2020	11/1	2	No	O	NA	R (08SEP2020)	N/N
	RESP	Dyspnoea/ shortness of breath	1	08SEP2020	11/1	1	No	O	NA	R (08SEP2020)	N/N
>55/ C4591001 1133 11331392	NERV	Headache/ HEADACHE	1	08SEP2020	7/2	1	No	O	NA/TC/TCN	R (09SEP2020)	N/N
	MUSC	Musculoskeletal stiffness/ LEFT SIDE NECK STIFFNESS	1	13SEP2020	12/13	1	No	O	NA/TC/TCN	R (25SEP2020)	N/N
>55/ C4591001 1133 11331412	GENRL	Chills/ Chills	2	30SEP2020	1/5	1	Yes		NA	R (04OCT2020)	N/N
		Injection site pain/ Pain at Injection site (Left arm)	2	30SEP2020	1/5	1	Yes		NA	R (04OCT2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	1/5	2	Yes		NA/TC/TCN	R (04OCT2020)	N/N
>55/ C4591001 1133 11331415	GASTR	Diarrhoea/ DIARRHEA	1	11SEP2020	3/2	1	Yes		NA	R (12SEP2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	2	02OCT2020	3/2	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1133 11331453	GENRL	Chills/ CHILLS	2	16OCT2020	3/3	1	Yes		NA	R (18OCT2020)	N/N
		Pyrexia/ FEVER	2	16OCT2020	3/3	1	Yes		NA	R (18OCT2020)	N/N
>55/ C4591001 1133 11331457	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
>55/ C4591001 1133 11331459	GENRL	Fatigue/ FATIGUE	2	10OCT2020	2/2	2	Yes		NA/TC	R (11OCT2020)	N/N
>55/ C4591001 1133 11331471	GENRL	Fatigue/ FATIGUE	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Injection site pain/ PAIN INJECTION SITE (LEFT UPPER ARM)	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
>55/ C4591001 1133 11331503	GENRL	Pyrexia/ Fever	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
>55/ C4591001 1134 11341002	BLOOD	Iron deficiency anaemia/ Iron Deficiency Anemia	1	18AUG2020	13/8	2	No	O	NA	R (25AUG2020)	N/N
>55/ C4591001	INJ&P	Sunburn/ Sunburn Bilateral Forearms	1	18AUG2020	12/8	1	No	O	NA	R (25AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1134 11341011 >55/ C4591001	METAB	Dehydration/ Dehydration	2	02SEP2020	3/9	2	No	O	NA	R (10SEP2020)	N/N
1134 11341016	GASTR	Dyspepsia/ INDIGESTION#	2	18FEB2021	172/8	1	No	O	NA/TC	R (25FEB2021)	N/N
>55/ C4591001	CARD	Angina pectoris/ CHEST PAIN (CARDIC)#	3	02FEB2021	1/C	2	Yes		P	N	N/N
1134 11341019 >55/ C4591001	INJ&P	Fall/ Fall	1	18AUG2020	9/1	2	No	O	NA	R (18AUG2020)	N/N
1134 11341024	MUSC	Arthralgia/ left knee pain	1	18AUG2020	9/15	2	No	O	NA	R (01SEP2020)	N/N
	METAB	Gout/ GOUT	2	14SEP2020	14/8	2	No	O	NA/TC	R (21SEP2020)	N/N
		Vitamin D deficiency/ VITAMIN D DEFICIENCY	2	14SEP2020	14/57	2	No	O	NA/TC	R (09NOV2020)	N/N
>55/ C4591001	INJ&P	Stress fracture/ LEFT LEG PAIN DUE TO STRESS FRACTURE	2	09NOV2020	71/22	2	No	O	NA/TC	R (30NOV2020)	N/N
1134 11341026 >55/ C4591001	MUSC	Back pain/ WORSENING OF BACK PAIN	2	02SEP2020	2/61	2	No	O	NA/TC	R (01NOV2020)	N/N
1134 11341035											

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pyrexia/ fever#	4	10MAR2021	2/1	2	Yes		NA/TC	R (10MAR2021)	N/N
	GENRL	Injection site pruritus/ itching at injection site#	4	12MAR2021	4/C	1	Yes		NA	N	N/N
>55/ C4591001 1134 11341037	INJ&P	Contusion/ CONTUSION ON HEAD	1	26AUG2020	16/29	1	No	O	NA	R (23SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	26AUG2020	16/43	1	No	O	NA	R (07OCT2020)	N/N
	CARD	Palpitations/ PALPITATIONS	2	30SEP2020	30/8	2	No	O	NA	R (07OCT2020)	N/N
	SKIN	Night sweats/ NIGHT SWEATS	2	30SEP2020	30/8	2	No	O	NA	R (07OCT2020)	N/N
	VASC	Hypertension/ HYPERTENSION	2	30SEP2020	30/8	1	No	O	NA/TC	R (07OCT2020)	N/N
	INFEC	Urinary tract infection/ Urinary tract infection#	4	01FEB2021	21/8	2	No	O	NA/TC	R (08FEB2021)	N/N
>55/ C4591001 1134 11341042	GASTR	Diarrhoea/ Loose stool	2	07SEP2020	7/1	1	Yes		NA	R (07SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	08NOV2020	69/2	1	No	O	NA	R (09NOV2020)	N/N
>55/ C4591001 1134 11341044	MUSC	Arthralgia/ Right Hip Pain	1	01SEP2020	21/11	2	No	O	NA	R (11SEP2020)	N/N
	EYE	Cataract/ Cataract to right eye	2	DEC2020	90/	3	No	O	NA/TCN	R (11MAR2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1134 11341045	MUSC	Arthralgia/ Pain to left elbow	1	24AUG2020	13/23	1	No	O	NA	R (15SEP2020)	N/N
>55/ C4591001 1134 11341052	INFEC	Ear infection/ BILATERAL EAR INFECTION	1	14SEP2020	34/8	1	No	O	NA/TC	R (21SEP2020)	N/N
	METAB	Glucose tolerance impaired/ PRE-DIABETIES	2	28DEC2020	95/C	1	No	O	NA	N	N/N
>55/ C4591001 1134 11341056	GASTR	Large intestine polyp/ COLON POLYPS (NON- CANCEROUS)#	4	11MAR2021	30/C	2	No	O	NA	N	N/N
>55/ C4591001 1134 11341058	GASTR	Intestinal obstruction/ Intestinal Obstruction	1	20AUG2020	9/15	3	No	O	NA/TCN	R (03SEP2020)	Y/N
>55/ C4591001 1134 11341066	GENRL	Fatigue/ FATIGUE#	4	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1134 11341081	GENRL	Pain/ body aches#	3	21JAN2021	2/1	1	Yes		NA	R (21JAN2021)	N/N
>55/ C4591001 1134 11341085	MUSC	Intervertebral disc compression/ COMPRESSED CERVICAL DISC	2	15DEC2020	99/17	3	No	O	NA/TC	R (31DEC2020)	Y/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1134 11341091	INJ&P	Fall/ FALL	1	04SEP2020	19/1	1	No	O	NA	R (04SEP2020)	N/N	
		Skin abrasion/ Right Lower Leg Abrasions	1	04SEP2020	19/8	2	No	O	NA	R (11SEP2020)	N/N	
	RENAL	Haematuria/ hematuria	2	30DEC2020	113/C	1	No	O	NA	RG	N/N	
>55/ C4591001 1134 11341092	GENRL	Injection site pain/ INJECTION SITE PAIN	1	17AUG2020	1/4	1	Yes		NA	R (20AUG2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	08SEP2020	1/4	2	Yes		NA	R (11SEP2020)	N/N	
	GENRL	Fatigue/ FATIGUE	2	09SEP2020	2/3	2	Yes		NA	R (11SEP2020)	N/N	
		Pyrexia/ FEVER	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N	
	MUSC	Myalgia/ MUSCLE ACHES	2	09SEP2020	2/3	2	Yes		NA	R (11SEP2020)	N/N	
	NERV	Headache/ HEADACHE	2	09SEP2020	2/3	2	Yes		NA	R (11SEP2020)	N/N	
>55/ C4591001 1134 11341095	GENRL	Fatigue/ FATIGUE#	4	06FEB2021	2/2	1	Yes		NA/TC	R (07FEB2021)	N/N	
>55/ C4591001 1134 11341096	MUSC	Arthralgia/ right shoulder pain#	2	FEB2021	146/C	2	No	O	NA	RG	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	CARD	Coronary artery disease/ worsening coronary artery disease (CAD)#	2	05MAR2021	178/C	3	No	O	NA/TC	RG	N/N	
	VASC	Hypertension/ worsening hypertension#	2	05MAR2021	178/C	3	No	O	NA/TC	RG	N/N	
>55/ C4591001 1134 11341098	INJ&P	Muscle strain/ right lower back pulled muscle	2	13OCT2020	29/50	3	No	O	NA/TC	R (01DEC2020)	N/N	
>55/ C4591001 1134 11341103	NERV	Diabetic neuropathy/ DIABETIC NEUROPATHY	2	08DEC2020	92/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1134 11341114	METAB	Glucose tolerance impaired/ pre-diabetes	2	15JAN2021	129/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1134 11341115	MUSC	Myalgia/ left arm muscle pain	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N	
>55/ C4591001 1134 11341120	GENRL	Injection site pain/ INJECTION SITE PAIN	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N	
>55/ C4591001 1134 11341122	GENRL	Injection site pain/ Soreness at the injection site#	3	17DEC2020	1/2	1	No	O	NA	R (18DEC2020)	N/N	
>55/ C4591001	SKIN	Hyperhidrosis/ excessive sweating	2	13SEP2020	4/1	1	Yes		NA	R (13SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1134 11341126 >55/ C4591001	GASTR	Nausea/ nausea	2	12SEP2020	2/2	2	Yes		NA	R (13SEP2020)	N/N
1134 11341142	MUSC	Arthralgia/ joint pain	2	12SEP2020	2/2	2	Yes		NA/TC	R (13SEP2020)	N/N
	NERV	Dizziness/ dizziness	2	12SEP2020	2/2	2	Yes		NA	R (13SEP2020)	N/N
>55/ C4591001	GASTR	Nausea/ nausea	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
1134 11341143		Vomiting/ vomiting	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Pyrexia/ low grade fever	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	METAB	Decreased appetite/ loss of appetite	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
>55/ C4591001	GENRL	Chills/ chills#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
1134 11341144											
>55/ C4591001	NERV	Dizziness/ Dizziness	2	05OCT2020	25/5	1	No	O	NA	R (09OCT2020)	N/N
1134 11341145											
>55/ C4591001	GENRL	Chills/ chills	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1134 11341160		Pain/ body aches	2	15SEP2020	1/5	2	Yes		NA	R (19SEP2020)	N/N
	INV	Body temperature increased/ elevated temperature	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N
	RESP	Nasal congestion/ nasal congestion	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
>55/ C4591001 1134 11341161	GASTR	Toothache/ right upper side tooth ache	1	27AUG2020	3/62	2	No	O	NA/TC	R (27OCT2020)	N/N
>55/ C4591001 1134 11341162	INFEC	Impetigo/ IMPETIGO	2	16SEP2020	2/16	2	No	O	NA/TC	R (01OCT2020)	N/N
	SKIN	Pruritus/ itching	2	16SEP2020	2/16	2	Yes		NA/TC	R (01OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	2	23FEB2021	162/C	2	No	O	NA	N	N/N
>55/ C4591001 1134 11341167	GENRL	Pyrexia/ fever#	4	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
	NERV	Headache/ headache#	4	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
>55/ C4591001 1134 11341181	GENRL	Pain/ Body Aches	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	VASC	Hypertension/ Worsening Hypertension	2	04OCT2020	19/3	2	No	O	NA/TC	R (06OCT2020)	N/N	
	MUSC	Arthralgia/ WORSENING RIGHT ANKLE PAIN	2	JAN2021	108/C	2	No	O	NA/TCN	N	N/N	
>55/ C4591001 1134 11341185	INFEC	Urinary tract infection/ urinary tract infection	1	09SEP2020	15/5	1	No	O	NA/TC	R (13SEP2020)	N/N	
>55/ C4591001 1134 11341193	METAB	Hypokalaemia/ hypokalemia	2	24DEC2020	99/C	2	No	O	NA/TC/TCN	N	N/N	
>55/ C4591001 1134 11341197	MUSC	Myalgia/ LEFT ARM MUSCLE PAIN	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N	
	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
	GASTR	Nausea/ NAUSEA	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	
	GENRL	Asthenia/ WEAKNESS	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	
>55/ C4591001 1134 11341202	NERV	Sciatica/ right side sciatica pain	2	OCT2020	15/C	2	No	O	NA	N	N/N	
>55/ C4591001 1134 11341215	EYE	Macular oedema/ MACULAR EDEMA	2	13JAN2021	118/C	1	No	O	NA	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1134 11341221	INJ&P	Concussion/ CONCUSSION	2	25SEP2020	5/6	1	No	O	NA	R (30SEP2020)	N/N	
	NERV	Dizziness/ LIGHtheadiness	2	25SEP2020	5/6	1	No	O	NA	R (30SEP2020)	N/N	
>55/ C4591001 1134 11341243	INJ&P	Fall/ FALL#	3	18FEB2021	21/1	3	No	O	NA/TC	R (18FEB2021)	N/N	
	NERV	Dizziness/ dizziness#	3	18FEB2021	21/C	2	No	O	NA/TC	N	N/N	
		Headache/ headache#	3	18FEB2021	21/3	2	No	O	NA/TC	R (20FEB2021)	N/N	
	VASC	Haematoma/ hematoma on back of head#	3	18FEB2021	21/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1134 11341245	GENRL	Chills/ CHILLS#	4	12FEB2021	1/3	2	Yes		NA	R (14FEB2021)	N/N	
	NERV	Headache/ HEADACHE#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N	
>55/ C4591001 1134 11341250	GENRL	Pain/ right side pain	1	14SEP2020	12/C	3	No	O	NA/TC	N	N/N	
	NEOPL	Adrenal gland cancer/ ADRENAL ADENOCARCINOMA	2	20OCT2020	27/C	4	No	O	NA/TC	N	Y/N	
>55/ C4591001	INFEC	Tooth infection/ tooth infection	1	09SEP2020	7/7	2	No	O	NA/TC	R (15SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1134 11341256 >55/ C4591001 1134 11341257	VASC	Hot flush/ hot flashes#	2	01MAR2021	158/C	2	No	O	NA/TCN	RG	N/N
>55/ C4591001 1134 11341265	MUSC	Intervertebral disc degeneration/ Worsened disc degeneration (L5-S1)	2	25SEP2020	1/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1134 11341271	GASTR	Diarrhoea/ DIARRHEA#	3	08FEB2021	1/6	1	Yes		NA	R (13FEB2021)	N/N
	NERV	Headache/ HEADACHE#	3	08FEB2021	1/6	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Chills/ CHILLS#	3	09FEB2021	2/5	1	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1134 11341284	GENRL	Injection site pain/ INJECTION SITE PAIN#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
>55/ C4591001 1134 11341309	GASTR	Nausea/ nausea	1	02OCT2020	24/2	2	No	O	NA	R (03OCT2020)	N/N
>55/ C4591001 1134 11341319	MUSC	Muscular weakness/ muscle weakness	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1134 11341342	NERV	Headache/ headache	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Chills/ Chills	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
>55/ C4591001 1134 11341347		Pain/ Body Aches	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	25FEB2021	1/5	1	Yes		NA	R (01MAR2021)	N/N
>55/ C4591001 1134 11341353	GENRL	Injection site pruritus/ itching at the injection site#	3	03MAR2021	7/C	1	Yes		NA	RG	N/N
	NERV	Headache/ intermittent headaches	1	17SEP2020	2/36	2	No	O	NA/TC	R (22OCT2020)	N/N
>55/ C4591001 1134 11341354	INFEC	Sinusitis/ sinus infection	1	23SEP2020	8/30	1	No	O	NA	R (22OCT2020)	N/N
	GENRL	Chills/ chills	2	05NOV2020	2/4	2	Yes		NA	R (08NOV2020)	N/N
	NERV	Headache/ headache	2	05NOV2020	2/4	2	Yes		NA	R (08NOV2020)	N/N
	GENRL	Fatigue/ fatigue#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	GASTR	Retching/ dry heaves#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills#	4	10FEB2021	2/1	2	Yes		NA	R (10FEB2021)	N/N
	SKIN	Night sweats/ night sweats#	4	10FEB2021	2/1	2	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1134 11341367	INFEC	Gingivitis/ lower right gum infection	2	22OCT2020	10/11	2	No	O	NA/TC	R (01NOV2020)	N/N
>55/ C4591001 1134 11341375	INJ&P	Fall/ FALL	2	30OCT2020	4/1	2	No	O	NA	R (30OCT2020)	N/N
		Skin laceration/ LEFT LEG LACERATION	2	30OCT2020	4/50	2	No	O	NA/TC	R (18DEC2020)	N/N
>55/ C4591001 1134 11341377	INFEC	Conjunctivitis/ Right Eye Conjunctivitis	2	24NOV2020	28/8	1	No	O	NA	R (01DEC2020)	N/N
>55/ C4591001 1134 11341380	INV	Blood pressure increased/ elevated blood pressure	2	18NOV2020	23/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1134 11341395	GENRL	Injection site pain/ injection site soreness#	3	21JAN2021	1/5	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	09OCT2020	1/15	1	Yes		NA	R (23OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1134 11341398 >55/ C4591001	GASTR	Abdominal pain upper/ stomach cramps#	3	10FEB2021	20/C	1	No	O	NA	RG	N/N
1134 11341405 >55/ C4591001	GENRL	Fatigue/ FATIGUE#	4	16FEB2021	2/2	2	Yes		NA	R (17FEB2021)	N/N
1134 11341411 >55/ C4591001	GASTR	Pyrexia/ FEVER# Diarrhoea/ Loose Stools	4 1	16FEB2021 22OCT2020	2/2 10/11	2 1	Yes Yes		NA NA	R (17FEB2021) R (01NOV2020)	N/N N/N
1134 11341412 >55/ C4591001	RESP	Epistaxis/ 2 hour nosebleed#	3	03MAR2021	7/1	1	No	O	NA	R (03MAR2021)	N/N
1134 11341415 >55/ C4591001	RESP	Epistaxis/ 1.5 hour nose bleed#	3	04MAR2021	8/1	1	No	O	NA	R (04MAR2021)	N/N
1134 11341419 >55/ C4591001	GENRL	Injection site pain/ injection site pain	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
1134 11341432 >55/ C4591001	INJ&P	Overdose/ HEROINE OVERDOSE	2	26NOV2020	16/3	4	No	O	NA	R (28NOV2020)	Y/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1135 11351003	VASC	Haematoma/ hematoma (right arm - antecubital)	1	10AUG2020	8/3	1	No	O	NA	R (12AUG2020)	N/N	
>55/ C4591001 1135 11351005	GENRL	Fatigue/ fatigue#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N	
	MUSC	Arthralgia/ left shoulder pain#	4	22FEB2021	1/C	1	Yes		NA	RG	N/N	
>55/ C4591001 1135 11351028	INJ&P	Contusion/ bruised left leg#	2	15FEB2021	173/15	1	No	O	NA	R (01MAR2021)	N/N	
		Fall/ Ski Fall (left leg)#	2	15FEB2021	173/1	1	No	O	NA	R (15FEB2021)	N/N	
>55/ C4591001 1135 11351031	GASTR	Toothache/ toothache - right upper molar	1	23AUG2020	19/9	1	No	O	NA/TC	R (31AUG2020)	N/N	
>55/ C4591001 1135 11351032	INJ&P	Joint dislocation/ right shoulder dislocation	1	20AUG2020	16/2	1	No	O	NA	R (21AUG2020)	N/N	
	MUSC	Osteopenia/ Osteopenia	1	21AUG2020	17/C	1	No	O	NA	N	N/N	
	MUSC	Rotator cuff syndrome/ right rotator cuff tear	2	OCT2020	36/C	2	No	O	NA/TC/TCN	RG	N/N	
>55/ C4591001	NERV	Hypoaesthesia/ numbness on the back of the head	2	04SEP2020	9/1	1	No	O	NA	R (04SEP2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1135 11351033	PSYCH	Completed suicide/ Suicide#	3	29JAN2021	5/1	4	No	O	NA/W	F (29JAN2021)	Y/N
>55/ C4591001 1135 11351039	RESP	Nasal congestion/ nasal congestion	2	29NOV2020	96/4	1	No	O	NA	R (02DEC2020)	N/N
>55/ C4591001 1135 11351045	INFEC	Cellulitis/ right lower limb cellulitis	2	04OCT2020	41/38	2	No	O	NA/TC	RS (10NOV2020)	N/N
	GENRL	Pain/ bodyaches#	4	02MAR2021	1/4	1	Yes		NA/TC	R (05MAR2021)	N/N
	GASTR	Nausea/ nausea#	4	03MAR2021	2/3	1	Yes		NA	R (05MAR2021)	N/N
	NERV	Headache/ headaches#	4	03MAR2021	2/3	1	Yes		NA/TC	R (05MAR2021)	N/N
>55/ C4591001 1135 11351048	GASTR	Nausea/ nausea#	3	29DEC2020	1/1	1	Yes		NA	R (29DEC2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	29DEC2020	1/1	1	Yes		NA/TC	R (29DEC2020)	N/N
	NERV	Headache/ headache#	3	30DEC2020	2/1	1	Yes		NA/TC	R (30DEC2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
		Pyrexia/ fever#	4	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1135 11351055	MUSC	Myalgia/ muscle aches#	4	19JAN2021	2/1	1	Yes		NA	R (19JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Pain/ bodyaches#	3	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N
		Injection site pain/ pain at injection site#	4	12MAR2021	1/C	1	Yes		NA	N	N/N
>55/ C4591001 1135 11351062	INFEC	Pain/ bodyaches#	4	12MAR2021	1/C	1	Yes		NA	N	N/N
		Ear infection/ left ear infection	2	21JAN2021	148/11	1	No	O	NA/TC	R (31JAN2021)	N/N
>55/ C4591001 1135 11351064	NERV	Paraesthesia/ tingling sensation - bilateral shoulders	1	24AUG2020	18/8	1	No	O	NA	R (31AUG2020)	N/N
>55/ C4591001 1135 11351070	MUSC	Pain in extremity/ left arm pain#	4	26FEB2021	17/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1135 11351071	IMMUN	Seasonal allergy/ worsening of seasonal allergies#	2	03FEB2021	161/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001	GASTR	Constipation/ constipation	2	SEP2020	5/	1	No	O	NA	R (28NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1135 11351074	GASTR	Abdominal pain upper/ left upper quadrant pain	2	22NOV2020	87/	1	No	O	NA	R	N/N
		Abdominal pain/ tender spleen	2	22NOV2020	87/7	1	No	O	NA	R (28NOV2020)	N/N
>55/ C4591001 1135 11351079	GASTR	Tongue ulceration/ tongue ulcers	1	10AUG2020	3/3	1	Yes		NA	R (12AUG2020)	N/N
	RESP	Throat irritation/ scratchy throat	1	10AUG2020	3/3	1	Yes		NA	R (12AUG2020)	N/N
	MUSC	Arthralgia/ knee pain - bilateral	1	20AUG2020	13/2	1	Yes		NA	R (21AUG2020)	N/N
>55/ C4591001 1135 11351098	INJ&P	Limb injury/ thumb on left hand injured	2	07SEP2020	8/8	1	No	O	NA/TC	R (14SEP2020)	N/N
	INFEC	Otitis media/ right middle ear infection#	3	11MAR2021	18/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1135 11351110	GASTR	Diarrhoea/ diarrhea	2	27SEP2020	28/2	1	No	O	NA	R (28SEP2020)	N/N
	GENRL	Fatigue/ fatigue#	4	12JAN2021	2/3	1	Yes		NA	R (14JAN2021)	N/N
		Pain/ bodyaches#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
		Pyrexia/ fever#	4	12JAN2021	2/2	1	Yes		NA/TC	R (13JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1135 11351116	MUSC	Arthralgia/ right hip pain	1	15AUG2020	3/10	1	Yes		NA/TC	R (24AUG2020)	N/N
>55/ C4591001 1135 11351135	METAB	Insulin resistance/ worsening of insulin resistance	2	31OCT2020	54/C	2	No	O	NA/TC	RG	N/N
	METAB	Hyperlipidaemia/ worsening of hyperlipidemia	2	19JAN2021	134/C	2	No	O	NA/TC	N	N/N
	GASTR	Gastroesophageal reflux disease/ acid reflux	2	01FEB2021	147/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1135 11351143	HEPAT	Cholecystitis acute/ acute cholecystitis	2	14OCT2020	36/4	3	No	O	NA/TC/TCN	R (17OCT2020)	Y/N
	INFEC	Urinary tract infection/ urinary tract infection	2	15OCT2020	37/3	1	No	O	NA/TC	R (17OCT2020)	N/N
	CARD	Myocardial infarction/ myocardial infarction	2	18NOV2020	71/3	2	No	O	NA/TC/TCN	R (20NOV2020)	Y/N
>55/ C4591001 1135 11351147	GENRL	Fatigue/ fatigue	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N
		Injection site pain/ injection site pain	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N
>55/ C4591001 1135 11351153	MUSC	Myalgia/ muscle pain	1	19AUG2020	2/3	1	Yes		NA/TC	R (21AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1135 11351157	INFEC	Conjunctivitis/ conjunctivitis (both eyes)#	3	23JAN2021	2/C	1	No	O	NA/TC	RG	N/N	
	GENRL	Fatigue/ fatigue#	4	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N	
		Pyrexia/ fever#	4	11FEB2021	1/3	1	Yes		NA/TC	R (13FEB2021)	N/N	
>55/ C4591001 1135 11351160	GASTR	Diarrhoea/ loose stool	1	19AUG2020	1/1	1	Yes		NA	R (19AUG2020)	N/N	
>55/ C4591001 1135 11351182	GENRL	Pyrexia/ Fever	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N	
>55/ C4591001 1135 11351187	MUSC	Intervertebral disc protrusion/ herniated disk of neck	2	12DEC2020	90/2	1	No	O	NA/TC/TCN	R (13DEC2020)	N/N	
>55/ C4591001 1135 11351218	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N	
>55/ C4591001 1135 11351219	INFEC	Tooth infection/ infection of left lower tooth #18	2	13OCT2020	27/1	1	No	O	NA/TC/TCN	R (13OCT2020)	N/N	
>55/ C4591001	GENRL	Fatigue/ fatigue	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1135 11351223		Injection site pain/ pain at injection site	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
	MUSC	Myalgia/ myalgia	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
	REPRO	Breast hyperplasia/ atypical hyperplasia of right breast	2	21JAN2021	123/C	1	No	O	NA/TCN	N	N/N
>55/ C4591001 1135 11351232	NERV	Paraesthesia/ paresthesia	1	15SEP2020	16/C	2	No	O	NA	RG	N/N
>55/ C4591001 1135 11351238	GENRL	Injection site pain/ soreness right arm injection site	1	31AUG2020	1/8	1	Yes		NA	R (07SEP2020)	N/N
>55/ C4591001 1135 11351246	MUSC	Back pain/ lower back pain	2	08DEC2020	77/C	1	No	O	NA/TC	N	N/N
	GENRL	Injection site swelling/ swelling at injection site#	3	22JAN2021	1/4	1	Yes		NA	R (25JAN2021)	N/N
>55/ C4591001 1135 11351254	GENRL	Pain/ bodyaches#	4	07JAN2021	2/1	1	Yes		NA/TC	R (07JAN2021)	N/N
		Pyrexia/ fever#	4	07JAN2021	2/2	1	Yes		NA/TC	R (08JAN2021)	N/N
	NERV	Headache/ headache#	4	07JAN2021	2/2	1	Yes		NA/TC	R (08JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1135 11351257	CARD	Atrial fibrillation/ Atrial fibrillation	2	NOV2020	40/	2	No	O	NA/TCN	R (09DEC2020)	N/N	
	NEOPL	Non-small cell lung cancer stage IV/ stage IV non-small cell lung cancer	2	16NOV2020	55/C	3	No	O	NA	RG	Y/N	
	CARD	Atrial fibrillation/ Atrial fibrillation	2	10DEC2020	79/5	2	No	O	NA/TCN	R (14DEC2020)	Y/N	
	CARD	Atrial fibrillation/ Atrial fibrillation	2	03JAN2021	103/2	2	No	O	NA/TCN	R (04JAN2021)	Y/N	
	CARD	Atrial fibrillation/ Atrial fibrillation	2	05JAN2021	105/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1135 11351258	NEOPL	Prostate cancer/ prostate cancer#	2	25JAN2021	126/C	2	No	O	NA/TCN	N	N/N	
	METAB	Diabetes mellitus/ worsening of diabetes#	2	09MAR2021	169/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1135 11351261	GENRL	Injection site pain/ pain on the injection site - left arm	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N	
	MUSC	Arthralgia/ knee pain - both legs	1	02SEP2020	2/1	1	No	O	NA	R (02SEP2020)	N/N	
	GENRL	Pain/ bodyaches	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N	
>55/ C4591001 1135 11351280	GASTR	Diarrhoea/ loose bowel movement	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1135 11351289	GENRL	Chills/ chills	2	25SEP2020	2/1	1	Yes		NA/TC	R (25SEP2020)	N/N
		Pyrexia/ Fever	2	25SEP2020	2/1	1	Yes		NA/TC	R (25SEP2020)	N/N
	INV	Heart rate increased/ Increased heart rate	2	25SEP2020	2/1	1	No	O	NA	R (25SEP2020)	N/N
	EYE	Cataract/ worsening cataract#	3	JAN2021	1/	2	No	O	NA/TC	R (22FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
		Injection site pain/ pain at injection site#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	MUSC	Arthralgia/ joint pain (generalized)#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	GASTR	Gastroesophageal reflux disease/ acid reflux	2	17NOV2020	54/C	1	No	O	NA/TC	RG	N/N
	GASTR	Gastroesophageal reflux disease/ GERD#	3	25FEB2021	14/C	1	No	O	NA/TC	RG	N/N
	GASTR	Gastroesophageal reflux disease/ GERD#	3	25FEB2021	14/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1135 11351299	GASTR	Gastroesophageal reflux disease/ GERD#	3	25FEB2021	14/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1135 11351300	GENRL	Chills/ chills#	4	12MAR2021	1/2	1	Yes		NA	R (13MAR2021)	N/N
		Injection site pain/ pain at injection site#	4	12MAR2021	1/2	1	Yes		NA	R (13MAR2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1135 11351312	GENRL	Injection site pain/ pain at injection site*		08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
>55/ C4591001 1135 11351316	GENRL	Fatigue/ fatigue	2	29SEP2020	2/4	1	Yes		NA	R (02OCT2020)	N/N	
		Injection site pain/ pain at injection site	2	29SEP2020	2/4	1	Yes		NA	R (02OCT2020)	N/N	
	NERV	Headache/ headache	2	29SEP2020	2/4	1	Yes		NA	R (02OCT2020)	N/N	
>55/ C4591001 1135 11351320	GENRL	Injection site pain/ pain at injection site#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N	
		Pain/ bodyaches#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N	
	NERV	Headache/ headache#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N	
>55/ C4591001 1135 11351321	GENRL	Injection site pain/ Pain at injection site	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N	
	GENRL	Injection site pain/ pain at injection site	2	28SEP2020	1/4	2	Yes		NA/TC	R (01OCT2020)	N/N	
>55/ C4591001 1135 11351325	METAB	Hyperlipidaemia/ hyperlipidemia	2	24NOV2020	57/C	1	No	O	NA/TC	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1135 11351333	EYE	Cataract/ right eye cataract	2	27OCT2020	30/1	1	No	O	NA/TC	R (27OCT2020)	N/N	
>55/ C4591001 1135 11351339	PSYCH	Anxiety/ worsening of anxiety	1	11SEP2020	3/21	2	No	O	NA/TC	R (01OCT2020)	N/N	
>55/ C4591001 1135 11351380	GENRL	Pain/ Body Aches	1	19SEP2020	2/3	1	Yes		NA/TC	R (21SEP2020)	N/N	
		Pyrexia/ Low grade temperature	1	19SEP2020	2/3	1	Yes		NA/TC	R (21SEP2020)	N/N	
>55/ C4591001 1135 11351409	GENRL	Pyrexia/ fever (low grade)	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N	
	MUSC	Myalgia/ muscle pain (whole body)	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N	
>55/ C4591001 1135 11351426	GENRL	Pain/ body aches	2	04NOV2020	20/7	1	No	O	NA	R (10NOV2020)	N/N	
	INJ&P	Road traffic accident/ Motor vehicle accident	2	04NOV2020	20/1	1	No	O	NA	R (04NOV2020)	N/N	
	NERV	Headache/ headache	2	04NOV2020	20/1	1	No	O	NA/TC	R (04NOV2020)	N/N	
>55/ C4591001	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	10SEP2020	24/12	2	Yes		NA	R (21SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1136 11361009	MUSC	Pain in extremity/ LEFT ARM PAIN	1	10SEP2020	24/28	2	Yes		NA	R (07OCT2020)	N/N	
>55/ C4591001 1136 11361011	MUSC	Arthralgia/ LEFT SHOULDER PAIN	2	18NOV2020	62/15	2	No	O	NA/TC	R (02DEC2020)	N/N	
	INJ&P	Skin abrasion/ RIGHT EAR ABRASION	2	25DEC2020	99/23	1	No	O	NA/TC	R (16JAN2021)	N/N	
	MUSC	Arthralgia/ RIGHT ANKLE PAIN	2	28DEC2020	102/5	2	No	O	NA/TC	R (01JAN2021)	N/N	
>55/ C4591001 1136 11361023	INFEC	Genital herpes/ worsening of genital herpes	1	09SEP2020	21/5	1	No	O	NA/TC	R (13SEP2020)	N/N	
	INFEC	Hordeolum/ RIGHT EYE STYE	1	17SEP2020	29/38	1	No	O	NA/TC	R (24OCT2020)	N/N	
	SKIN	Skin lesion/ EXACERBATION OF ATYPICAL SKIN LESION RIGHT THIGH- BENIGN	2	SEP2020	1/	1	No	O	NA/TCN	R	N/N	
	MUSC	Pain in extremity/ left arm soreness#	2	22DEC2020	89/5	1	Yes		NA	R (26DEC2020)	N/N	
>55/ C4591001 1136 11361038	INFEC	Conjunctivitis/ conjunctivitis OS	2	08FEB2021	152/8	1	No	O	NA/TC	R (15FEB2021)	N/N	
>55/ C4591001	GENRL	Chills/ mild chills#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1136 11361041 >55/ C4591001 1136 11361050	GENRL	Chills/ chills#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		Pain/ body aches#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		Pyrexia/ fever#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	MUSC	Myalgia/ muscle aches#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1136 11361055	GENRL	Pyrexia/ fever (102.0 F)	2	22SEP2020	1/4	2	No	O	NA/TC	R (25SEP2020)	N/N
>55/ C4591001 1136 11361057	GENRL	Injection site pain/ left arm pain at injection site#	2	04FEB2021	123/2	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1136 11361066	GENRL	Injection site erythema/ injection site redness	1	16SEP2020	3/2	1	Yes		NA	R (17SEP2020)	N/N
	SKIN	Rash/ neck rash	1	16SEP2020	3/2	1	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C4591001 1136 11361070	GENRL	Injection site pain/ pain injection site#	2	22DEC2020	42/2	1	Yes		NA	R (23DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1136 11361074	GENRL	Injection site pain/ injection site pain*		21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N	
	GENRL	Pain/ body aches	1	22OCT2020	2/3	1	Yes		NA	R (24OCT2020)	N/N	
>55/ C4591001 1136 11361075	GENRL	Injection site pain/ injection site tenderness	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N	
>55/ C4591001 1136 11361078	INV	Blood pressure increased/ elevated blood pressure	1	03NOV2020	13/C	1	No	O	NA	N	N/N	
	GENRL	Chills/ chills	1	11NOV2020	21/2	1	Yes		NA	R (12NOV2020)	N/N	
	SKIN	Night sweats/ night sweats	1	11NOV2020	21/2	1	Yes		NA	R (12NOV2020)	N/N	
	GENRL	Injection site pain/ injection site pain	2	22NOV2020	12/2	1	Yes		NA	R (23NOV2020)	N/N	
		Pain/ body aches	2	22NOV2020	12/2	1	Yes		NA	R (23NOV2020)	N/N	
>55/ C4591001 1136 11361079	GASTR	Nausea/ nausea	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N	
	GENRL	Injection site pain/ pain at injection site#	2	03FEB2021	84/3	1	Yes		NA	R (05FEB2021)	N/N	
>55/ C4591001	MUSC	Neck pain/ neck pain	1	28OCT2020	7/31	1	No	O	NA	R (27NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1136 11361080	NERV	Headache/ headaches	1	28OCT2020	7/31	1	No	O	NA/TC	R (27NOV2020)	N/N
	GENRL	Axillary pain/ right arm pit pain	1	06NOV2020	16/2	1	No	O	NA	R (07NOV2020)	N/N
>55/ C4591001 1136 11361085	GENRL	Injection site pain/ pain at injection site#	2	20JAN2021	66/1	1	Yes		NA	R (20JAN2021)	N/N
>55/ C4591001 1136 11361093	GENRL	Fatigue/ exhaustion*		28OCT2020	1/1	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Malaise/ malaise	1	17NOV2020	21/1	1	Yes		NA	R (17NOV2020)	N/N
	NERV	Dysgeusia/ sweet taste in mouth	1	17NOV2020	21/1	1	Yes		NA	R (17NOV2020)	N/N
		Headache/ headache, mild	1	17NOV2020	21/1	1	Yes		NA	R (17NOV2020)	N/N
>55/ C4591001 1136 11361096	GENRL	Chills/ chills	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
		Pain/ body aches	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
>55/ C4591001 1136 11361097	MUSC	Pain in extremity/ left arm pain#	2	28JAN2021	71/4	2	Yes		NA	R (31JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ left arm injection site pain#	4	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Dizziness/ lightheadedness#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
>55/ C4591001 1136 11361102	GENRL	Injection site pain/ sore in injection site, right arm*		29OCT2020	1/1	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain, right	2	20NOV2020	2/2	1	Yes		NA	R (21NOV2020)	N/N
	CARD	Cardiac arrest/ cardiac arrest	2	19DEC2020	31/1	4	No	O	NA/TC/TCN/W	F (19DEC2020)	Y/N
>55/ C4591001 1136 11361103	GASTR	Gastroesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISEASE	1	03NOV2020	6/C	1	No	O	NA	RG	N/N
>55/ C4591001 1136 11361107	GENRL	Injection site pain/ injection site pain	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
	GENRL	Chills/ chills	1	30OCT2020	2/3	1	Yes		NA	R (01NOV2020)	N/N
>55/ C4591001 1136 11361110	MUSC	Pain in extremity/ left arm pain#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1139 11391004	GENRL	Injection site erythema/ Erythema Distal to Injection Site	2	20AUG2020	1/1	1	No	O	NA	R (20AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1139 11391005	GENRL	Injection site discolouration/ Discoloration at injection site	1	29JUL2020	1/16	1	Yes		NA	R (13AUG2020)	N/N
>55/ C4591001 1139 11391009	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	20OCT2020	62/C	1	No	O	NA/TC	RG	N/N
		Type 2 diabetes mellitus/ Type 2 Diabetes	2	20OCT2020	62/C	1	No	O	NA	RG	N/N
>55/ C4591001 1139 11391024	NEOPL	Hormone receptor positive breast cancer/ Malignant neoplasm of upper-outer quadrant of right breast in female, estrogen receptor positive#	2	02FEB2021	168/C	3	No	O	NA	N	Y/N
>55/ C4591001 1139 11391026	GENRL	Injection site bruising/ Injection site bruising	1	31JUL2020	1/16	2	Yes		NA	R (15AUG2020)	N/N
>55/ C4591001 1139 11391034	SKIN	Dermatitis contact/ Poison ivy- lower extremities	1	16AUG2020	14/C	2	No	O	NA/TC/TCN	RG	N/N
>55/ C4591001 1139 11391045	NERV	Paraesthesia/ Tingling in left arm	1	05AUG2020	1/1	1	Yes		NA	R (05AUG2020)	N/Y
>55/ C4591001 1139 11391055	INJ&P	Fall/ Accidental Fall	2	14SEP2020	20/1	2	No	O	NA	R (14SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Foot fracture/ Fractured fourth and fifth metatarsal	2	14SEP2020	20/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1139 11391068	BLOOD	Lymphadenopathy/ Left Axillary lymph node swelling	1	13AUG2020	8/4	1	Yes		NA	R (16AUG2020)	N/N	
>55/ C4591001 1139 11391093	MUSC	Osteoarthritis/ Osteoarthritis of right knee	2	09NOV2020	14/C	2	No	O	NA	N	N/N	
>55/ C4591001 1139 11391111	SKIN	Dyshidrotic eczema/ Dyshidrotic Eczema - Location(s): Right Hand and Right Toe	1	01NOV2020	17/45	1	No	O	NA/TC	R (15DEC2020)	N/N	
>55/ C4591001 1139 11391124	MUSC	Muscle spasms/ Lumbar paraspinal muscle spasm	2	18NOV2020	7/C	2	No	O	NA	RG	N/N	
>55/ C4591001 1140 11401002	CARD	Coronary artery dissection/ Spontaneous coronary artery dissection	2	28AUG2020	12/1	4	No	O	NA	R (28AUG2020)	Y/N	
		Myocardial ischaemia/ Myocardial Ischemia	2	28AUG2020	12/1	1	No	O	NA	R (28AUG2020)	N/N	
>55/ C4591001 1140 11401012	GENRL	Injection site pain/ Pain at injection site#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N	
	MUSC	Myalgia/ Myalgias#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1140 11401034	GENRL	Injection site pain/ Left arm injection site pain	1	05AUG2020	2/1	3	Yes		NA	R (05AUG2020)	N/N
>55/ C4591001 1140 11401035	SKIN	Urticaria/ urticaria	1	13AUG2020	10/1	2	No	O	P/TC/W	R (13AUG2020)	N/N
>55/ C4591001 1140 11401036	GENRL	Pyrexia/ Fever	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	10SEP2020	3/1	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10SEP2020	3/1	1	Yes		NA	R (10SEP2020)	N/N
		Pain/ Body Aches	2	10SEP2020	3/1	1	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1140 11401041	INJ&P	Muscle strain/ muscle strain L hip	1	11AUG2020	7/C	2	No	O	NA	N	N/N
>55/ C4591001 1140 11401042	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	19DEC2020	2/3	1	Yes		NA	R (21DEC2020)	N/N
	MUSC	Myalgia/ myalgias#	3	19DEC2020	2/3	1	Yes		NA	R (21DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GASTR	Abdominal distension/ Bloating#	4	07FEB2021	31/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1140 11401043	EAR	Ear pain/ Bilateral Otalgia	1	19AUG2020	15/C	1	No	O	NA	N	N/N	
>55/ C4591001 1140 11401047	VASC	Hypertension/ hypertension	1	05AUG2020	1/C	2	No	O	NA/TC	N	N/N	
	MUSC	Musculoskeletal pain/ Left Buttock Pain	1	23AUG2020	19/C	1	No	O	NA	N	N/N	
>55/ C4591001 1140 11401066	NEOPL	Thyroid cancer/ Thyroid Cancer	2	18SEP2020	25/C	3	No	O	NA	N	Y/N	
	SURG	Radioactive iodine therapy/ Radioactive Iodine Treatment#	2	08FEB2021	168/1	3	No	O	NA	R (08FEB2021)	N/N	
>55/ C4591001 1140 11401078	GASTR	Diarrhoea/ Diarrhea	1	19AUG2020	13/13	1	No	O	NA	R (31AUG2020)	N/N	
	HEPAT	Cholecystitis acute/ Acute Cholecystitis	2	16SEP2020	20/15	3	No	O	NA/TC	R (30SEP2020)	Y/N	
>55/ C4591001 1140 11401082	INJ&P	Arthropod sting/ Bee-Sting	1	10AUG2020	4/1	2	No	O	NA/TC	R (10AUG2020)	N/N	
	MUSC	Myalgia/ myalgias#	3	24FEB2021	1/3	1	Yes		NA/TC	R (26FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1140 11401083	MUSC	Myalgia/ Myalgias#	3	24FEB2021	1/1	1	Yes		NA	R (24FEB2021)	N/N
>55/ C4591001 1140 11401104	MUSC	Back pain/ Low Back Pain	1	18AUG2020	6/1	1	No	O	NA	R (18AUG2020)	N/N
	GASTR	Nausea/ Nausea#	3	23FEB2021	1/1	1	Yes		NA	R (23FEB2021)	N/Y
	GENRL	Vaccination site pain/ Arm Pain at vaccination site#	3	24FEB2021	2/3	1	Yes		NA	R (26FEB2021)	N/N
>55/ C4591001 1140 11401114	GENRL	Injection site pain/ pain at injection site#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
>55/ C4591001 1140 11401117	CARD	Cardiac arrest/ Cardiac Arrest	2	29DEC2020	117/1	4	No	O	NA/W	F (29DEC2020)	Y/N
>55/ C4591001 1140 11401125	MUSC	Rotator cuff syndrome/ right rotator cuff tear	2	06JAN2021	125/63	2	No	O	NA	R (09MAR2021)	N/N
>55/ C4591001 1140 11401132	GENRL	Injection site pain/ Pain at injection site#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	MUSC	Osteoarthritis/ Worsening Of MedHx- Osteoarthritis#	4	21FEB2021	11/8	2	No	O	NA/TC	R (28FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1140 11401133	VASC	Phlebitis/ phlebitis*		17AUG2020	1/22	1	No	O	NA/TC	R (07SEP2020)	N/N	
>55/ C4591001 1140 11401138	GENRL	Fatigue/ Fatigue#	3	25FEB2021	1/3	2	Yes		NA	R (27FEB2021)	N/N	
		Malaise/ Malaise#	3	25FEB2021	1/3	2	Yes		NA	R (27FEB2021)	N/N	
>55/ C4591001 1140 11401140	NEOPL	Basal cell carcinoma/ Basal cell skin cancer- Right ear	2	05NOV2020	58/37	2	No	O	NA/TCN	R (11DEC2020)	N/N	
>55/ C4591001 1140 11401143	INJ&P	Back injury/ Back Pain (post traumatic)	2	20DEC2020	103/C	2	No	O	NA	N	N/N	
		Fall/ Fall	2	20DEC2020	103/1	2	No	O	NA	R (20DEC2020)	N/N	
		Joint injury/ Right hip pain (post traumatic)	2	20DEC2020	103/C	2	No	O	NA	N	N/N	
	GENRL	Injection site pain/ pain at injection#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N	
>55/ C4591001 1140 11401145	GENRL	Injection site pain/ pain at injection site	1	18AUG2020	1/2	2	Yes		NA/TC	R (19AUG2020)	N/N	
>55/ C4591001	GENRL	Fatigue/ fatigue	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine Subject	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1140 11401146		Injection site pain/ Pain at injection site	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
>55/ C4591001 1140 11401155	GENRL	Fatigue/ Fatigue	2	12SEP2020	4/2	2	Yes		NA	R (13SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	12SEP2020	4/2	2	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1140 11401156	CARD	Aortic valve incompetence/ Aortic Valve Dysfunction	2	01OCT2020	23/C	2	No	O	NA	RG	Y/N
	GENRL	Injection site pain/ pain at injection site#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1140 11401163	GENRL	Fatigue/ fatigue#	4	05FEB2021	2/2	2	Yes		NA	R (06FEB2021)	N/N
	NERV	Headache/ headache#	4	05FEB2021	2/1	1	Yes		NA/TC	R (05FEB2021)	N/N
>55/ C4591001 1140 11401173	GENRL	Pyrexia/ fever	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ pain at injection site	2	14SEP2020	1/4	1	Yes		NA/TC	R (17SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1140 11401179	INJ&P	Meniscus injury/ L Knee Meniscus tear	2	02DEC2020	80/C	3	No	O	NA/TC/TCN	RG	N/N	
	SURG	Meniscus operation/ L- Knee Meniscus repair surgery#	2	26JAN2021	135/1	3	No	O	NA/TC/TCN	R (26JAN2021)	N/N	
	INJ&P	Wrist fracture/ L- Broken wrist#	2	27JAN2021	136/C	3	No	O	NA/TC/TCN	RG	N/N	
>55/ C4591001 1140 11401181	GENRL	Feeling abnormal/ Brain Fog#	4	07FEB2021	5/C	2	No	O	NA	N	N/N	
		Gait disturbance/ Slowed Gait#	4	07FEB2021	5/C	2	No	O	NA	N	N/N	
	MUSC	Mobility decreased/ Decreased Left Hand Mobility#	4	07FEB2021	5/C	2	No	O	NA	N	N/N	
	NEOPL	Brain neoplasm/ Brain Tumor#	4	07FEB2021	5/C	4	No	O	NA	N	Y/N	
	NERV	Headache/ Headache#	4	07FEB2021	5/C	2	No	O	NA	N	N/N	
		Speech disorder/ Slowed Speech#	4	07FEB2021	5/C	2	No	O	NA	N	N/N	
>55/ C4591001 1140 11401182	INV	Body temperature decreased/ Low Temperature	1	14SEP2020	22/1	1	No	O	NA	R (14SEP2020)	N/N	
	GASTR	Nausea/ Nausea	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N	
	MUSC	Myalgia/ Muscle Aches	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1140 11401185	INFEC	Sinusitis/ Sinus Infection	1	25AUG2020	2/16	2	No	O	NA	R (09SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/3	2	Yes		NA	R (17SEP2020)	N/N	
		Pyrexia/ Fever	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N	
	MUSC	Myalgia/ Generalized Myalgias	2	15SEP2020	2/3	2	Yes		NA	R (17SEP2020)	N/N	
	NERV	Headache/ Headache	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N	
	PSYCH	Insomnia/ Insomnia	2	15SEP2020	2/3	2	Yes		NA	R (17SEP2020)	N/N	
>55/ C4591001 1140 11401190	GENRL	Injection site pain/ pain at injection site#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N	
	INFEC	Tooth infection/ tooth infection#	3	20FEB2021	12/6	1	No	O	NA/TC	R (25FEB2021)	N/N	
>55/ C4591001 1140 11401194	GENRL	Injection site pain/ pain at injection site	1	26AUG2020	1/7	1	Yes		NA	R (01SEP2020)	N/N	
	GASTR	Diarrhoea/ loose stool	1	29AUG2020	4/1	1	Yes		NA	R (29AUG2020)	N/N	
	MUSC	Myalgia/ Left arm muscular pain	1	29AUG2020	4/1	1	Yes		NA	R (29AUG2020)	N/N	
>55/ C4591001	GENRL	Fatigue/ Fatigue	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1140 11401197		Pyrexia/ Fever	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1140 11401200	GENRL	Injection site pain/ Pain at injection site#	3	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N
>55/ C4591001 1140 11401208	GENRL	Injection site pain/ Pain at injection site#	3	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
>55/ C4591001 1140 11401213	GENRL	Injection site pain/ Pain at Injection Site	1	28AUG2020	1/2	2	Yes		NA	R (29AUG2020)	N/N
>55/ C4591001 1140 11401222	GENRL	Injection site pain/ Pain at injection site	1	31AUG2020	1/2	2	Yes		NA/TC	R (01SEP2020)	N/N
>55/ C4591001 1140 11401223	GENRL	Injection site pain/ Pain at injection site	2	21SEP2020	1/1	2	Yes		NA/TC	R (21SEP2020)	N/N
>55/ C4591001 1140 11401226	GENRL	Injection site pain/ Pain at Injection site#	3	16FEB2021	1/C	1	Yes		NA	RG	N/Y
>55/ C4591001 1140 11401226	BLOOD	Lymphopenia/ Lymphopenia	1	15SEP2020	15/154	2	Yes		NA	R (15FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	BLOOD	Leukopenia/ Leukopenia	2	29OCT2020	35/110	1	Yes		NA	R (15FEB2021)	N/N
		Neutropenia/ Neutropenia	2	29OCT2020	35/110	1	Yes		NA	R (15FEB2021)	N/N
>55/ C4591001 1140 11401230	NERV	Headache/ headache	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	23SEP2020	3/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1140 11401235	GENRL	Injection site pain/ Pain at injection site	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
>55/ C4591001 1140 11401236	GENRL	Chills/ chills	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
		Fatigue/ fatigue	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Pain in extremity/ Left arm soreness	2	24SEP2020	2/5	2	Yes		NA/TC	R (28SEP2020)	N/N
>55/ C4591001 1140 11401237	MUSC	Pain in extremity/ Pain in upper right arm	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1140 11401238	MUSC	Pain in extremity/ Pain in upper R arm	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
	SKIN	Night sweats/ Night Sweats	2	25SEP2020	2/C	1	Yes		NA	RG	N/N
	GASTR	Gastrointestinal pain/ Worsening GI Cramping	1	08SEP2020	7/13	3	No	O	NA	R (20SEP2020)	N/N
		Small intestinal obstruction/ Small Bowel Obstruction	1	08SEP2020	7/13	3	No	O	NA	R (20SEP2020)	Y/N
	INFEC	Urinary tract infection/ Urinary Tract Infection#	2	21JAN2021	119/18	2	No	O	NA/TC	R (07FEB2021)	N/N
	RENAL	Bladder irritation/ Bladder irritation#	2	21JAN2021	119/18	1	No	O	NA/TC	R (07FEB2021)	N/N
	VASC	Hypertension/ hypertension*		02SEP2020	1/C	2	No	O	NA/TC	N	N/N
	RENAL	Urinary bladder polyp/ Bladder polyps#	3	04JAN2021	13/19	1	No	O	NA/TCN	R (22JAN2021)	N/N
	ENDO	Pituitary cyst/ pituitary gland cyst#	2	26FEB2021	157/C	2	No	O	NA	N	N/N
>55/ C4591001	MUSC	Pain in extremity/ Sore Arm-LEFT	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1140 11401254	GENRL	Malaise/ general malaise	2	23SEP2020	2/2	2	Yes	NA/TC	R	(24SEP2020)	N/N
	MUSC	Myalgia/ generalized myalgias	2	23SEP2020	2/2	2	Yes	NA/TC	R	(24SEP2020)	N/N
	NERV	Headache/ headache	2	23SEP2020	2/2	1	Yes	NA/TC	R	(24SEP2020)	N/N
>55/ C4591001 1140 11401256	GASTR	Diarrhoea/ diarrhea	2	24SEP2020	1/1	1	Yes	NA	R	(24SEP2020)	N/N
	GENRL	Fatigue/ fatigue#	3	21DEC2020	1/4	1	Yes	NA	R	(24DEC2020)	N/N
>55/ C4591001 1140 11401266	GENRL	Injection site pain/ Pain at injection site	2	28OCT2020	1/8	1	Yes	NA	R	(04NOV2020)	N/Y
>55/ C4591001 1140 11401268	GENRL	Injection site pain/ pain at injection site	1	08OCT2020	1/4	1	Yes	NA/TC	R	(11OCT2020)	N/N
>55/ C4591001 1140 11401271	GENRL	Chills/ Chills#	4	07JAN2021	1/2	1	Yes	NA	R	(08JAN2021)	N/N
		Fatigue/ Fatigue#	3	07JAN2021	22/4	1	Yes	NA	R	(10JAN2021)	N/N
		Pyrexia/ Fever#	4	07JAN2021	1/3	2	Yes	NA/TC	R	(09JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1140 11401276	NERV	Headache/ Headache#	4	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	08JAN2021	2/3	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Asthenia/ Weakness	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
		Injection site pain/ Pain at injection site	1	09OCT2020	1/2	2	Yes		NA	R (10OCT2020)	N/N
	NERV	Headache/ Headache	1	09OCT2020	1/2	2	Yes		NA	R (10OCT2020)	N/N
	GENRL	Asthenia/ Weakness	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N
		Injection site pain/ Pain at injection site	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N
>55/ C4591001 1140 11401277	NERV	Headache/ Headache	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N
	MUSC	Osteoarthritis/ Exacerbated Osteoarthritis	2	09NOV2020	11/C	2	No	O	NA	RG	N/N
>55/ C4591001 1140 11401278	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	08JAN2021	1/1	2	Yes		NA	R (08JAN2021)	N/N
	MUSC	Pain in extremity/ Left arm soreness#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1140 11401280	NERV	Dizziness/ Light headed	1	16OCT2020	4/1	2	No	O	NA	R (16OCT2020)	N/N
>55/ C4591001 1140 11401283	GASTR	Diarrhoea/ Loose Stool	1	18OCT2020	5/1	1	No	O	NA	R (18OCT2020)	N/N
>55/ C4591001 1140 11401288	GENRL	Injection site pain/ Pain at injection site	1	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Chills/ Chills	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
		Pyrexia/ Fever	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
>55/ C4591001 1140 11401289	GENRL	Injection site pain/ Pain at injection site#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
>55/ C4591001 1140 11401292	GENRL	Injection site pain/ pain at injection site	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
>55/ C4591001 1140 11401293	GENRL	Injection site pain/ pain at injection site	2	05NOV2020	1/2	1	Yes		NA/TC	R (06NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1140 11401305	GENRL	Injection site pain/ Pain at injection site	1	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/Y
>55/ C4591001 1140 11401312	GENRL	Injection site pain/ Pain at injection site	1	28OCT2020	1/4	1	Yes		NA	R (31OCT2020)	N/N
>55/ C4591001 1141 11411001	SKIN	Macule/ Skin Macule on left upper arm	1	06AUG2020	8/11	1	Yes		NA	R (16AUG2020)	N/N
>55/ C4591001 1141 11411015	GENRL	Injection site pain/ Injection site tenderness#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1141 11411028	MUSC	Back pain/ Back Pain	2	27AUG2020	2/21	3	Yes		NA	R (16SEP2020)	N/N
	GENRL	Face oedema/ Facial edema	2	01SEP2020	7/2	1	No	O	NA	R (02SEP2020)	N/N
	SKIN	Papule/ skin papules	2	01SEP2020	7/3	1	No	O	NA	R (03SEP2020)	N/N
	SKIN	Rash maculo-papular/ Maculopapular rash	2	26OCT2020	62/9	3	No	O	NA/TC	R (03NOV2020)	N/N
	GASTR	Diarrhoea/ Loose stools	2	27OCT2020	63/8	1	No	O	NA	R (03NOV2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ injection site soreness#	3	23DEC2020	1/1	1	Yes		NA	R (23DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411047 >55/ C4591001 1141 11411058	GENRL	Injection site pain/ injection site pain#	3	28DEC2020	1/5	1	Yes		NA	R (01JAN2021)	N/N
	GENRL	Injection site pain/ injection site soreness#	4	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N
	INV	Body temperature increased/ elevated body temperature 99.1F#	4	22JAN2021	2/1	1	Yes		NA	R (22JAN2021)	N/N
	NERV	Headache/ Headache#	4	22JAN2021	2/1	1	Yes		NA/TC	R (22JAN2021)	N/N
	GENRL	Injection site erythema/ erythema injectin site#	4	23JAN2021	3/7	2	Yes		NA	R (29JAN2021)	N/N
		Injection site pain/ tenderness at injection site#	4	23JAN2021	3/7	2	Yes		NA	R (29JAN2021)	N/N
		Injection site swelling/ swelling at injection site#	4	23JAN2021	3/7	2	Yes		NA	R (29JAN2021)	N/N
		Injection site warmth/ warmth at injection site#	4	23JAN2021	3/7	2	Yes		NA	R (29JAN2021)	N/N
>55/ C4591001 1141 11411059	INJ&P	Wound/ Puncture wounds, Right Hand	2	08SEP2020	9/7	1	No	O	NA/TC	R (14SEP2020)	N/N
>55/ C4591001 1141 11411069	GENRL	Injection site pain/ Injection site tenderness#	3	26JAN2021	2/4	1	Yes		NA	R (29JAN2021)	N/N
>55/ C4591001	GENRL	Fatigue/ Fatigue#	4	23JAN2021	2/1	2	Yes		NA	R (23JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411083	NERV	Headache/ headache (intermittent)#	4	23JAN2021	2/1	2	Yes		NA	R (23JAN2021)	N/N
>55/ C4591001 1141 11411100	GENRL	Injection site pain/ Tenderness at injection site	2	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site erythema/ Erythema at injection site	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
		Injection site swelling/ Swelling at injection site	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1141 11411101	GENRL	Injection site pain/ injection site soreness	1	19AUG2020	1/2	1	Yes		NA	R (20AUG2020)	N/N
>55/ C4591001 1141 11411105	GENRL	Injection site plaque/ skin plaque injection area left upper extremity	1	20AUG2020	2/21	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10SEP2020	1/3	2	Yes		NA	R (12SEP2020)	N/N
	MUSC	Myalgia/ myalgia	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
>55/ C4591001 1141 11411111	GENRL	Injection site pain/ injection pain	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/Y

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> of AE	Cause Investigational Vaccine Dose/ Subject	Action: Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	2	12SEP2020	2/3	3	Yes	NA	R (14SEP2020)	N/N
		Injection site pain/ Injection site pain	2	12SEP2020	2/121	2	Yes	NA/TC	R (10JAN2021)	N/N
	MUSC	Arthralgia/ Bilateral Knee Arthralgia	2	12SEP2020	2/3	2	Yes	NA	R (14SEP2020)	N/N
		Pain in extremity/ Leg Aches Bilateral	2	12SEP2020	2/3	2	Yes	NA	R (14SEP2020)	N/N
	NERV	Headache/ Headache	2	12SEP2020	2/3	1	Yes	NA	R (14SEP2020)	N/N
>55/ C4591001 1141 11411134	GENRL	Injection site pain/ injection site pain	1	26AUG2020	1/3	1	Yes	NA	R (28AUG2020)	N/N
>55/ C4591001 1141 11411138	GENRL	Fatigue/ Fatigue#	4	22JAN2021	2/1	1	Yes	NA	R (22JAN2021)	N/N
		Injection site pain/ injection site soreness#	4	22JAN2021	2/1	1	Yes	NA	R (22JAN2021)	N/N
		Pyrexia/ fever (100.4F)#	4	22JAN2021	2/1	1	Yes	NA/TC	R (22JAN2021)	N/N
	MUSC	Pain in extremity/ achy legs (bilateral)#	4	22JAN2021	2/1	1	Yes	NA	R (22JAN2021)	N/N
>55/ C4591001 1141 11411143	GENRL	Chills/ Chills	2	19SEP2020	2/2	1	Yes	NA	R (20SEP2020)	N/N
		Fatigue/ Fatigue	2	19SEP2020	2/2	1	Yes	NA	R (20SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	2	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N
	NEOPL	Breast cancer/ Breast Cancer of Right Breast#	2	04FEB2021	140/C	3	No	O	NA	N	N/N
	INJ&P	Procedural dizziness/ Post Anesthesia Dizziness#	2	03MAR2021	167/2	3	No	O	NA	R (04MAR2021)	Y/N
>55/ C4591001 1141 11411145	GENRL	Injection site pain/ injection site pain#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
>55/ C4591001 1141 11411147	GENRL	Injection site pain/ Injection site soreness left arm	2	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/Y
	GENRL	Injection site pain/ tenderness at injection site#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	GASTR	Nausea/ nausea#	3	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Pyrexia/ fever (100.6)#	3	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1141 11411155	GENRL	Injection site pain/ arm pain at injection site	1	01SEP2020	2/2	2	Yes		NA	R (02SEP2020)	N/N
		Pyrexia/ fever	1	01SEP2020	2/2	2	Yes		NA	R (02SEP2020)	N/N
	MUSC	Myalgia/ myalgias	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
	NERV	Headache/ headache	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	22SEP2020	2/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	MUSC	Myalgia/ Myalgia Generalized	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C4591001 1141 11411157	GENRL	Injection site pain/ injection site pain left	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
	MUSC	Myalgia/ diffuse arm myalgia	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Pyrexia/ low grade fever	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C4591001 1141 11411160	GENRL	Injection site bruising/ bruise at injection site	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/Y
		Injection site pain/ injection site pain	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/Y
	GENRL	Injection site pain/ injection site pain#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
>55/ C4591001 1141 11411178	GENRL	Injection site pain/ injection site pain#	3	24JAN2021	3/2	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1141 11411183	INV	Body temperature increased/ elevated body temperature (99.9F)#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
	GENRL	Pyrexia/ low grade fever	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
	MUSC	Arthralgia/ arthralgia	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Pyrexia/ Low Grade Fever	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Arthralgia/ Arthralgia	2	30SEP2020	2/2	1	Yes		NA/TCN	R (01OCT2020)	N/N
	GASTR	Vomiting/ Emesis	2	28DEC2020	91/2	3	No	O	NA/TC	R (29DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ Headache#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	3	09FEB2021	2/2	2	Yes		NA	R (10FEB2021)	N/N
	MUSC	Arthralgia/ Generalized Arthralgia#	3	09FEB2021	2/2	2	Yes		NA/TCN	R (10FEB2021)	N/N
>55/ C4591001 1141 11411189	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	3/1	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	01OCT2020	2/3	2	Yes		NA/TC	R (03OCT2020)	N/N
		Malaise/ Malaise	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1141 11411191	MUSC	Pyrexia/ Low grade Fever	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		Joint range of motion decreased/ Range of upward motion decreased in Vaccinated arm	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	01OCT2020	1/5	1	Yes		NA	R (05OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C4591001 1141 11411196	GENRL	Injection site pain/ Injection Site Pain#	3	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Chills/ chills#	4	19FEB2021	2/3	1	Yes		NA	R (21FEB2021)	N/N
		Fatigue/ Fatigue#	4	19FEB2021	2/3	1	Yes		NA	R (21FEB2021)	N/N
		Feeling hot/ warm sensation#	4	19FEB2021	2/3	1	Yes		NA	R (21FEB2021)	N/N
		Injection site pain/ injection site pain#	4	19FEB2021	2/7	1	Yes		NA	R (25FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1141 11411200	MUSC	Myalgia/ myalgia#	4	19FEB2021	2/3	1	Yes		NA/TC	R (21FEB2021)	N/N
	GENRL	Injection site pain/ injection pain site soreness	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site swelling/ injection site swelling	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	INV	Body temperature increased/ elevated body temperature	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Dizziness/ Dizziness	1	14SEP2020	4/1	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Tenderness/Pain	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Pyrexia/ Fever (Tmax 101.2)	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1141 11411207	NERV	Headache/ Headache	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
	GASTR	Vomiting/ Emesis	2	08OCT2020	2/1	1	No	O	NA	R (08OCT2020)	N/N
>55/ C4591001 1141 11411210	MUSC	Myalgia/ myalgias#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
	INFEC	Infected dermal cyst/ Inflamed Epidermal Inclusion Cyst	2	11DEC2020	66/8	1	No	O	NA/TC	R (18DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache#	4	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
>55/ C4591001 1141 11411216	GENRL	Injection site pain/ injection site soreness left arm	1	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness	2	07OCT2020	1/2	1	Yes		NA/TC	R (08OCT2020)	N/N
>55/ C4591001 1141 11411232	GENRL	Injection site pain/ tenderness at injection site	1	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
		Malaise/ Malaise	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
		Pain/ Body aches	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
>55/ C4591001 1141 11411233	GENRL	Chills/ Chills	1	19SEP2020	2/1	2	Yes		NA	R (19SEP2020)	N/N
		Fatigue/ Fatigue <sup>19</sup>	1	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
		Injection site pain/ Injection site pain left arm	1	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ Myalgia back area	1	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ Headache	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1141 11411244	GENRL	Injection site pain/ Injection Site Soreness	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N	
	NERV	Headache/ Headache	2	14OCT2020	6/1	2	Yes		NA/TC	R (14OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N	
	RESP	Oropharyngeal pain/ Sore Throat	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
	GENRL	Chills/ Chills	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N	
				2	16OCT2020	2/2	3	Yes		NA/TC	R (17OCT2020)	N/N
			Injection site pain/ Injection Site Pain Left Arm	2	16OCT2020	2/2	2	Yes		NA	R (17OCT2020)	N/N
			Pyrexia/ Fever	2	16OCT2020	2/2	3	Yes		NA/TC	R (17OCT2020)	N/N
	INV	Body temperature increased/ Elevated Body Temperature	2	16OCT2020	2/2	2	Yes			NA/TC	R (17OCT2020)	N/N
MUSC	Myalgia/ Generalized Myalgias	2	16OCT2020	2/2	2	Yes			NA/TC	R (17OCT2020)	N/N	
		Myalgia/ Muscle Aches	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N	
NERV	Headache/ Headache	2	16OCT2020	2/2	1	Yes			NA/TC	R (17OCT2020)	N/N	
>55/ C4591001	MUSC	Muscle spasms/ Back Spasms	1	17OCT2020	11/9	3	No	O	NA/TC/TCN	R (25OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411253	MUSC	Myalgia/ Muscle achiness in back (shoveling snow)	2	05JAN2021	70/2	2	No	O	NA/TC	R (06JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1141 11411258	GENRL	Injection site pain/ injection site pain#	3	23DEC2020	2/1	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Chills/ chills#	4	15JAN2021	2/1	2	Yes		NA	R (15JAN2021)	N/N
		Pyrexia/ Fever (101.5F)#	4	15JAN2021	2/3	2	Yes		NA	R (17JAN2021)	N/N
	MUSC	Pain in extremity/ sore arm (left arm shoulder to elbow)#	4	17JAN2021	4/3	2	Yes		NA	R (19JAN2021)	N/N
	NERV	Paraesthesia/ prickly skin sensation left arm (shoulder to elbow)#	4	17JAN2021	4/3	1	Yes		NA	R (19JAN2021)	N/N
>55/ C4591001 1141 11411259	GENRL	Injection site pain/ injection site soreness#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Pyrexia/ Low grade fever (100.4 F)#	4	12JAN2021	2/1	2	Yes		NA	R (12JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	12JAN2021	2/1	2	Yes		NA	R (12JAN2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ injection site pain	1	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1141 11411268	INFEC	Folliculitis/ folliculitis right axillary	1	06NOV2020	12/11	1	No	O	NA	R (16NOV2020)	N/N	
	GENRL	Injection site pain/ injection site pain	2	16NOV2020	1/2	1	Yes		NA	R (17NOV2020)	N/N	
>55/ C4591001 1142 11421003	BLOOD	Lymphocytosis/ Atypical Lymphocytosis	2	26OCT2020	71/93	3	No	O	NA	R (26JAN2021)	N/N	
>55/ C4591001 1142 11421005	GENRL	Injection site pain/ injection site pain#	3	04JAN2021	1/4	1	Yes		NA	R (07JAN2021)	N/N	
	GASTR	Diarrhoea/ diarrhea#	3	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N	
	GENRL	Chills/ chills#	3	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N	
		Malaise/ malaise#	3	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N	
	INV	Body temperature increased/ elevated temperature 100.2F#	3	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N	
	GENRL	Pain/ Body aches#	4	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N	
>55/ C4591001 1142 11421006	GENRL	Injection site pain/ injection site pain#	3	05JAN2021	2/3	1	Yes		NA	R (07JAN2021)	N/N	
	MUSC	Pain in extremity/ sore arm#	4	26JAN2021	2/4	1	Yes		NA	R (29JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1142 11421032	GENRL	Injection site erythema/ redness at injection site#	4	05FEB2021	12/5	1	Yes		NA	R (09FEB2021)	N/N
		Pyrexia/ Fever#	4	05FEB2021	12/4	1	No	O	NA	R (08FEB2021)	N/N
	INFEC	Oral herpes/ fever blisters#	4	05FEB2021	12/5	1	No	O	NA	R (09FEB2021)	N/N
	VASC	Orthostatic hypotension/ Possible postural hypotension	2	31AUG2020	4/1	3	No	O	NA/TC	R (31AUG2020)	Y/N
	GENRL	Injection site pain/ injection site pain#	3	04JAN2021	1/3	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	3	31DEC2020	2/2	1	Yes		NA	R (01JAN2021)	N/N
	GASTR	Colitis/ Colitis	2	05SEP2020	8/C	3	No	CD	NA/TC	RG	Y/N
	GENRL	Injection site pain/ pain at injection site#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Joint pain	2	03SEP2020	7/2	1	Yes		NA	R (04SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1142 11421065	MUSC	Arthralgia/ Generalized Joint Pain#	4	19JAN2021	1/4	1	Yes		NA	R (22JAN2021)	N/N
		Myalgia/ Muscle Pain#	4	19JAN2021	1/4	1	Yes		NA	R (22JAN2021)	N/Y
>55/ C4591001 1142 11421069	GENRL	Injection site pain/ injection site pain#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	3	18DEC2020	2/2	1	Yes		NA	R (19DEC2020)	N/N
	MUSC	Myalgia/ muscle aches#	3	18DEC2020	2/2	1	Yes		NA	R (19DEC2020)	N/N
>55/ C4591001 1142 11421073	VASC	Aortic aneurysm/ Ascending Aortic Aneurysm#	2	04JAN2021	126/C	4	No	O	NA/TCN	RG	Y/N
>55/ C4591001 1142 11421074	GENRL	Injection site pain/ injection site pain#	3	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Chills/ chills#	4	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
		Pain/ body aches#	4	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
		Pyrexia/ fever#	4	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	05JAN2021	1/	1	Yes		NA	R	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1142 11421086 >55/ C4591001 1142 11421095	GENRL	Injection site pain/ injection site pain#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
		Pyrexia/ fever#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
>55/ C4591001 1142 11421098	GENRL	Injection site pain/ injection site pain#	3	13JAN2021	1/2	2	Yes		NA	R (14JAN2021)	N/N
	GENRL	Chills/ chills#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
		Pain/ body aches#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	NERV	Headache/ headache#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Injection site pruritus/ itch at injection site#	4	05FEB2021	5/1	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1142 11421104	NERV	Tension headache/ tension headache	1	14AUG2020	1/2	3	No	O	NA/TC	R (15AUG2020)	N/Y
	GENRL	Chills/ chills#	4	27JAN2021	1/2	2	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1142 11421108	GENRL	Injection site pain/ injection site pain#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Axillary pain/ left axillary pain#	3	05JAN2021	2/1	1	Yes		NA	R (05JAN2021)	N/N
	NERV	Headache/ headache#	3	07JAN2021	4/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Chills/ chills#	4	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Pain/ body aches#	4	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
>55/ C4591001 1142 11421111	GASTR	Abdominal pain/ Abdominal Pain	1	26AUG2020	10/41	2	Yes		NA	R (05OCT2020)	N/N
	SKIN	Night sweats/ Night sweats	1	29AUG2020	13/C	3	Yes		NA	RG	N/N
>55/ C4591001 1142 11421114	MUSC	Rotator cuff syndrome/ torn rotator cuff (R)	1	02SEP2020	16/C	2	No	O	NA/TC/TCN	RG	N/N
>55/ C4591001 1142 11421116	GENRL	Injection site pain/ injection site pain#	3	30DEC2020	2/2	1	Yes		NA	R (31DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
>55/ C4591001 1142 11421120	GENRL	Fatigue/ fatigue#	3	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N
		Injection site pain/ injection site pain#	3	26FEB2021	2/4	1	Yes		NA	R (01MAR2021)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1142 11421125	GENRL	Injection site pain/ Injection site pain#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
>55/ C4591001 1142 11421135	GENRL	Injection site pain/ injection site pain#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001 1142 11421136	EYE	Ocular discomfort/ eye discomfort#	3	04JAN2021	1/1	1	Yes		NA	R (04JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
		Injection site pain/ injection site pain#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	25JAN2021	1/3	2	Yes		NA	R (27JAN2021)	N/N
		Pain/ aches#	4	25JAN2021	1/3	2	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001 1142 11421139	GENRL	Pyrexia/ fever#	4	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N
>55/ C4591001 1142 11421146	GENRL	Injection site pain/ Injection site pain	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N



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>55/ C4591001 1142 11421148	INJ&P	Muscle strain/ muscle strain of lower leg/calf	2	25SEP2020	12/C	1	No	O	NA/TC	RG	N/N	
	GENRL	Injection site pain/ injection site pain#	3	04JAN2021	1/4	2	Yes		NA	R (07JAN2021)	N/N	
>55/ C4591001 1142 11421152	GENRL	Injection site pain/ injection site pain#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N	
>55/ C4591001 1142 11421154	GENRL	Injection site pain/ injection site pain#	3	04FEB2021	1/1	1	Yes		NA	R (04FEB2021)	N/N	
	INJ&P	Skin laceration/ scalp laceration#	3	17FEB2021	14/2	2	No	O	NA/TCN	R (18FEB2021)	N/N	
>55/ C4591001 1142 11421160	GENRL	Pyrexia/ fever 101.0 F	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N	
>55/ C4591001 1142 11421167	GENRL	Chills/ chills#	4	06JAN2021	2/2	2	Yes		NA	R (07JAN2021)	N/N	
		Fatigue/ fatigue#	4	06JAN2021	2/2	2	Yes		NA	R (07JAN2021)	N/N	
		Injection site pain/ injection site pain#	4	06JAN2021	2/3	2	Yes		NA	R (08JAN2021)	N/N	
		Pyrexia/ fever#	4	06JAN2021	2/2	2	Yes		NA	R (07JAN2021)	N/N	

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>55/ C4591001 1142 11421171	GENRL	Fatigue/ Fatigue#	3	31DEC2020	1/3	1	Yes		NA	R (02JAN2021)	N/N
	NERV	Headache/ Headache#	3	31DEC2020	1/1	1	Yes		NA	R (31DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	4	19JAN2021	1/3	2	Yes		NA	R (21JAN2021)	N/N
>55/ C4591001 1142 11421174	GENRL	Fatigue/ fatigue#	4	06JAN2021	1/1	1	Yes		NA	R (06JAN2021)	N/N
		Injection site pain/ injection site pain#	4	06JAN2021	1/1	1	Yes		NA	R (06JAN2021)	N/N
>55/ C4591001 1142 11421176	GENRL	Fatigue/ fatigue#	3	06FEB2021	2/1	2	Yes		NA	R (06FEB2021)	N/N
		Injection site pain/ injection site pain#	3	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N
	GENRL	Chills/ chills#	4	24FEB2021	1/3	2	Yes		NA	R (26FEB2021)	N/N
	GENRL	Injection site erythema/ injection site redness#	4	25FEB2021	2/2	2	Yes		NA	R (26FEB2021)	N/N
		Injection site pain/ injection site pain#	4	25FEB2021	2/2	2	Yes		NA	R (26FEB2021)	N/N
	NERV	Lethargy/ lethargy#	4	25FEB2021	2/2	2	Yes		NA	R (26FEB2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ injection site pain (left deltoid)	1	02SEP2020	1/3	1	Yes		NA/TCN	R (04SEP2020)	N/N

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1142 11421177	GENRL	Axillary pain/ left axillary tenderness	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		Injection site pain/ injection site pain (left deltoid)	2	24SEP2020	2/3	1	Yes		NA/TC/TCN	R (26SEP2020)	N/N
	MUSC	Arthralgia/ intermittent point tenderness of left elbow at olecranon process	2	NOV2020	40/C	1	No	O	NA	RG	N/N
		Arthropathy/ Cyst at left wrist	2	NOV2020	40/C	1	No	O	NA	RG	N/N
>55/ C4591001 1142 11421191	GENRL	Injection site erythema/ injection site redness	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
		Injection site pruritus/ injection site itching	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
>55/ C4591001 1142 11421193	GENRL	Injection site pain/ injection site pain#	3	31DEC2020	1/2	1	Yes		NA	R (01JAN2021)	N/N
	INJ&P	Contusion/ bruising at left forearm#	4	24JAN2021	3/15	1	Yes		NA	R (07FEB2021)	N/N
>55/ C4591001 1142 11421201	GENRL	Pain/ body aches#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N

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>55/ C4591001 1142 11421207	GENRL	Chills/ chills#	4	22JAN2021	2/1	2	Yes		NA	R (22JAN2021)	N/N	
		Malaise/ malaise#	4	22JAN2021	2/1	2	Yes		NA	R (22JAN2021)	N/N	
		Pyrexia/ fever of 101.4#	4	22JAN2021	2/1	2	Yes		NA	R (22JAN2021)	N/N	
		NERV	Headache/ headache#	4	22JAN2021	2/1	2	Yes		NA	R (22JAN2021)	N/N
>55/ C4591001 1142 11421208	GENRL	Injection site pain/ injection site pain#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N	
	GENRL	Injection site pain/ injection site pain#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
>55/ C4591001 1142 11421209	GENRL	Injection site pain/ injection site pain	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N	
		Injection site warmth/ injection site warmth	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N	
	SKIN	Hand dermatitis/ worsening of eczema of hands#	2	FEB2021	127/C	2	No	O	NA	RG	N/N	
>55/ C4591001 1142 11421210	GENRL	Injection site pain/ injection site pain#	3	05JAN2021	1/2	2	Yes		NA	R (06JAN2021)	N/N	
	GENRL	Pain/ body aches#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	

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>55/ C4591001 1142 11421213	GASTR	Pyrexia/ fever#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	
		Inguinal hernia/ left inguinal hernia	2	01JAN2021	93/C	2	No	O	NA/TCN	N	N/N	
	GENRL	Injection site pain/ injection site pain#	3	05FEB2021	2/2	2	Yes		NA	R (06FEB2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	24FEB2021	2/4	1	Yes		NA	R (27FEB2021)	N/N	
	MUSC	Injection site pain/ injection site pain#	4	24FEB2021	2/4	1	Yes		NA	R (27FEB2021)	N/N	
>55/ C4591001 1142 11421215	MUSC	Neck pain/ neck soreness#	4	24FEB2021	2/4	1	Yes		NA	R (27FEB2021)	N/N	
	MUSC	Spondylolisthesis/ Worsening of spondylolisthesis	2	01JAN2021	92/C	3	No	O	NA	N	Y/N	
>55/ C4591001 1142 11421225	GENRL	Malaise/ malaise#	3	01JAN2021	2/1	1	Yes		NA	R (01JAN2021)	N/N	
	GENRL	Injection site pain/ injection site pain#	4	20JAN2021	2/3	2	Yes		NA	R (22JAN2021)	N/N	
		Pain/ body aches#	4	20JAN2021	2/3	2	Yes		NA	R (22JAN2021)	N/N	
		Pyrexia/ fever#	4	20JAN2021	2/3	2	Yes		NA	R (22JAN2021)	N/N	
>55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	10FEB2021	1/1	1	Yes		NA	R (10FEB2021)	N/N	

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1142 11421226 >55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
1142 11421227 >55/ C4591001	GENRL	Fatigue/ Fatigue	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
1142 11421232 11421232	GENRL	Fatigue/ Fatigue	2	07OCT2020	1/4	3	Yes		NA	R (10OCT2020)	N/N
		Injection site pain/ Injection site pain	2	07OCT2020	1/4	3	Yes		NA	R (10OCT2020)	N/N
		Pain/ Body aches	2	07OCT2020	1/4	3	Yes		NA	R (10OCT2020)	N/N
	NERV	Headache/ Headache	2	07OCT2020	1/4	3	Yes		NA	R (10OCT2020)	N/N
>55/ C4591001	GENRL	Fatigue/ fatigue#	4	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N
1142 11421236 >55/ C4591001	GENRL	Injection site pain/ injection site soreness#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
1142 11421238		Injection site swelling/ swelling at injection site#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	09JAN2021	2/3	2	Yes		NA	R (11JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1142 11421240 >55/ C4591001 1142 11421243	GENRL	Malaise/ Malaise	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N	
>55/ C4591001 1142 11421247	CARD	Ventricular arrhythmia/ Ventricular arrhythmias	2	14OCT2020	1/8	3	Yes		NA/TC	R (21OCT2020)	Y/N	
>55/ C4591001 1142 11421249	GENRL	Injection site pain/ injection site pain#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N	
>55/ C4591001 1142 11421259	GENRL	Injection site pain/ Injection site soreness	1	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N	
	NERV	Headache/ Headache	1	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site soreness	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N	
	NERV	Headache/ Headache	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N	
>55/ C4591001 1142 11421267	GENRL	Chills/ chills	2	27OCT2020	2/1	2	Yes		NA/TC	R (27OCT2020)	N/N	
		Pyrexia/ fever	2	27OCT2020	2/1	2	Yes		NA/TC	R (27OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Myalgia/ muscle aches	2	27OCT2020	2/1	2	Yes		NA/TC	R (27OCT2020)	N/N	
>55/ C4591001 1142 11421279	NERV	Headache/ headache#	3	06JAN2021	2/1	1	Yes		NA	R (06JAN2021)	N/N	
>55/ C4591001 1142 11421294	GENRL	Injection site pain/ injection site pain#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N	
>55/ C4591001 1142 11421297†	GENRL	Injection site mass/ bump at injection site#	3	30DEC2020	1/C	1	Yes		NA	RG	N/N	
		Injection site pain/ injection site pain#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N	
>55/ C4591001 1142 11421301	GENRL	Injection site pain/ injection site pain#	3	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N	
	GENRL	Chills/ chills#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	
		Injection site pain/ injection site pain#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	
>55/ C4591001 1142 11421304	GENRL	Injection site bruising/ Bruising at injection site	1	27OCT2020	1/51	1	Yes		NA	R (16DEC2020)	N/N	
>55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	28DEC2020	1/2	1	Yes		NA	R (29DEC2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1142 11421309	GENRL	Chills/ chills#	4	20JAN2021	1/4	2	Yes		NA	R (23JAN2021)	N/N
		Pain/ body aches#	4	20JAN2021	1/4	2	Yes		NA	R (23JAN2021)	N/N
		Pyrexia/ fever#	4	20JAN2021	1/4	2	Yes		NA	R (23JAN2021)	N/N
>55/ C4591001 1145 11451006	GENRL	Fatigue/ fatigue#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
	MUSC	Pain in extremity/ left arm soreness#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1145 11451008	GENRL	Pain/ body ache	2	08SEP2020	7/2	1	Yes		NA/TC	R (09SEP2020)	N/N
>55/ C4591001 1145 11451012	MUSC	Back pain/ back pain	1	16AUG2020	3/16	2	No	O	NA/TCN	R (31AUG2020)	N/N
>55/ C4591001 1145 11451014	GENRL	Injection site pain/ injection site pain ( Left Arm)	2	30SEP2020	29/2	1	Yes		NA	R (01OCT2020)	N/N
>55/ C4591001 1145 11451016	NERV	Headache/ Headache	2	11SEP2020	2/4	1	Yes		NA	R (14SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1145 11451023	GENRL	Fatigue/ Fatigue	2	12SEP2020	3/3	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Asthenia/ Weakness	1	19AUG2020	2/2	2	Yes		NA	R (20AUG2020)	N/N
		Injection site pain/ Injection site pain	1	19AUG2020	2/2	3	Yes		NA/TC	R (20AUG2020)	N/N
>55/ C4591001 1145 11451024	GENRL	Injection site pain/ Pain at injection site	1	18AUG2020	1/1	1	Yes		NA	R (18AUG2020)	N/Y
	GENRL	Chills/ chills	2	09SEP2020	2/3	2	Yes		NA	R (11SEP2020)	N/N
		Fatigue/ fatigue	2	09SEP2020	2/3	2	Yes		NA	R (11SEP2020)	N/N
	MUSC	Arthralgia/ generalized joint pain	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
		Myalgia/ muscle pain	2	09SEP2020	2/3	2	Yes		NA	R (11SEP2020)	N/N
	NERV	Headache/ headache	2	09SEP2020	2/3	2	Yes		NA	R (11SEP2020)	N/N
	GENRL	Chills/ chills	2	11SEP2020	4/4	1	Yes		NA	R (14SEP2020)	N/N
		Injection site pain/ injection site pain	2	11SEP2020	4/4	1	Yes		NA	R (14SEP2020)	N/N
>55/ C4591001		Injection site swelling/ swelling at injection site left arm	2	11SEP2020	4/4	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	11SEP2020	3/1	1	Yes		NA/TC	R (11SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1145 11451027	MUSC	Myalgia/ muscle aches	2	11SEP2020	3/1	1	Yes		NA/TC	R (11SEP2020)	N/N
	NERV	Headache/ Headache	2	11SEP2020	3/1	1	Yes		NA/TC	R (11SEP2020)	N/N
>55/ C4591001 1145 11451038	GENRL	Injection site pain/ Pain at injection site	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/Y
	MUSC	Myalgia/ Muscle pain	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	15SEP2020	1/4	3	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C4591001 1145 11451040	INJ&P	Contusion/ bruise on head#	4	29JAN2021	4/9	2	No	O	NA	R (06FEB2021)	N/N
		Eye contusion/ bruises on left eye#	4	29JAN2021	4/9	2	No	O	NA	R (06FEB2021)	N/N
		Fall/ fall#	4	29JAN2021	4/1	3	No	O	NA	R (29JAN2021)	N/N
	INJ&P	Skin laceration/ scalp laceration#	4	30JAN2021	5/8	3	No	O	NA/TCN	R (06FEB2021)	N/N
>55/ C4591001 1145 11451041	GENRL	Injection site pain/ pain at injection site	2	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/Y
>55/ C4591001	GENRL	Asthenia/ Asthenia (weakness)	2	15SEP2020	1/2	1	Yes		NA/TCN	R (16SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1145 11451052		Injection site pain/ left injection site pain	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
	PSYCH	Insomnia/ Insomnia	2	16SEP2020	2/1	2	Yes		NA	R (16SEP2020)	N/N	
>55/ C4591001 1145 11451055	CARD	Atrial fibrillation/ atrial fibrillation	2	12DEC2020	87/2	3	No	O	NA/TC	R (13DEC2020)	Y/N	
>55/ C4591001 1145 11451056	CARD	Tachycardia/ tachycardia	2	07OCT2020	21/2	3	No	O	NA	R (08OCT2020)	Y/N	
	CARD	Pericardial effusion/ small pericardial effusion	2	08OCT2020	22/C	2	No	O	NA	RG	N/N	
>55/ C4591001 1145 11451061	INJ&P	Fall/ Fall	1	16SEP2020	17/1	2	No	O	NA	R (16SEP2020)	N/N	
		Limb injury/ LEFT LOWER LEG PAIN (POST- TRAUMATIC)	1	16SEP2020	17/71	2	No	O	NA	R (25NOV2020)	N/N	
>55/ C4591001 1145 11451065	SKIN	Pruritus/ Itching legs	1	06SEP2020	4/1	1	Yes		NA	R (06SEP2020)	N/N	
>55/ C4591001 1145 11451072	GENRL	Fatigue/ Fatigue	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1145 11451073	GENRL	Injection site pain/ Injection site pain	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N
		Injection site pain/ Injection site pain	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
>55/ C4591001 1145 11451076	NERV	Parkinsonism/ parkinsonism	1	18SEP2020	15/C	1	No	O	P	N	N/N
>55/ C4591001 1145 11451078	GENRL	Fatigue/ Fatigue	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	NERV	Injection site pain/ Injection site pain	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	NERV	Headache/ Headache	1	05SEP2020	2/2	1	Yes		NA/TC	R (06SEP2020)	N/N
	MUSC	Musculoskeletal stiffness/ Neck stiffness	1	15SEP2020	12/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	GASTR	Nausea/ NAUSEOUS	1	24SEP2020	21/3	1	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ headache	2	24SEP2020	1/3	2	Yes		NA	R (26SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		Fatigue/ FATIGUE	2	25SEP2020	2/2	3	Yes		NA	R (26SEP2020)	N/N
	NERV	Dizziness/ DIZZINESS	2	25SEP2020	2/2	2	Yes		NA	R (26SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1145 11451083	GENRL	Injection site pain/ Injection site pain	1	09SEP2020	1/3	2	Yes		NA	R (11SEP2020)	N/N
		Injection site swelling/ Injection site swelling	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Injection site warmth/ Injection site warmth	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	METAB	Decreased appetite/ Loss of appetite	1	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N
	VASC	Flushing/ Facial flushing	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Chills/ Chills	1	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
		Fatigue/ Fatigue	1	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	29SEP2020	1/3	2	Yes		NA	R (01OCT2020)	N/N
	METAB	Decreased appetite/ anorexia	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	VASC	Flushing/ facial flushing	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
GENRL	Fatigue/ fatigue	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N	
>55/ C4591001 1145 11451084	GENRL	Injection site pain/ injection site pain*		09SEP2020	1/3	2	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1145 11451089	GENRL	Injection site pain/ injection site pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
>55/ C4591001 1145 11451095	GASTR	Vomiting/ vomitting#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
	GENRL	Chills/ chills#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
		Fatigue/ fatigue#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ injection site pain (left arm)#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
		Pyrexia/ fever#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1145 11451096	GENRL	Chills/ chills#	4	09FEB2021	1/3	3	Yes		NA	R (11FEB2021)	N/N
		Fatigue/ fatigue#	4	09FEB2021	1/3	2	Yes		NA	R (11FEB2021)	N/N
		Pyrexia/ fever#	4	09FEB2021	1/1	1	Yes		NA	R (09FEB2021)	N/N
	MUSC	Myalgia/ muscle aches#	4	09FEB2021	1/3	2	Yes		NA	R (11FEB2021)	N/N
		Pain in extremity/ left arm soreness#	4	09FEB2021	1/3	2	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Arthralgia/ generalized joint pain#	4	10FEB2021	2/2	2	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1145 11451100	GENRL	Injection site pain/ injection site pain	1	11SEP2020	1/2	2	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site erythema/ injection site redness	2	01OCT2020	1/4	1	Yes		NA	R (04OCT2020)	N/N
>55/ C4591001 1145 11451102	GENRL	Injection site pain/ Left Arm injection site pain	1	11SEP2020	1/2	2	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	01OCT2020	1/3	3	Yes		NA	R (03OCT2020)	N/N
	MUSC	Arthralgia/ joint aches	2	02OCT2020	2/2	3	Yes		NA	R (03OCT2020)	N/N
		Myalgia/ muscle aches	2	02OCT2020	2/2	3	Yes		NA	R (03OCT2020)	N/N
>55/ C4591001 1145 11451113	GASTR	Nausea/ nausea	1	19NOV2020	24/1	2	Yes		NA	R (19NOV2020)	N/N
	GENRL	Chills/ chills	1	19NOV2020	24/3	2	Yes		NA	R (21NOV2020)	N/N
		Injection site pain/ injection site pain	1	19NOV2020	24/4	2	Yes		NA	R (22NOV2020)	N/N
	NERV	Headache/ headache	1	19NOV2020	24/3	2	Yes		NA	R (21NOV2020)	N/N
>55/ C4591001	MUSC	Arthralgia/ Migratory arthralgias-left wrist,right	3	09JAN2021	4/18	2	Yes		NA	R (26JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1146 11461001		wrist,right elbow right shoulder, right rib. Only pain#									
>55/ C4591001 1146 11461015	NERV	Transient ischaemic attack/ Transient Ischemic Attack#	3	11JAN2021	6/2	2	No	O	NA	R (12JAN2021)	Y/N
>55/ C4591001 1146 11461024	MUSC	Pain in extremity/ Arm Pain#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1146 11461024	GASTR	Faeces soft/ Change in bowel movements -Softer Stool	1	16AUG2020	3/66	1	Yes		NA	R (20OCT2020)	N/N
>55/ C4591001 1146 11461027	INV	Blood glucose increased/ Increased glucose	2	02OCT2020	19/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1146 11461037	GENRL	Fatigue/ Fatigue#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
>55/ C4591001 1146 11461039	MUSC	Pain in extremity/ Mild Arm Pain#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
>55/ C4591001 1146 11461039	GENRL	Fatigue/ Fatigue	1	17AUG2020	1/8	1	Yes		NA	R (24AUG2020)	N/N
>55/ C4591001		Injection site erythema/ Redness at injection site	1	17AUG2020	1/8	1	Yes		NA	R (24AUG2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ injection site pain	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/Y

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1146 11461060	GENRL	Injection site pain/ Injection site pain	2	08SEP2020	1/5	1	Yes		NA	R (12SEP2020)	N/Y	
>55/ C4591001 1146 11461062	GENRL	Injection site pain/ injection site pain	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N	
>55/ C4591001 1146 11461064	GENRL	Injection site pain/ injection site pain	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/Y	
	GENRL	Fatigue/ Fatigue	2	10SEP2020	3/3	1	Yes		NA	R (12SEP2020)	N/N	
		Pain/ Body Aches	2	10SEP2020	3/3	1	Yes		NA	R (12SEP2020)	N/N	
		Pyrexia/ Fever of 100.3	2	10SEP2020	3/3	1	Yes		NA/TC	R (12SEP2020)	N/N	
	NERV	Headache/ Headache	2	10SEP2020	3/3	1	Yes		NA	R (12SEP2020)	N/N	
>55/ C4591001 1146 11461065	INV	Blood glucose increased/ Increase in blood sugar	1	12SEP2020	24/C	1	No	O	NA	N	N/N	
>55/ C4591001 1146 11461072	GENRL	Fatigue/ fatigue after vaccine 1	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N	
		Injection site pain/ Injection site pain after vaccine 1	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site pain after vaccine 2	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Pain/ body aches	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
>55/ C4591001 1146 11461073	GENRL	Chills/ Chills#	4	04FEB2021	2/5	3	Yes		NA	R (08FEB2021)	N/N
	MUSC	Myalgia/ Muscle aches on the left side.#	4	04FEB2021	2/5	3	Yes		NA	R (08FEB2021)	N/N
>55/ C4591001 1146 11461087	GENRL	Chills/ Chills#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	4	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1146 11461088	SKIN	Rash/ Rash, generalized.	2	01DEC2020	83/17	1	No	O	NA/TC	R (17DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site pain#	3	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Chills/ Chills#	3	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
		Fatigue/ Fatigue#	3	09JAN2021	2/3	1	Yes		NA	R (11JAN2021)	N/N
	GENRL	Chills/ Chills#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1146 11461095	MUSC	Musculoskeletal stiffness/ Muscle Stiffness#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1146 11461101	GENRL	Injection site pain/ Injection Site Pain#	4	25FEB2021	1/2	1	Yes		NA	R (26FEB2021)	N/N
	INFEC	Hordeolum/ Stye of left eye	2	28SEP2020	15/7	1	No	O	NA/TCN	R (04OCT2020)	N/N
>55/ C4591001 1146 11461109	INV	Blood glucose increased/ Increase in baseline blood sugar	1	01SEP2020	8/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1146 11461127	CARD	Coronary artery occlusion/ Mid Left Anterior Descending Coronary Artery Occlusion#	2	20JAN2021	128/1	2	No	CND	NA/TCN	R (20JAN2021)	Y/N
	GENRL	Injection site pain/ Injection site pain >30 minutes post vaccine 1	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
>55/ C4591001 1146 11461132	GENRL	Injection site pain/ Injection site pain >30 minutes post vaccine 2	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Pyrexia/ Fever 99.8 post vaccine	1	28AUG2020	2/3	1	Yes		NA	R (30AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1146 11461136	GENRL	Injection site pain/ Injection site pain post vaccine	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	
>55/ C4591001 1146 11461136	INFEC	Urinary tract infection/ Urinary Tract Infection	2	07DEC2020	81/4	2	No	O	NA/TC	R (10DEC2020)	N/N	
>55/ C4591001 1146 11461137	GENRL	Chills/ Chills#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N	
>55/ C4591001 1146 11461137	GENRL	Injection site pain/ Injection site pain post vaccine	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N	
>55/ C4591001 1146 11461143	GENRL	Injection site pain/ Injection site pain post vaccine	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
>55/ C4591001 1146 11461143	GENRL	Injection site pain/ Injection site pain >30 minutes after vaccine administration	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N	
>55/ C4591001 1146 11461148	GENRL	Fatigue/ fatigue	2	16SEP2020	1/4	1	Yes		NA	R (19SEP2020)	N/N	
>55/ C4591001 1146 11461148	GENRL	Injection site pain/ Injection site pain >30 minutes post vaccine	2	16SEP2020	1/4	1	Yes		NA	R (19SEP2020)	N/N	
>55/ C4591001 1146 11461148	GENRL	Pain/ Body Aches#	4	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N	
>55/ C4591001 1146 11461149	GENRL	Injection site pain/ Injection site pain >30 minutes after vaccine administration	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site pain >30 minutes after vaccine administration	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1146 11461152	INJ&P	Chest injury/ Bruised ribs	2	07OCT2020	22/15	1	No	O	NA	R (21OCT2020)	N/N
		Fall/ Fall off ladder	2	07OCT2020	22/1	1	No	O	NA/TCN	R (07OCT2020)	N/N
	RESP	Chronic obstructive pulmonary disease/ Chronic Obstructive Pulmonary Disease with acute exacerbation#	2	06FEB2021	144/7	3	No	O	NA/TC/TCN	R (12FEB2021)	Y/N
>55/ C4591001 1146 11461153	GENRL	Chest pain/ Exertional chest pain	2	04OCT2020	19/12	2	No	O	NA	R (15OCT2020)	N/N
>55/ C4591001 1146 11461154	MUSC	Pain in extremity/ Left Arm Pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001 1146 11461156	GENRL	Fatigue/ Fatigue#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
		Pain/ Body aches#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001	RESP	Interstitial lung disease/ Interstitial Pneumonitis	1	09SEP2020	10/1	2	No	O	NA	R (09SEP2020)	Y/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1146 11461161	RESP	Atelectasis/ Bibasilar Atelectasis on chest xray	1	10SEP2020	11/31	1	No	O	NA	R (10OCT2020)	N/N	
>55/ C4591001 1146 11461162	GENRL	Chills/ Chills#	4	04FEB2021	2/1	1	Yes		NA/TC	R (04FEB2021)	N/N	
>55/ C4591001 1146 11461174	MUSC	Pain in extremity/ Arm Pain#	4	04FEB2021	2/1	1	Yes		NA/TC	R (04FEB2021)	N/N	
>55/ C4591001 1146 11461174	INV	Low density lipoprotein increased/ Elevated LDL	2	16OCT2020	24/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1146 11461180	GASTR	Colitis ulcerative/ Ulcerative colitis	2	12OCT2020	22/11	2	No	O	NA/TC	R (22OCT2020)	N/N	
>55/ C4591001 1146 11461181	GENRL	Cyst/ Cyst-like mass on back of head	1	07SEP2020	7/4	2	No	O	NA	R (10SEP2020)	N/N	
>55/ C4591001 1146 11461191	METAB	Hyperglycaemia/ Hyperglycemia	2	11JAN2021	113/3	3	No	O	NA	R (13JAN2021)	Y/N	
>55/ C4591001 1146 11461191	INFEC	Pneumonia/ Pneumonia#	4	17FEB2021	3/5	3	No	O	NA	R (21FEB2021)	Y/N	
>55/ C4591001	GENRL	Chills/ Chills#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1146 11461222		Pain/ Body aches#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N	
>55/ C4591001 1146 11461232	GENRL	Fatigue/ Fatigue	1	05OCT2020	22/3	2	Yes		NA	R (07OCT2020)	N/N	
		Injection site pain/ Injection Site pain	2	05OCT2020	1/3	2	Yes		NA	R (07OCT2020)	N/Y	
		Pyrexia/ Fever of 101.0F	2	05OCT2020	1/3	1	Yes		NA/TC	R (07OCT2020)	N/Y	
>55/ C4591001 1146 11461244	MUSC	Pain in extremity/ Arm Pain#	4	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N	
>55/ C4591001 1146 11461252	INJ&P	Fall/ Fall#	3	05FEB2021	11/1	1	No	O	NA	R (05FEB2021)	N/N	
	MUSC	Rotator cuff syndrome/ tear of left rotator cuff#	3	05FEB2021	11/1	2	No	O	NA/TCN	R (05FEB2021)	N/N	
>55/ C4591001 1146 11461264	RESP	Pulmonary embolism/ Pulmonary Emboli	2	08NOV2020	26/8	2	No	O	NA/TC	R (15NOV2020)	Y/N	
>55/ C4591001 1147 11471009	RESP	Oropharyngeal pain/ sore throat	1	05AUG2020	3/1	1	No	O	NA	R (05AUG2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1147 11471015	GENRL	Injection site pain/ Pain at injection site#	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1147 11471062	EYE	Eye pain/ bilateral eye pain	1	11AUG2020	5/2	1	No	O	NA/TC	R (12AUG2020)	N/N
	INV	Blood triglycerides increased/ Elevated triglycerides	2	14SEP2020	18/C	1	No	O	NA/TCN	N	N/N
>55/ C4591001 1147 11471071	GENRL	Chills/ Chills#	4	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
	INV	Body temperature increased/ body temperature increased#	4	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
	NERV	Headache/ Headache#	4	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
>55/ C4591001 1147 11471082	GENRL	Injection site irritation/ Injection site irritation#	4	09JAN2021	3/C	1	Yes		NA	RG	N/N
		Injection site pain/ Injection site pain#	4	09JAN2021	3/C	1	Yes		NA/TC	N	N/N
		Injection site swelling/ Injection site swelling#	4	09JAN2021	3/C	1	Yes		NA/TC	N	N/N
		Pyrexia/ Fever#	4	09JAN2021	3/3	1	Yes		NA/TC	R (11JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache#	4	09JAN2021	3/2	1	Yes		NA/TC	R (10JAN2021)	N/N
	RESP	Cough/ Cough#	4	09JAN2021	3/1	1	Yes		NA/TC	R (09JAN2021)	N/N
>55/ C4591001 1147 11471086	SKIN	Dermatitis contact/ allergic contact dermatitis caused by clothing irritation on sensitive skin in lower right abdomen	1	17AUG2020	8/8	1	No	O	NA/TC	R (24AUG2020)	N/N
	NEOPL	Seborrheic keratosis/ inflamed seborrheic keratosis	1	18AUG2020	9/1	1	No	O	NA/TCN	R (18AUG2020)	N/N
>55/ C4591001 1147 11471091	METAB	Iron deficiency/ iron deficiency	1	13AUG2020	3/C	1	No	O	NA	N	N/N
>55/ C4591001 1147 11471106	MUSC	Exostosis/ Bone spur on right knuckle index finger	2	14SEP2020	13/18	1	No	O	NA/TC	R (01OCT2020)	N/N
>55/ C4591001 1147 11471108	EAR	Ear discomfort/ ear fullness	2	01OCT2020	30/C	1	No	O	NA/TC/TCN	N	N/N
	INV	Blood urea increased/ Elevated BUN	2	01OCT2020	30/C	1	No	O	NA	N	N/N
		Mean cell haemoglobin decreased/ decreased mean corpuscular hemoglobin concentrate	2	01OCT2020	30/C	1	No	O	NA	N	N/N
		Mean cell volume increased/ elevated mean corpuscular hemoglobin	2	01OCT2020	30/C	1	No	O	NA	N	N/N
		Mean cell volume increased/ elevated mean corpuscular volume	2	01OCT2020	30/C	1	No	O	NA	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1147 11471124	NERV	Dizziness/ dizziness	1	17AUG2020	4/1	1	No	O	NA	R (17AUG2020)	N/N	
>55/ C4591001 1147 11471200	RESP	Nasal congestion/ Nasal Congestion	1	31AUG2020	4/C	1	No	O	NA	N	N/N	
		Oropharyngeal pain/ Sore throat	1	31AUG2020	4/C	1	No	O	NA	N	N/N	
		Paranasal sinus hypersecretion/ Cough r/t Sinus drainage	1	31AUG2020	4/C	1	No	O	NA	N	N/N	
>55/ C4591001 1147 11471208	GASTR	Inguinal hernia/ Left inguinal hernia (exacerbation)	2	08OCT2020	17/C	1	No	O	NA	N	N/N	
>55/ C4591001 1147 11471221	INFEC	Hordeolum/ Stye on left eyelid	1	09SEP2020	7/C	1	No	O	NA	N	N/N	
>55/ C4591001 1147 11471224	GENRL	Fatigue/ Fatigue#	4	23JAN2021	4/C	1	Yes		NA/TC	RG	N/N	
		Injection site pain/ Injection site pain#	4	23JAN2021	4/C	1	Yes		NA/TC	RG	N/N	
		Pyrexia/ Fever (101.2)#	4	23JAN2021	4/C	2	Yes		NA/TC	RG	N/N	
	MUSC	Myalgia/ Muscle pain#	4	23JAN2021	4/C	1	Yes		NA/TC	RG	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1147 11471230	INFEC	COVID-19/ COVID-19	2	29JAN2021	120/9	4	No	O	NA/TC/TCN	R (06FEB2021)	Y/N	
	RESP	Acute respiratory failure/ Acute hypoxemic respiratory failure	2	29JAN2021	120/9	4	No	O	NA/TC/TCN	R (06FEB2021)	Y/N	
>55/ C4591001 1147 11471239	INV	High density lipoprotein increased/ Increased HDL (95)	1	18SEP2020	9/C	1	No	O	NA	N	N/N	
	REPRO	Ovarian mass/ Ovarian Mass	1	21SEP2020	12/C	2	No	O	NA/TCN	RG	Y/N	
	INV	Blood chloride decreased/ Decreased Chloride (94)	1	24SEP2020	15/C	1	No	O	NA	N	N/N	
		Blood sodium decreased/ Decreased Sodium (131)	1	24SEP2020	15/C	1	No	O	NA	N	N/N	
		Urine ketone body present/ Trace Ketones (Urinalysis)	1	24SEP2020	15/C	1	No	O	NA	N	N/N	
		White blood cells urine positive/ Trace Leukocytes in Urinalysis	1	24SEP2020	15/C	1	No	O	NA	N	N/N	
	GASTR	Abdominal pain lower/ Left Lower Quadrant Pain	1	25SEP2020	16/C	1	No	O	NA/TCN	N	N/N	
>55/ C4591001 1149 11491009	GENRL	Injection site pain/ Pain at injection site (left arm)#	3	21JAN2021	1/1	1	Yes		NA/TC	R (21JAN2021)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	4	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N	
	NERV	Headache/ Headache#	4	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1149 11491018	GENRL	Injection site pain/ Tenderness at Injection site	2	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/Y
>55/ C4591001 1149 11491041	GENRL	Pain/ body aches	1	18AUG2020	8/2	1	Yes		NA	R (19AUG2020)	N/N
	NERV	Headache/ Headaches	1	18AUG2020	8/2	1	Yes		NA	R (19AUG2020)	N/N
>55/ C4591001 1149 11491048	GENRL	Injection site pain/ Pain at injection site#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1149 11491056	GENRL	Injection site pain/ Soreness at injection site#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1149 11491078	MUSC	Pain in extremity/ Left arm soreness#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site with movement#	4	04FEB2021	1/4	1	Yes		NA	R (07FEB2021)	N/N
>55/ C4591001 1149 11491080	GENRL	Injection site pain/ left arm injection site pain with motion	2	08SEP2020	1/8	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	09SEP2020	2/6	1	Yes		NA	R (14SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1149 11491090	GENRL	Chills/ chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Pyrexia/ fever	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
>55/ C4591001 1149 11491102	GENRL	Fatigue/ fatigue	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
>55/ C4591001 1149 11491112	GENRL	Injection site pain/ Pain at injection site#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1149 11491118	GENRL	Injection site pain/ Tenderness at injection site#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	NERV	Headache/ Frontal Headache#	3	20JAN2021	1/5	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	11FEB2021	2/1	1	Yes		NA/TC	R (11FEB2021)	N/N
		Pyrexia/ Fever#	4	11FEB2021	2/1	1	Yes		NA/TC	R (11FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1149 11491131	NERV	Headache/ Headache#	4	11FEB2021	2/1	1	Yes		NA/TC	R (11FEB2021)	N/N	
	MUSC	Myalgia/ muscle aches	1	24AUG2020	1/2	1	Yes		NA	R (25AUG2020)	N/N	
		Pain in extremity/ left arm soreness	1	24AUG2020	1/5	1	Yes		NA	R (28AUG2020)	N/N	
>55/ C4591001 1149 11491132	GENRL	Chills/ chills	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N	
>55/ C4591001 1149 11491134	MUSC	Pain in extremity/ left arm pain	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N	
	NERV	Headache/ Headache*		24AUG2020	1/4	1	Yes		NA	R (27AUG2020)	N/N	
		Paraesthesia/ Right Arm Paresthesia*		24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N	
>55/ C4591001 1149 11491138	NERV	Headache/ headache	2	14SEP2020	1/4	1	Yes		NA	R (17SEP2020)	N/N	
	GENRL	Pyrexia/ fever	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N	
	GENRL	Injection site pain/ left arm pain at injection site	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N	
	GASTR	Abdominal distension/ bloating	1	14SEP2020	21/1	1	No	O	NA	R (14SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1149 11491139	MUSC	Nausea/ nausea	1	14SEP2020	21/1	1	No	O	NA	R (14SEP2020)	N/N
		Myalgia/ myalgia	2	29SEP2020	15/5	1	No	O	NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Chills/ Chills#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
		Fatigue/ Fatigue#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
		Pyrexia/ Fever 99.1#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
>55/ C4591001 1149 11491143	GENRL	Fatigue/ fatigue	1	14SEP2020	21/1	1	No	O	NA	R (14SEP2020)	N/N
		Pain/ body aches	1	14SEP2020	21/1	1	No	O	NA	R (14SEP2020)	N/N
	SKIN	Pyrexia/ fever	1	14SEP2020	21/1	1	No	O	NA/TC	R (14SEP2020)	N/N
>55/ C4591001 1149 11491143	SKIN	Rash/ Rash over buttocks#	3	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
	GENRL	Injection site pain/ Mild pain at injection site#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1149 11491152	MUSC	Pain in extremity/ Left arm pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
>55/ C4591001 1149 11491153	MUSC	Myalgia/ Myalgia	2	19SEP2020	4/2	1	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ Headaches	2	19SEP2020	4/2	1	Yes		NA	R (20SEP2020)	N/N
	RESP	Nasal congestion/ Nasal Congestion	2	02OCT2020	17/4	1	No	O	NA	R (05OCT2020)	N/N
>55/ C4591001 1149 11491168	MUSC	Pain in extremity/ Left arm pain	1	28AUG2020	1/4	1	Yes		NA	R (31AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N
	NERV	Headache/ Headache	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
	PSYCH	Insomnia/ Increased Insomnia	2	19SEP2020	2/8	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1149 11491184	GENRL	Fatigue/ fatigue	1	06SEP2020	5/5	1	Yes		NA	R (10SEP2020)	N/N
		Malaise/ malaise	1	06SEP2020	5/5	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache	1	06SEP2020	5/5	1	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1149 11491185	MUSC	Pain in extremity/ Pain in left arm	1	06SEP2020	5/6	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Pyrexia/ Low grade fever#	3	04FEB2021	2/3	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1149 11491192	GENRL	Injection site pain/ Tenderness at injection site#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	02FEB2021	2/3	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1149 11491193	GENRL	Injection site pain/ right arm pain with touch at injection site	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
>55/ C4591001 1149 11491196	GENRL	Injection site pain/ Pain at injection site#	3	26FEB2021	16/2	1	Yes		NA	R (27FEB2021)	N/N
>55/ C4591001 1149 11491200	GENRL	Injection site pain/ left arm pain at injection site.	1	05SEP2020	2/7	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Chills/ chills	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	26SEP2020	2/4	1	Yes		NA	R (29SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1149 11491214	MUSC	Injection site pain/ Tenderness in Left arm (injection site)	2	26SEP2020	2/4	1	Yes	NA	NA	R (29SEP2020)	N/N
		Injection site pain/ left arm pain at injection site.	2	26SEP2020	2/2	1	Yes	NA	NA	R (27SEP2020)	N/N
		Pyrexia/ Fever	2	26SEP2020	2/2	1	Yes	NA	NA	R (27SEP2020)	N/N
		Myalgia/ Diffuse muscle aching	2	26SEP2020	2/4	1	Yes	NA	NA	R (29SEP2020)	N/N
		Headache/ Headache	2	26SEP2020	2/4	1	Yes	NA	NA	R (29SEP2020)	N/N
	GENRL	Fatigue/ fatigue & lassitude	1	09SEP2020	2/3	1	Yes	NA	NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	04FEB2021	1/2	1	Yes	NA	NA	R (05FEB2021)	N/N
	GENRL	Injection site erythema/ Redness at injection site#	4	06FEB2021	3/10	1	Yes	NA	NA	R (15FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/1	1	Yes	NA	NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	01FEB2021	1/2	1	Yes	NA	NA	R (02FEB2021)	N/N
>55/ C4591001 1149 11491225	GENRL	Injection site pain/ Left Arm Pain at injection site	1	14SEP2020	1/2	1	Yes	NA	NA	R (15SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1149 11491239	MUSC	Pain in extremity/ Right arm pain with motion	1	22SEP2020	8/4	1	Yes		NA	R (25SEP2020)	N/N
	BLOOD	Lymphadenopathy/ swollen lymph node in right axilla	1	05OCT2020	21/8	1	No	O	NA/TC	R (12OCT2020)	N/N
	INFEC	Subcutaneous abscess/ Abscess Right Armpit	1	05OCT2020	21/8	1	No	O	NA	R (12OCT2020)	N/N
	GENRL	Chest pain/ Chest pain (cocaine induce)	1	15JAN2021	123/2	1	No	O	NA	R (16JAN2021)	Y/N
	GENRL	Drug withdrawal syndrome/ Opioid dependence withdrawal	1	21JAN2021	129/6	4	No	O	NA	R (26JAN2021)	Y/N
>55/ C4591001 1149 11491251	MUSC	Pain in extremity/ Left arm pain	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Chills/ chills	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
		Pyrexia/ fever	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
>55/ C4591001 1149 11491257	GENRL	Chills/ chills	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
		Injection site pain/ Left arm pain at injection site	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
		Pyrexia/ fever	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1149 11491260	NERV	Headache/ headache	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
	MUSC	Neck pain/ Cervicalgia	1	21SEP2020	4/3	1	Yes		NA	R (23SEP2020)	N/N
	INFEC	Otitis externa/ Right otitis externa	1	30SEP2020	13/4	1	No	O	NA	R (03OCT2020)	N/N
>55/ C4591001 1149 11491261	INFEC	Otitis externa/ Right otitis externa	1	04OCT2020	17/C	1	No	O	NA	N	N/N
	GENRL	Fatigue/ Tiredness#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Soreness at injection site (left arm)#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1149 11491264	GENRL	Fatigue/ Fatigue	1	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Left arm pain at injection site	1	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ Left arm pain at injection site	2	12OCT2020	1/1	1	Yes		NA/TC	R (12OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
	GENRL	Injection site pain/ Right shoulder pain at injection site#	3	01MAR2021	1/2	1	Yes		NA	R (02MAR2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1149 11491265 >55/ C4591001 1149 11491288	GENRL	Injection site pain/ pain at injection site (arm)	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	PSYCH	Insomnia/ insomnia	1	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ body aches/ myalgia	1	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ headache	1	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1149 11491298	GENRL	Injection site pain/ right arm injection site pain	1	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
>55/ C4591001 1149 11491299	GENRL	Injection site pain/ Tenderness at injection site (left arm)#	3	20JAN2021	1/5	1	Yes		NA	R (24JAN2021)	N/N
>55/ C4591001 1149 11491301	GENRL	Injection site pain/ left arm injection site pain	1	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ fever	1	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	27SEP2020	4/3	1	Yes		NA	R (29SEP2020)	N/N
		Injection site pain/ Injection site pain with touch & motion in deltoid muscles	1	27SEP2020	4/3	1	Yes		NA	R (29SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1149 11491309	GENRL	Injection site pain/ Right arm pain at injection site with motion	2	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
		Pyrexia/ Low grade fever 100.5	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C4591001 1149 11491313	INJ&P	Fall/ fall	2	OCT2020	1/	1	No	O	NA	R	N/N
			2	OCT2020	1/	1	No	O	NA	R	N/N
	INJ&P	Head injury/ Acute Trauma Head Injury	2	30OCT2020	16/5	3	No	O	NA	R (03NOV2020)	Y/N
	NERV	Cervicogenic headache/ Cervicogenic headache	2	30OCT2020	16/5	3	No	O	NA	R (03NOV2020)	Y/N
	GENRL	Injection site pain/ Pain (with movement) in left arm at injection site	1	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
>55/ C4591001 1149 11491319	GENRL	Injection site pain/ Injection site pain with touch in left arm	1	25SEP2020	1/5	1	Yes		NA	R (29SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site#	3	02FEB2021	1/4	1	Yes		NA	R (05FEB2021)	N/N
	NERV	Headache/ Headache#	3	05FEB2021	4/2	1	Yes		NA	R (06FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1149 11491326	GENRL	Injection site pain/ left arm injection site pain	1	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/N
>55/ C4591001 1149 11491330	GENRL	Injection site pain/ Tenderness at injection site (left arm)#	3	22JAN2021	2/3	1	Yes		NA	R (24JAN2021)	N/N
>55/ C4591001 1149 11491338	GENRL	Injection site pain/ Tenderness at injection site#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
>55/ C4591001 1152 11521013	METAB	Hypercholesterolaemia/ hypercholesterolemia diagnosed	2	28SEP2020	27/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1152 11521041	IMMUN	Seasonal allergy/ Worsened seasonal allergies#	3	23FEB2021	19/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1152 11521047	GENRL	Injection site swelling/ Swelling at injection site	2	01SEP2020	1/2	1	Yes		NA/TCN	R (02SEP2020)	N/N
	GENRL	Pyrexia/ Fever#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	2/4	1	Yes		NA/TC	R (19FEB2021)	N/N
>55/ C4591001	INJ&P	Muscle strain/ back strain	1	31AUG2020	19/2	2	No	O	NA/TC	R (01SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1152 11521050	MUSC	Synovial cyst/ ganglion cyst left wrist	2	09SEP2020	9/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1152 11521067	INJ&P	Fall/ FALL	2	12JAN2021	132/1	2	No	O	NA	R (12JAN2021)	N/N	
		Wrist fracture/ Broken Left Wrist	2	12JAN2021	132/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1152 11521092	GASTR	Diarrhoea/ diarrhea	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N	
		Vomiting/ vomiting	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N	
>55/ C4591001 1152 11521095	RENAL	Pollakiuria/ urinary frequency	2	06OCT2020	27/27	1	No	O	NA	R (01NOV2020)	N/N	
	PSYCH	Bipolar disorder/ worsening of bipolar disorder	2	29OCT2020	50/9	3	No	O	NA/TC	R (06NOV2020)	Y/N	
	GENRL	Chills/ Chills#	4	27FEB2021	2/1	1	Yes		NA	R (27FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	27FEB2021	2/1	1	Yes		NA	R (27FEB2021)	N/N	
	PSYCH	Bipolar disorder/ Worsening of Bipolar Disorder#	4	13MAR2021	16/C	3	No	O	NA	RG	Y/N	
>55/ C4591001	GASTR	Diarrhoea/ diarrhea	1	21AUG2020	2/15	2	Yes		NA/TC	R (04SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1152 11521123	GENRL	Chills/ chills	1	21AUG2020	2/15	2	Yes		NA	R (04SEP2020)	N/N
		Fatigue/ fatigue	1	21AUG2020	2/24	2	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ headache	1	21AUG2020	2/15	2	Yes		NA/TC	R (04SEP2020)	N/N
	MUSC	Arthralgia/ bilateral hip pain	2	08OCT2020	29/2	1	No	O	NA	R (09OCT2020)	N/N
		Arthralgia/ bilateral knee pain	2	08OCT2020	29/2	1	No	O	NA	R (09OCT2020)	N/N
>55/ C4591001 1152 11521136	INV	Fractional exhaled nitric oxide increased/ elevated exhaled nitric oxide level	2	02OCT2020	22/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1152 11521141	GENRL	Chills/ Chills#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1152 11521161	GENRL	Injection site pain/ Injection Site Pain	1	24AUG2020	1/4	1	Yes		NA	R (27AUG2020)	N/N
		Injection site swelling/ Injection Site Swelling	1	24AUG2020	1/4	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Injection site swelling/ Injection Site Swelling	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N	
>55/ C4591001 1152 11521203	GENRL	Pyrexia/ Fever	1	26AUG2020	2/2	1	Yes		NA/TC	R (27AUG2020)	N/N	
>55/ C4591001 1152 11521233	INFEC	Localised infection/ infection left index finger	2	01OCT2020	17/13	2	No	O	NA/TC	R (13OCT2020)	N/N	
>55/ C4591001 1152 11521251	RENAL	Nephrolithiasis/ Kidney Stone#	2	23JAN2021	131/2	3	No	O	NA	R (24JAN2021)	N/N	
>55/ C4591001 1152 11521260	NEOPL	Malignant melanoma/ malignant melanoma	1	04SEP2020	5/35	3	No	O	NA/TC/TCN	R (08OCT2020)	Y/N	
	GASTR	Diarrhoea/ Diarrhea#	4	12FEB2021	1/1	1	Yes		NA	R (12FEB2021)	N/N	
>55/ C4591001 1152 11521266	GENRL	Chills/ Chills	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N	
		Fatigue/ Fatigue	2	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N	
		Pain/ Body Aches	2	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N	
		Pyrexia/ Fever	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1152 11521280	MUSC	Myalgia/ Myalgia	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
>55/ C4591001 1152 11521314	GENRL	Pyrexia/ Fever (102.8 F)	2	22SEP2020	1/2	3	Yes		NA/TC	R (23SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	22SEP2020	1/2	2	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C4591001 1152 11521337	GASTR	Abdominal pain lower/ left lower quadrant abdominal pain	2	04DEC2020	74/4	2	No	O	NA/TC	R (07DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	08JAN2021	1/5	2	Yes		NA/TC	R (12JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	09JAN2021	2/2	2	Yes		NA/TC	R (10JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	09JAN2021	2/2	2	Yes		NA/TC	R (10JAN2021)	N/N
	NERV	Headache/ Headaches#	4	10JAN2021	3/3	2	Yes		NA/TC	R (12JAN2021)	N/N
>55/ C4591001 1152 11521349	GENRL	Injection site pain/ Injection Site Pain#	4	08JAN2021	1/3	2	Yes		NA/TC	R (10JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	09JAN2021	2/2	2	Yes		NA/TC	R (10JAN2021)	N/N
>55/ C4591001	MUSC	Muscle spasms/ back muscle spasms	1	04SEP2020	1/2	3	No	O	NA	R (05SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1152 11521359	GENRL	Injection site induration/ injection site induration	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
		Injection site pain/ injection site tenderness	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
	NERV	Dysgeusia/ sour taste	1	06SEP2020	3/5	2	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1152 11521368	GENRL	Chills/ Chills#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
>55/ C4591001 1152 11521380	GENRL	Injection site pain/ Injection Site Pain	2	29SEP2020	2/4	1	Yes		NA	R (02OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C4591001 1152 11521386	SKIN	Rash/ rash on legs	1	22SEP2020	15/7	2	No	O	NA/TC	R (28SEP2020)	N/N
>55/ C4591001 1152 11521388	GENRL	Fatigue/ Fatigue	2	28SEP2020	1/1	1	Yes		NA	R (28SEP2020)	N/N
>55/ C4591001 1152 11521389	GENRL	Fatigue/ Fatigue	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1152 11521392	MUSC	Myalgia/ Myalgia	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ Headache	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
	NERV	Headache/ Headache	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
	RESP	Nasal congestion/ Nasal Congestion#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
	GENRL	Pyrexia/ Fever (101 F)#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
>55/ C4591001 1152 11521411	CARD	Myocardial infarction/ Myocardial Infarction	2	04FEB2021	129/C	4	No	O	NA/TC/TCN	RG	Y/N
>55/ C4591001 1152 11521417	INFEC	Herpes zoster/ shingles	1	15SEP2020	7/20	2	Yes		NA/TC	R (04OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1152 11521471	GENRL	Injection site swelling/ Injection Site Reaction (swelling)	1	24SEP2020	1/1	1	Yes		NA/TCN	R (24SEP2020)	N/Y
>55/ C4591001 1152 11521476	EAR	Deafness unilateral/ hearing loss right ear	1	14OCT2020	20/10	3	Yes		P/TC	R (23OCT2020)	N/N
>55/ C4591001 1152 11521486	INJ&P	Fall/ Fall#	3	28JAN2021	4/1	2	No	O	NA/TCN	R (28JAN2021)	N/N
		Skin laceration/ Right eyebrow laceration#	3	28JAN2021	4/9	2	No	O	NA/TC	R (05FEB2021)	N/N
	INJ&P	Fall/ Slipped and fell coming down stairs#	3	07FEB2021	14/1	2	No	O	NA/TC/TCN	R (07FEB2021)	N/N
		Skin laceration/ Right eyebrow laceration#	3	07FEB2021	14/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1152 11521488	GENRL	Fatigue/ Fatigue	2	22OCT2020	2/3	1	Yes		NA	R (24OCT2020)	N/N
		Injection site pain/ Injection Site Arm Soreness	2	22OCT2020	2/3	1	Yes		NA	R (24OCT2020)	N/N
	NERV	Headache/ Headache	2	22OCT2020	2/3	1	Yes		NA	R (24OCT2020)	N/N
>55/ C4591001 1152 11521495	INFEC	Tooth infection/ dental infection	2	16NOV2020	20/14	2	No	O	NA/TC	R (29NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1152 11521497	INFEC	Shigella sepsis/ sepsis related to Shigella infection	1	26OCT2020	20/17	4	No	O	NA/TC/TCN/W	F (11NOV2020)	Y/N	
	NERV	Syncope/ vasovagal syncope	1	26OCT2020	20/1	3	No	O	NA	R (26OCT2020)	N/N	
>55/ C4591001 1152 11521513	EYE	Glaucoma/ Glaucoma	2	NOV2020	1/C	2	No	O	NA/TCN	N	N/N	
	INFEC	Eye infection/ eye infection	2	16NOV2020	13/30	2	No	O	NA/TC	R (15DEC2020)	N/N	
>55/ C4591001 1152 11521514	GENRL	Chills/ Chills	2	04NOV2020	1/2	1	Yes		NA	R (05NOV2020)	N/N	
		Injection site pain/ Injection Site Soreness	2	04NOV2020	1/6	1	Yes		NA	R (09NOV2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	05NOV2020	2/1	1	Yes		NA	R (05NOV2020)	N/N	
>55/ C4591001 1152 11521516	CARD	Atrial fibrillation/ worsening of atrial fibrillation	1	17OCT2020	5/12	2	No	O	NA/TC	R (28OCT2020)	N/N	
>55/ C4591001 1152 11521524	GENRL	Fatigue/ Fatigue	2	05NOV2020	1/4	1	Yes		NA	R (08NOV2020)	N/N	
	MUSC	Myalgia/ Muscle Aches	2	05NOV2020	1/4	1	Yes		NA	R (08NOV2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1152 11521528	GASTR	Nausea/ Nausea	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Chills/ Chills	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
	NERV	Headache/ Headache	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	08NOV2020	4/1	2	Yes		NA/TC	R (08NOV2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	15OCT2020	1/2	2	Yes		NA	R (16OCT2020)	N/N
	NERV	Headache/ Headache	1	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	1	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	05NOV2020	1/3	1	Yes		NA/TC	R (07NOV2020)	N/N
>55/ C4591001 1152 11521532	NERV	Headache/ Headache	2	05NOV2020	1/2	1	Yes		NA/TC	R (06NOV2020)	N/N
	GENRL	Pyrexia/ Fever	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
	GASTR	Nausea/ Nausea#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001	GENRL	Chills/ Chills#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	05NOV2020	2/3	1	Yes		NA/TC	R (07NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1152 11521535	MUSC	Pain in extremity/ Arm Soreness	2	05NOV2020	2/3	1	Yes		NA/TC	R (07NOV2020)	N/N
>55/ C4591001 1152 11521539	RENAL	Nephrolithiasis/ Nephrolithiasis	2	28NOV2020	25/C	3	No	O	NA/TCN	N	N/N
>55/ C4591001 1152 11521540	GENRL	Chills/ Chills	2	04NOV2020	1/3	1	Yes		NA/TC	R (06NOV2020)	N/N
		Fatigue/ Fatigue	2	04NOV2020	1/3	1	Yes		NA/TC	R (06NOV2020)	N/N
		Injection site pain/ injection site pain	2	04NOV2020	1/4	1	Yes		NA/TC	R (07NOV2020)	N/N
	NERV	Headache/ Headache	2	05NOV2020	2/1	1	Yes		NA/TC	R (05NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	06NOV2020	3/1	1	Yes		NA	R (06NOV2020)	N/N
>55/ C4591001 1152 11521544	GASTR	Nausea/ Nausea#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
		Vomiting/ Vomiting#	4	12FEB2021	1/1	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Chills/ Chills#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
		Fatigue/ Fatigue#	4	12FEB2021	1/4	1	Yes		NA	R (15FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1152 11521553	MUSC	Pyrexia/ Fever 102.2 F#	4	12FEB2021	1/2	3	Yes		NA	R (13FEB2021)	N/N
		Myalgia/ Myalgia#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
	NERV	Headache/ Headaches#	4	12FEB2021	1/4	1	Yes		NA	R (15FEB2021)	N/N
	INFEC	Ear infection/ left ear infection	1	24OCT2020	4/12	1	No	O	NA	R (04NOV2020)	N/N
>55/ C4591001 1152 11521558	INFEC	Gingival abscess/ gum abscess	1	28OCT2020	8/12	1	No	O	NA/TC	R (08NOV2020)	N/N
	GENRL	Chills/ Chills	2	12NOV2020	2/1	2	Yes		NA	R (12NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	12NOV2020	2/1	2	Yes		NA	R (12NOV2020)	N/N
>55/ C4591001 1152 11521562	NERV	Headache/ Headache	2	12NOV2020	2/1	2	Yes		NA/TC	R (12NOV2020)	N/N
	GENRL	Malaise/ malaise	1	22OCT2020	1/1	2	Yes		NA/TC	R (22OCT2020)	N/N
	NERV	Pain/ body aches	1	22OCT2020	1/1	2	Yes		NA/TC	R (22OCT2020)	N/N
		Headache/ intermittent headache	1	22OCT2020	1/5	2	Yes		NA/TC	R (26OCT2020)	N/N
MUSC	Arthralgia/ sore left shoulder	1	23OCT2020	2/4	2	Yes		NA	R (26OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1152 11521563	NERV	Dizziness/ dizziness	2	10NOV2020	1/1	1	No	O	NA	R (10NOV2020)	N/Y
	MUSC	Pain in extremity/ right arm soreness	1	22OCT2020	1/5	2	Yes		NA/TC	R (26OCT2020)	N/N
>55/ C4591001 1152 11521572	NERV	Headache/ intermittent headache	1	23OCT2020	2/4	1	Yes		NA	R (26OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE*		27OCT2020	1/3	1	Yes		NA	R (29OCT2020)	N/N
>55/ C4591001 1152 11521579	GENRL	Fatigue/ Fatigue	2	16NOV2020	1/3	1	Yes		NA/TC	R (18NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	17NOV2020	2/2	2	Yes		NA/TC	R (18NOV2020)	N/N
	GENRL	Injection site pain/ injection site pain	1	29OCT2020	1/2	2	Yes		NA/TC	R (30OCT2020)	N/N
	NERV	Lethargy/ lethargy	1	30OCT2020	2/3	1	Yes		NA	R (01NOV2020)	N/N
	MUSC	Arthralgia/ right elbow pain	1	15NOV2020	18/6	1	No	O	NA	R (20NOV2020)	N/N
>55/ C4591001 1152 11521581	GENRL	Pain/ pain left side of body	2	03DEC2020	17/26	1	No	O	NA/TC	R (28DEC2020)	N/N
	INJ&P	Fall/ fall	2	03DEC2020	17/1	2	No	O	NA	R (03DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1152 11521582	GENRL	Chills/ Chills	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	18NOV2020	2/2	1	Yes		NA/TC	R (19NOV2020)	N/N
	NERV	Headache/ Headache	2	18NOV2020	2/2	1	Yes		NA/TC	R (19NOV2020)	N/N
>55/ C4591001 1152 11521585	GASTR	Haemorrhoids/ hemorrhoids	1	19NOV2020	21/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1156 11561001	RESP	Oropharyngeal pain/ SORE THROAT	1	23AUG2020	5/8	1	No	O	NA	R (30AUG2020)	N/N
	INJ&P	Facial bones fracture/ FRACTURE OF ROOF OF RIGHT ORBITAL (GRADE 3)	2	06OCT2020	29/70	3	No	O	NA/TC	R (14DEC2020)	Y/N
		Fall/ FALL FROM BICYCLE	2	06OCT2020	29/1	2	No	O	NA	R (06OCT2020)	N/N
		Muscle strain/ PARTIAL TEAR OF THE RIGHT TRAPEZIUS MUSCLE (GRADE 1)	2	06OCT2020	29/150	2	No	O	NA/TC	R (04MAR2021)	N/N
		Traumatic intracranial haemorrhage/ TRAUMATIC INTRACRANIAL HEMORRHAGE	2	06OCT2020	29/150	3	No	O	NA/TC	R (04MAR2021)	Y/N
		Arthropathy/ WIDENING OF ACROMIOCLAVICULAR JOINT SPACE (GRADE 1)	2	06OCT2020	29/150	2	No	O	NA/TC	R (04MAR2021)	N/N
MUSC											

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Subarachnoid haemorrhage/ SUBARACHNOID HEMORRHAGE	2	06OCT2020	29/12	4	No	O	NA/TC	R (17OCT2020)	Y/N
>55/ C4591001 1156 11561020	GASTR	Diarrhoea/ diarrhea	2	16SEP2020	3/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	16SEP2020	3/5	1	Yes		NA	R (20SEP2020)	N/N
>55/ C4591001 1156 11561025	MUSC	Arthralgia/ arthralgia	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001 1156 11561037	MUSC	Myalgia/ muscle soreness	2	16SEP2020	2/2	1	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C4591001 1156 11561084	MUSC	Myalgia/ myalgia	2	21SEP2020	1/5	1	Yes		NA/TC	R (25SEP2020)	N/N
>55/ C4591001 1156 11561095	GENRL	Chills/ CHILLS	2	29SEP2020	7/2	1	Yes		NA	R (30SEP2020)	N/N
	NERV	Hypoaesthesia/ NUMBNESS OF LEFT UPPER EXTREMITY	2	23OCT2020	31/39	1	No	O	NA	R (30NOV2020)	N/N
		Paraesthesia/ TINGLING OF LEFT UPPER EXTREMITY	2	23OCT2020	31/39	1	No	O	NA	R (30NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1156 11561099	INFEC	Rash pustular/ bilateral papulopustular lesion on face	2	20OCT2020	26/1	1	No	O	NA/TC	R (20OCT2020)	N/N	
>55/ C4591001 1156 11561100	INFEC	Onychomycosis/ ONYCHOMYCOSIS	2	25SEP2020	1/C	1	No	O	NA/TC	RG	N/N	
	MUSC	Back pain/ LUMBAGO	2	30SEP2020	6/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1156 11561114	MUSC	Arthritis reactive/ REACTIVE ARTHRITIS	2	29SEP2020	2/8	1	Yes		NA	R (06OCT2020)	N/N	
>55/ C4591001 1156 11561127	GENRL	Pyrexia/ fever	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N	
	MUSC	Myalgia/ myalgia	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N	
>55/ C4591001 1156 11561144	EAR	Vertigo positional/ BENIGN PAROXYSMAL POSITIONAL VERTIGO	2	12OCT2020	6/4	1	No	O	NA/TC	R (15OCT2020)	N/N	
>55/ C4591001 1156 11561151	GASTR	Diarrhoea/ diarrhea	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N	
>55/ C4591001	GASTR	Diarrhoea/ diarrhea	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1156 11561152 >55/ C4591001	INJ&P	Road traffic accident/ MOTOR VEHICLE ACCIDENT	2	24DEC2020	74/1	4	No	O	NA/W	F (24DEC2020)	Y/N
1156 11561160† >55/ C4591001	GENRL	Chills/ CHILLS	1	02OCT2020	5/3	1	Yes		NA	R (04OCT2020)	N/N
1156 11561184	MUSC	Myalgia/ MUSCLE PAIN	1	02OCT2020	5/3	1	Yes		NA	R (04OCT2020)	N/N
	GASTR	Dysphagia/ DYSPHAGIA	2	14NOV2020	26/5	1	No	O	NA	R (18NOV2020)	N/N
	INFEC	Diverticulitis/ DIVERTICULITIS OF COLON	2	14NOV2020	26/11	1	No	O	NA/TC	R (24NOV2020)	N/N
>55/ C4591001	GASTR	Diarrhoea/ DIARRHEA	1	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N
1156 11561279	MUSC	Myalgia/ MUSCLE PAIN	1	29OCT2020	2/2	1	Yes		NA/TC	R (30OCT2020)	N/N
>55/ C4591001	MUSC	Myalgia/ MYALGIA	2	18NOV2020	2/7	1	Yes		NA	R (24NOV2020)	N/N
1156 11561280	INFEC	Balanitis candida/ CANDIDA BALANITIS	2	04DEC2020	18/29	1	No	O	NA/TC	R (01JAN2021)	N/N
>55/ C4591001	INJ&P	Muscle injury/ Left Hamstring Injury	1	29AUG2020	18/C	1	No	O	NA	N	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1157 11571007 >55/ C4591001 1157 11571008	RESP	Cough/ Cough	2	18SEP2020	15/1	1	No	O	NA	R (18SEP2020)	N/N
>55/ C4591001 1157 11571014	VASC	Hypertension/ Hypertension#	2	22FEB2021	172/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1157 11571014	GENRL	Injection site pain/ Pain at injection site	2	04SEP2020	1/4	1	Yes		NA	R (07SEP2020)	N/N
>55/ C4591001 1157 11571024	INFEC	Bronchitis/ Bronchitis	2	06OCT2020	33/20	3	No	O	NA/TC	R (25OCT2020)	N/N
>55/ C4591001 1157 11571031	GENRL	Pyrexia/ Fever#	4	02MAR2021	1/2	1	Yes		NA	R (03MAR2021)	N/N
>55/ C4591001 1157 11571035	INFEC	Urinary tract infection/ Urinary tract Infection#	2	02MAR2021	175/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1157 11571044	VASC	Hypertension/ Exacerbation of Hypertension#	2	27FEB2021	172/C	2	No	O	NA/TC	N	N/N
>55/ C4591001	NERV	Carpal tunnel syndrome/ Carpal Tunnel Syndrome	1	24AUG2020	6/93	2	No	O	NA	R (24NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1157 11571051 >55/ C4591001	VASC	Deep vein thrombosis/ Left Leg Edema (possible Left DVT)#	4	26FEB2021	12/C	2	No	O	NA/TC	N	N/N
1157 11571058 >55/ C4591001	BLOOD	Lymphadenopathy/ Lymphadenopathy left side of neck	1	03SEP2020	15/11	2	Yes		NA	R (13SEP2020)	N/N
1157 11571066	RENAL	Haematuria/ Hematuria	1	04SEP2020	16/41	1	No	O	NA	R (14OCT2020)	N/N
>55/ C4591001 1157 11571075	MUSC	Fibromyalgia/ Fibromyalgia	2	09DEC2020	86/C	1	No	O	NA	N	N/N
	GASTR	Irritable bowel syndrome/ Irritable Bowel Syndrome Exacerbation#	4	16FEB2021	2/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1157 11571079	SURG	Facet joint block/ Radio Frequency Facet Block	2	21SEP2020	7/1	2	No	O	NA	R (21SEP2020)	N/N
>55/ C4591001 1157 11571096	GENRL	Injection site pain/ Injection Site Pain	1	15SEP2020	21/6	2	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ Left Biceps Pain	1	15SEP2020	21/6	2	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1157 11571099	INJ&P	Ankle fracture/ Right Lateral Malleolar Fracture (Right Ankle)	2	13NOV2020	60/1	2	No	O	NA/TC	R (13NOV2020)	N/N	
		Fall/ Fall	2	13NOV2020	60/1	2	No	O	NA	R (13NOV2020)	N/N	
>55/ C4591001 1157 11571116	INFEC	Conjunctivitis/ Bilateral Conjunctivitis	2	28SEP2020	6/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1157 11571128	MUSC	Myalgia/ General Muscle Aches	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N	
>55/ C4591001 1157 11571129	GASTR	Oral pain/ Sub-lingual Pain#	3	01FEB2021	8/10	1	No	O	NA	R (10FEB2021)	N/N	
>55/ C4591001 1157 11571134	NERV	Tremor/ Tremor	2	13OCT2020	20/C	2	No	CD	NA	N	N/N	
	NERV	Transient ischaemic attack/ Suspected Transient Ischemic Attack	2	27OCT2020	34/2	3	No	O	NA/TC	R (28OCT2020)	Y/N	
>55/ C4591001 1157 11571139	REPRO	Erectile dysfunction/ Erectile Dysfunction	1	04SEP2020	3/C	1	Yes		NA	N	N/N	
>55/ C4591001	SKIN	Ecchymosis/ Ecchymosis Bilateral Forearms#	3	30JAN2021	12/20	1	No	O	NA	R (18FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1157 11571147 >55/ C4591001	MUSC	Myalgia/ Myalgia (Whole Body)	2	03NOV2020	2/4	1	Yes		NA	R (06NOV2020)	N/N
1157 11571150	NERV	Headache/ Headache	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N
>55/ C4591001	MUSC	Tendonitis/ Tendonitis Right Shoulder	2	11JAN2021	71/C	2	No	O	NA/TC	N	N/N
1157 11571152	INJ&P	Spinal compression fracture/ Compression Fracture of L4 Vertebrae	2	04JAN2021	64/C	2	No	O	NA/TC	N	N/N
1157 11571155	GENRL	Injection site pain/ Pain at injection site	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N
>55/ C4591001	MUSC	Myalgia/ Myalgia (Whole Body)	2	09NOV2020	1/4	1	Yes		NA/TC	R (12NOV2020)	N/N
1157 11571167	NERV	Headache/ Headache	2	10NOV2020	2/3	2	Yes		NA/TC	R (12NOV2020)	N/N
>55/ C4591001	GASTR	Diarrhoea/ Diarrhea	1	26OCT2020	1/1	1	Yes		NA	R (26OCT2020)	N/N
1157 11571178	GENRL	Fatigue/ Fatigue	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1161 11611025	GENRL	Injection site erythema/ Redness around injection site	2	18NOV2020	2/8	1	Yes		NA	R (25NOV2020)	N/N
		Injection site swelling/ Swelling around injection site	2	18NOV2020	2/8	2	Yes		NA	R (25NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	18NOV2020	2/3	2	Yes		NA/TC	R (20NOV2020)	N/N
	NERV	Headache/ Headache	2	18NOV2020	2/1	1	Yes		NA	R (18NOV2020)	N/N
	MUSC	Tendonitis/ Tendonitis left arm	1	08SEP2020	37/91	1	No	O	NA/TC	R (07DEC2020)	N/N
	INFEC	Urinary tract infection/ Urinary tract infection	2	01DEC2020	34/3	1	No	O	NA/TC	R (03DEC2020)	N/N
	BLOOD	Splenomegaly/ splenomegaly	2	10NOV2020	7/4	2	No	O	NA	R (13NOV2020)	N/N
	RENAL	Oedematous kidney/ bilateral renal sinus edema	2	10NOV2020	7/4	2	No	O	NA	R (13NOV2020)	N/N
		Perinephric oedema/ bilateral perinephric edema	2	10NOV2020	7/4	2	No	O	NA	R (13NOV2020)	N/N
		Renal cyst haemorrhage/ hemorrhagic cyst of the medial interpolar left kidney	2	10NOV2020	7/C	1	No	O	NA	N	N/N
METAB	Lactic acidosis/ lactic acidosis	2	12NOV2020	9/2	3	No	O	NA	R (13NOV2020)	N/N	
RENAL	Acute kidney injury/ acute on chronic renal failure	2	12NOV2020	9/2	3	No	O	NA	R (13NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1161 11611031	SKIN	Pruritus/ PRURITUS, GENERALIZED	1	17OCT2020	74/C	1	No	O	NA	N	N/N	
		Urticaria/ Urticaria, Generalized	1	17OCT2020	74/C	1	No	O	NA	N	N/N	
	SKIN	Ecchymosis/ ecchymosis (rt forearm)#	4	29JAN2021	3/19	1	Yes		NA	R (16FEB2021)	N/N	
		Petechiae/ petechiae (rt forearm)#	4	29JAN2021	3/19	1	Yes		NA	R (16FEB2021)	N/N	
	SKIN	Ecchymosis/ ecchymosis (lt forearm)#	4	31JAN2021	5/17	1	Yes		NA	R (16FEB2021)	N/N	
		Petechiae/ petechiae (lt forearm)#	4	31JAN2021	5/17	1	Yes		NA	R (16FEB2021)	N/N	
>55/ C4591001 1161 11611038	INJ&P	Fall/ Fell off step	1	15OCT2020	72/1	1	No	O	NA	R (15OCT2020)	N/N	
		Humerus fracture/ Lt Shoulder fracture of humeral head	1	15OCT2020	72/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1161 11611042	NERV	Carpal tunnel syndrome/ worsening of carpal tunnel syndrome in lt hand	1	15OCT2020	71/C	1	No	O	NA/TC/TCN	RG	N/N	
	INJ&P	Fall/ Fall from chair#	2	22JAN2021	86/1	2	No	O	NA	R (22JAN2021)	N/N	
		Hip fracture/ Lt Hip fracture#	2	22JAN2021	86/C	2	No	O	NA/TC	N	N/N	
	GENRL	Oedema peripheral/ 2+ peripheral edema bilateral#	2	22FEB2021	117/C	1	No	O	NA	RG	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	SURG	Incisional drainage/ Incisional Drainage#	2	22FEB2021	117/C	1	No	O	NA	RG	N/N
>55/ C4591001 1162 11621014	RESP	Oropharyngeal pain/ sore throat*		03AUG2020	-3/2	1	No	CND	NA	R (04AUG2020)	N/N
>55/ C4591001 1162 11621052	GENRL	Injection site pain/ Arm soreness (injection site pain)	2	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
>55/ C4591001 1162 11621059	INFEC	Pneumonia/ pneumonia	2	03SEP2020	2/11	3	No	O	NA/TC	R (13SEP2020)	Y/N
>55/ C4591001 1162 11621071	GENRL	Fatigue/ Moderate Fatigue	2	02SEP2020	2/9	1	No	O	NA/TC	R (10SEP2020)	N/N
>55/ C4591001 1162 11621149	MUSC	Myalgia/ muscle aches	1	19AUG2020	2/3	1	Yes		NA	R (21AUG2020)	N/N
>55/ C4591001 1162 11621160	MUSC	Back pain/ Back Pain	1	28AUG2020	11/3	1	No	O	NA	R (30AUG2020)	N/N
	GASTR	Diarrhoea/ Loose stools	1	29AUG2020	12/2	1	No	O	NA	R (30AUG2020)	N/N
>55/ C4591001	MUSC	Neck pain/ Neck pain	1	26SEP2020	33/2	2	No	O	NA/TC	R (27SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1162 11621194	GASTR	Diarrhoea/ Diarrhea	1	27SEP2020	34/2	1	No	O	NA	R (28SEP2020)	N/N	
>55/ C4591001 1162 11621196	MUSC	Arthralgia/ R Hip Pain	2	08NOV2020	54/2	1	No	O	NA	R (09NOV2020)	N/N	
>55/ C4591001 1162 11621276	CARD	Myocardial infarction/ myocardial infarction	2	10NOV2020	47/3	2	No	O	NA/TC/TCN	R (12NOV2020)	Y/N	
>55/ C4591001 1162 11621277	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
		Pyrexia/ Fever	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
	NERV	Headache/ Headache	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
>55/ C4591001 1162 11621288	RESP	Cough/ Cough	2	02OCT2020	5/2	1	No	O	NA	R (03OCT2020)	N/N	
>55/ C4591001 1162 11621312	INFEC	Cellulitis/ Left leg Cellulitis	1	19SEP2020	12/C	2	No	O	NA/TC/TCN	RG	N/N	
>55/ C4591001	VASC	Arteriosclerosis/ Atherosclerotic Disease	1	13SEP2020	4/1	4	No	O	NA/W	F (13SEP2020)	Y/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1162 11621327 >55/ C4591001 1162 11621359	GENRL	Fatigue/ Fatigue	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N	
>55/ C4591001 1162 11621523	VASC	Hypertension/ Hypertension	2	NOV2020	1/C	1	No	O	NA	N	N/N	
>55/ C4591001 1163 11631008	PSYCH	Anxiety/ ANXIETY	1	03NOV2020	96/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1163 11631020	GENRL	Injection site pain/ INJECTION SITE LEFT DELTOID MUSCLE PAIN#	4	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N	
>55/ C4591001 1163 11631053	GENRL	Injection site pain/ INJECTION SITE PAIN(SORENESS) LEFT DELTOID#	4	30JAN2021	2/3	1	Yes		NA	R (01FEB2021)	N/N	
>55/ C4591001 1163 11631068	GENRL	Injection site pain/ INJECTION SITE PAIN (SORENESS) LEFT DELTOID#	4	30JAN2021	2/3	1	Yes		NA	R (01FEB2021)	N/N	
>55/ C4591001 1163 11631070	GENRL	Injection site pain/ Left arm pain to injection site	2	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/Y	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1163 11631092	NEOPL	Breast cancer/ Right Breast Cancer	2	28SEP2020	28/47	1	No	O	NA/TC/TCN	R (13NOV2020)	N/N
>55/ C4591001 1163 11631099	GENRL	Injection site pain/ LOCAL INJECTION SITE SORENESS (LEFT) DELTOID	2	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
	NERV	Dizziness/ DIZZINESS	2	01SEP2020	2/2	1	No	O	NA	R (02SEP2020)	N/N
>55/ C4591001 1166 11661031	EYE	Retinal detachment/ LEFT EYE RETINAL DETACHMENT	2	01DEC2020	82/4	3	No	O	NA/TCN	R (04DEC2020)	N/N
>55/ C4591001 1166 11661075	GENRL	Fatigue/ FATIGUE#	4	14JAN2021	3/2	1	Yes		NA	R (15JAN2021)	N/N
>55/ C4591001 1166 11661100	MUSC	Musculoskeletal stiffness/ LEFT ARM STIFFNESS#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1167 11671015	INFEC	Urinary tract infection/ Urinary Tract Infection	2	27OCT2020	48/16	1	No	O	NA/TC	R (11NOV2020)	N/N
>55/ C4591001 1167 11671016	GENRL	Chills/ chills#	4	04MAR2021	2/2	1	Yes		NA	R (05MAR2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Pain/ body aches#	4	04MAR2021	2/2	1	Yes		NA	R (05MAR2021)	N/N
		Headache/ headache#	4	04MAR2021	2/2	1	Yes		NA	R (05MAR2021)	N/N
>55/ C4591001 1167 11671062	MUSC	Neck pain/ Cervicalgia#	3	01JAN2021	17/C	2	No	O	NA/TC/TCN	N	N/N
	ENDO	Thyroid mass/ worsening thyroid nodule#	4	13JAN2021	9/C	1	No	O	NA	N	N/N
>55/ C4591001 1167 11671069	CONG	Hypertrophic cardiomyopathy/ Hypertrophic cardiomyopathy#	4	08MAR2021	42/C	2	No	O	NA/TC	N	Y/N
>55/ C4591001 1167 11671076	GASTR	Diarrhoea/ Diarrhea#	3	13FEB2021	3/2	1	Yes		NA	R (14FEB2021)	N/N
>55/ C4591001 1167 11671077	INJ&P	Brain contusion/ contusion of the frontal lobe	2	28NOV2020	75/26	2	No	O	NA/TC	R (23DEC2020)	Y/N
		Fall/ Fall	2	28NOV2020	75/1	3	No	O	NA/TC	R (28NOV2020)	N/N
>55/ C4591001 1167 11671085	CARD	Angina unstable/ Unstable Angina Pectoris	2	20OCT2020	34/1	2	No	O	NA/TC/TCN	R (20OCT2020)	Y/N
>55/ C4591001	MUSC	Arthralgia/ Generalized joint pain#	4	03FEB2021	1/3	1	Yes		NA/TC	R (05FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1167 11671127 >55/ C4591001	GENRL	Injection site erythema/ redness at injection site	2	26SEP2020	3/8	1	Yes		NA/TC	R (03OCT2020)	N/N
1167 11671137 >55/ C4591001	GENRL	Discomfort/ Non painful pressure Sensation left side body face, arm, leg#	3	11FEB2021	2/C	1	Yes		NA	RG	N/N
1167 11671182 >55/ C4591001	GENRL	Pyrexia/ Fever#	3	19DEC2020	2/2	1	Yes		NA/TC	R (20DEC2020)	N/N
1167 11671203 >55/ C4591001	GASTR	Diarrhoea/ Diarrhea#	3	20DEC2020	3/1	1	Yes		NA	R (20DEC2020)	N/N
1167 11671226 >55/ C4591001	VASC	Aortic rupture/ Aortic Rupture	2	18NOV2020	65/1	4	No	O	NA/W	F (18NOV2020)	Y/N
1168 11681083 >55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	1/4	2	Yes		NA	R (06SEP2020)	N/N
1168 11681131 >55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/3	2	Yes		NA	R (26SEP2020)	N/N
	GENRL	Chills/ chills	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1168 11681139		Fatigue/ fatigue	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N	
		Pyrexia/ low grade fever	2	26SEP2020	2/3	2	Yes		NA	R (28SEP2020)	N/N	
	MUSC	Myalgia/ myalgia	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N	
>55/ C4591001 1168 11681150	MUSC	Arthralgia/ JOINT PAIN	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N	
	NERV	Headache/ HEADACHE	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N	
>55/ C4591001 1168 11681173	MUSC	Myalgia/ myalgia	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N	
>55/ C4591001 1168 11681205	NERV	Headache/ headache	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N	
>55/ C4591001 1168 11681225	BLOOD	Lymphadenopathy/ SWOLLEN LYMPH NODES#	4	01FEB2021	5/4	1	Yes		NA	R (04FEB2021)	N/N	
>55/ C4591001 1168 11681235	GENRL	Injection site pain/ INJECTION SITE PAIN	1	02NOV2020	4/3	1	Yes		NA	R (04NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1168 11681240	GENRL	Injection site erythema/ redness at the injection site	1	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
		Injection site pruritus/ itching at the injection site	1	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
		Injection site swelling/ swelling at the injection site	1	27OCT2020	2/9	1	Yes		NA	R (04NOV2020)	N/N
	MUSC	Myalgia/ myalgia	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N
>55/ C4591001 1169 11691003	GENRL	Injection site pain/ Injection site Pain#	3	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Chills/ Chills#	4	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
		Fatigue/ Fatigue#	4	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
	NERV	Headache/ Headache#	4	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site pain#	4	29JAN2021	3/3	1	Yes		NA	R (31JAN2021)	N/N
		Injection site pruritus/ Injection Site Pruritus#	4	29JAN2021	3/3	1	Yes		NA	R (31JAN2021)	N/N
>55/ C4591001 1169 11691004	GENRL	Fatigue/ Acute Fatigue#	3	06JAN2021	2/1	1	Yes		NA	R (06JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1169 11691005	GENRL	Feeling hot/ Feeling warm, checked temp 98.4#	3	06JAN2021	2/1	1	Yes		NA	R (06JAN2021)	N/N	
		Injection site pain/ soreness in arm at injection site#	3	06JAN2021	2/1	1	Yes		NA	R (06JAN2021)	N/N	
		Pain/ Body Aches#	3	06JAN2021	2/1	1	Yes		NA	R (06JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	26JAN2021	1/3	1	Yes		NA/TC	R (28JAN2021)	N/N	
		Chills/ Chills#	4	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N	
	MUSC	Pain in extremity/ Soreness Left Arm	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N	
	GENRL	Injection site pain/ Sore Injection Site	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N	
	>55/ C4591001 1169 11691006	GENRL	Injection site pain/ Soreness at Injection Site	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Soreness at Injection Site	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	>55/ C4591001 1169 11691008	GENRL	Fatigue/ Fatigue	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
		Injection site pain/ Pain at injection site	1	03SEP2020	1/4	1	Yes		NA	R (06SEP2020)	N/N	
		Injection site pruritus/ Itching at injection site	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Injection site swelling/ swelling at injection site	1	03SEP2020	1/4	1	Yes		NA	R (06SEP2020)	N/N	
		Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N	
		Injection site pain/ Pain at injection site	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N	
		Injection site pruritus/ Itching at injection site	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N	
		Injection site swelling/ Swelling at injection site	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N	
>55/ C4591001 1169 11691013	RESP	Cough/ Dry Cough	1	05SEP2020	2/2	1	No	O	NA	R (06SEP2020)	N/N	
	GENRL	Rhinorrhoea/ Rhinorrhea	1	05SEP2020	2/2	1	No	O	NA	R (06SEP2020)	N/N	
		Injection site pain/ Injection Site pain	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N	
		Pain/ Generalized Body Aches	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N	
		Injection site pain/ Injection Site Pain#	3	05JAN2021	1/3	2	Yes		NA/TC	R (07JAN2021)	N/N	
>55/ C4591001 1169 11691015	GENRL	Chills/ Chills#	3	06JAN2021	2/2	2	Yes		NA/TC	R (07JAN2021)	N/N	
		Pain/ Generalized Body Aches#	3	06JAN2021	2/2	2	Yes		NA/TC	R (07JAN2021)	N/N	
		Pyrexia/ Fever#	3	06JAN2021	2/2	2	Yes		NA/TC	R (07JAN2021)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Moderate Injection Site pain#	4	28JAN2021	1/3	2	Yes		NA	R (30JAN2021)	N/N
		Pain/ Generalized Body Aches#	4	28JAN2021	1/3	2	Yes		NA	R (30JAN2021)	N/N
	NERV	Headache/ Headache#	4	28JAN2021	1/3	2	Yes		NA	R (30JAN2021)	N/N
		Mental impairment/ Mental Dullness#	4	28JAN2021	1/1	2	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1169 11691016	GENRL	Injection site pain/ Pain at injection site	1	04SEP2020	1/4	1	Yes		NA	R (07SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C4591001 1169 11691028	GENRL	Injection site pain/ Injection Site Soreness	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/Y
	RESP	Bronchospasm/ Exercise Induced Bronchospasm	2	10NOV2020	42/1	1	No	O	NA	R (10NOV2020)	N/N
	GENRL	Injection site pain/ Mild injection site pain#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
>55/ C4591001 1169 11691032	GENRL	Injection site pain/ Pain at injection site	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Mild Pain at Injection Site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C4591001	MUSC	Myalgia/ Entire body muscle pain	1	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1169 11691035	MUSC	Myalgia/ Entire body muscle pain	2	03OCT2020	2/3	2	Yes		NA/TC	R (05OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
		Pyrexia/ Low Grade Fever#	4	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
	METAB	Decreased appetite/ Decreased Appetite#	4	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
>55/ C4591001 1169 11691037	MUSC	Pain in extremity/ Pain in left arm	1	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Pain/ Generalized Body Aches	1	24SEP2020	14/3	1	No	O	NA/TC	R (26SEP2020)	N/N
	GENRL	Chills/ chills	1	26SEP2020	16/2	1	No	O	NA/TC	R (27SEP2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	1	26SEP2020	16/2	1	No	O	NA/TC	R (27SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	01OCT2020	1/2	1	No	O	NA	R (02OCT2020)	N/N
		Injection site pain/ Arm Soreness at Injection Site	2	01OCT2020	1/3	1	Yes		NA/TC	R (03OCT2020)	N/N
		Pyrexia/ Fever	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
	NERV	Headache/ Headache	2	01OCT2020	1/3	1	No	O	NA/TC	R (03OCT2020)	N/N
>55/ C4591001	MUSC	Arthralgia/ Painfull Right Shoulder	2	22OCT2020	18/6	2	No	O	NA/TC	R (27OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1169 11691042		Neck pain/ Painfull Neck	2	22OCT2020	18/6	2	No	O	NA/TC	R (27OCT2020)	N/N	
	GASTR	Nausea/ Nausea#	4	30JAN2021	2/1	2	Yes		NA	R (30JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	30JAN2021	2/1	2	Yes		NA	R (30JAN2021)	N/N	
		Injection site pain/ Injection Site Pain#	4	30JAN2021	2/2	2	Yes		NA	R (31JAN2021)	N/N	
	NERV	Dizziness/ Dizziness#	4	30JAN2021	2/1	2	Yes		NA	R (30JAN2021)	N/N	
>55/ C4591001 1169 11691050	NERV	Headache/ Headache	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	
	GENRL	Injection site pain/ Mild injection Site pain	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N	
>55/ C4591001 1169 11691051	GENRL	Injection site pain/ Pain at injection site	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
		Injection site pain/ Tenderness at injection site	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
>55/ C4591001 1169 11691052	INFEC	Rhinitis/ Rhinitis	1	04OCT2020	19/8	1	No	O	NA/TC	R (11OCT2020)	N/N	
	NERV	Sinus headache/ Right Sided Sinus Headache	1	04OCT2020	19/8	1	No	O	NA/TC	R (11OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1169 11691061	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Mild pain at injection site	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
>55/ C4591001 1169 11691066	GENRL	Injection site pain/ Injection Site Pain#	4	29JAN2021	2/4	2	Yes		NA	R (01FEB2021)	N/N
		Pain/ Generalized Body Aches#	4	29JAN2021	2/4	2	Yes		NA	R (01FEB2021)	N/N
		Pyrexia/ Fever#	4	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
>55/ C4591001 1169 11691068	GENRL	Injection site pain/ injection site pain	1	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N
	MUSC	Joint range of motion decreased/ mild range of motion deficit left arm	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
	GASTR	Constipation/ worsening constipation	2	16OCT2020	8/22	2	No	O	NA/TC	R (06NOV2020)	N/N
>55/ C4591001 1169 11691070	MUSC	Pain in extremity/ Pain in left arm	1	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	19SEP2020	2/2	1	No	O	NA/TC	R (20SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	2	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
	MUSC	Arthralgia/ Entire Body Joint Aches	2	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
>55/ C4591001 1169 11691071	GENRL	Chills/ Chills Post Shingrix Vaccine	2	13NOV2020	38/1	2	No	O	NA/TC	R (13NOV2020)	N/N
>55/ C4591001 1169 11691074†	EYE	Retinal haemorrhage/ Left Eye Retinal hemorrhage	1	03OCT2020	2/C	2	No	O	NA	N	N/N
		Vitreous detachment/ Bilateral Vitreous Detachment	1	03OCT2020	2/C	2	No	O	NA	N	N/N
>55/ C4591001 1170 11701004	GASTR	Diarrhoea/ Diarrhea	2	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N
	GENRL	Chills/ Chills	2	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N
		Injection site erythema/ Injection Site Redness	2	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N
		Myalgia/ Muscle Pain	2	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N
	NERV	Headache/ Headache	2	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ Injection Site Pain#	3	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1170 11701028	MUSC	Myalgia/ Generalized Muscle Pain#	3	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N	
	GENRL	Injection site pain/ Injection Site Soreness#	4	01FEB2021	1/4	2	Yes		NA	R (04FEB2021)	N/N	
	GENRL	Chills/ Chills#	4	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N	
		Fatigue/ Fatigue#	4	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N	
		Malaise/ Malaise#	4	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N	
		Pain/ Body Aches#	4	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N	
>55/ C4591001 1170 11701030	GENRL	Chills/ Chills	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N	
		Pyrexia/ Fever	2	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N	
>55/ C4591001 1170 11701032	GENRL	Injection site pain/ Injection Site Pain	1	18AUG2020	1/3	1	Yes		NA	R (20AUG2020)	N/N	
	GENRL	Fatigue/ Fatigue#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N	
	NERV	Headache/ Headache#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N	
>55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701039	GENRL	Chills/ Chills	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	NERV	Headache/ Headache	2	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N
>55/ C4591001 1170 11701046	GENRL	Injection site pain/ Pain at Injection Site	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	2	10SEP2020	1/4	1	Yes		NA	R (13SEP2020)	N/N
>55/ C4591001 1170 11701050	GENRL	Injection site pain/ Injection Site Pain	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	30JAN2021	2/1	1	Yes		NA	R (30JAN2021)	N/N
>55/ C4591001 1170 11701053	GENRL	Injection site pain/ Injection Site Pain	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1170 11701058	MUSC	Myalgia/ Muscle Pain Generalized	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GASTR	Constipation/ Constipation	2	14SEP2020	4/3	2	No	O	NA/TC	R (16SEP2020)	N/N
>55/ C4591001 1170 11701061	MUSC	Arthralgia/ Worsening Joint Pain	2	14SEP2020	4/48	2	No	O	NA/TC	R (31OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N
>55/ C4591001 1170 11701062	GENRL	Chills/ Chills#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
		Fatigue/ Fatigue#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
		Pyrexia/ Fever#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
	NERV	Headache/ Headache#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N
>55/ C4591001	NERV	Headache/ Headache	1	25AUG2020	2/21	1	Yes		NA/TC	R (14SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	15SEP2020	2/3	1	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C4591001	SKIN	Rash/ General Body Rash	2	19SEP2020	6/8	1	Yes		NA/TC	R (26SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701066	GENRL	Injection site pain/ Injection Site Pain#	3	28DEC2020	1/3	1	Yes		NA	R (30DEC2020)	N/N
	MUSC	Myalgia/ General Muscle Pain#	4	18JAN2021	1/4	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
	NERV	Headache/ headache#	4	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
>55/ C4591001 1170 11701067	GENRL	Chills/ Chills	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		Fatigue/ Fatigue	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
>55/ C4591001 1170 11701068	NERV	Headache/ Headache	1	26AUG2020	3/1	1	Yes		NA	R (26AUG2020)	N/N
>55/ C4591001 1170 11701070	GENRL	Fatigue/ Fatigue#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N
		Injection site pain/ Pain at Injection Site#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N
	NERV	Headache/ Headache#	4	19JAN2021	1/1	1	Yes		NA	R (19JAN2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701078	GASTR	Diarrhoea/ Diarrhea	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
>55/ C4591001 1170 11701080	GENRL	Injection site erythema/ Injection Site Redness#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
		Injection site swelling/ Injection Site Swelling#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
>55/ C4591001 1170 11701083	GENRL	Fatigue/ Fatigue	1	27AUG2020	2/21	1	Yes		NA	R (16SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001 1170 11701090	GENRL	Fatigue/ Fatigue	2	23SEP2020	8/2	1	Yes		NA	R (24SEP2020)	N/N
		Malaise/ Malaise	2	23SEP2020	8/2	1	Yes		NA	R (24SEP2020)	N/N
	CARD	Coronary artery disease/ Newly Diagnosed Coronary Artery Disease	2	01OCT2020	16/78	3	No	O	NA/TC/TCN	R (17DEC2020)	Y/N
	EYE	Vision blurred/ Blurred Vision	2	01OCT2020	16/31	2	No	O	NA	R (31OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1170 11701109	GENRL	Asthenia/ General Weakness	2	01OCT2020	16/31	2	No	O	NA	R (31OCT2020)	N/N
	NERV	Dizziness/ Dizziness	2	01OCT2020	16/31	2	No	O	NA	R (31OCT2020)	N/N
		Syncope/ Syncope	2	01OCT2020	16/1	3	No	O	NA	R (01OCT2020)	N/N
	RESP	Dyspnoea/ Shortness of Breath	2	01OCT2020	16/78	2	No	O	NA/TCN	R (17DEC2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	2/3	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Chills/ Chills	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Injection site erythema/ Redness at Injection Site	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Injection site swelling/ Swelling at Injection Site	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness	2	19SEP2020	2/3	2	Yes		NA/TC	R (21SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1170 11701124	GASTR	Diarrhoea/ Diarrhea	2	22SEP2020	5/2	1	Yes		NA	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	23SEP2020	6/3	2	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site swelling/ Injection Site Swelling	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1170 11701130	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
>55/ C4591001 1170 11701132	GENRL	Injection site pain/ Pain at injection site#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
	NERV	Tremor/ Shakiness	1	07SEP2020	8/1	1	Yes		NA	R (07SEP2020)	N/N
	GENRL	Injection site swelling/ Injection Site Swelling#	3	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/N
>55/ C4591001 1170 11701133	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1170 11701134	GENRL	Injection site pain/ Injection Site Pain#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
>55/ C4591001 1170 11701140	GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
>55/ C4591001 1170 11701141	GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1170 11701142	GENRL	Injection site pain/ Pain at injection site#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1170 11701147	GENRL	Chills/ Chills	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
	MUSC	Arthralgia/ Generalized Joint Pain	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N	
	NERV	Headache/ Headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
>55/ C4591001 1170 11701148	GENRL	Chills/ Chills#	4	29JAN2021	2/2	2	Yes		NA	R (30JAN2021)	N/N	
		Pyrexia/ Fever#	4	29JAN2021	2/2	2	Yes		NA	R (30JAN2021)	N/N	
>55/ C4591001 1170 11701155	GENRL	Fatigue/ Fatigue	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N	
		Injection site pain/ Injection site pain	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N	
		Injection site pain/ Injection Site Pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Chills/ Chills	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
		Pyrexia/ Fever	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N	
	MUSC	Myalgia/ Generalized Muscle Pain	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1170 11701157	NERV	Headache/ Headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
		Injection site erythema/ injection site redness#	4	27JAN2021	2/6	1	Yes		NA	R (01FEB2021)	N/N
		Injection site pain/ injection site pain#	4	27JAN2021	2/6	1	Yes		NA	R (01FEB2021)	N/N
		Injection site swelling/ injection site swelling#	4	27JAN2021	2/6	1	Yes		NA	R (01FEB2021)	N/N
		Pyrexia/ fever#	4	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
>55/ C4591001 1170 11701160	MUSC	Myalgia/ general muscle pain#	4	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
	NERV	Headache/ headache#	4	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Myalgia/ General Muscle Pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1170 11701161	NERV	Headache/ Headache	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	2/3	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1170 11701169	MUSC	Myalgia/ General Muscle Pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N
>55/ C4591001 1170 11701172	GENRL	Chills/ Chills	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
>55/ C4591001 1170 11701172		Injection site pain/ Injection Site Pain	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	MUSC	Myalgia/ General Muscle Pain	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Cyst/ Cyst on Left Pinky	2	09OCT2020	17/C	1	No	O	NA	N	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1170 11701175	GENRL	Injection site pain/ Injection site pain#	4	21JAN2021	2/1	1	Yes		NA	R (21JAN2021)	N/N
>55/ C4591001 1170 11701177	GENRL	Fatigue/ Fatigue	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	NERV	Headache/ Headache	1	02SEP2020	1/2	1	Yes		NA/TC	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	27JAN2021	1/1	1	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ Pain at injection site#	4	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
	NERV	Headache/ Headache#	4	27JAN2021	1/1	1	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001 1170 11701186	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Chills/ Chills	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
		Malaise/ Malaise	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Arthralgia/ Generalized Joint Pain	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		Myalgia/ Myalgias	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1170 11701188	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
>55/ C4591001 1170 11701194	GENRL	Fatigue/ Fatigue	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain	1	04SEP2020	2/3	1	Yes		NA/TC	R (06SEP2020)	N/N
		Myalgia/ General Muscle Pain	1	04SEP2020	2/3	1	Yes		NA/TC	R (06SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
		Injection site pain/ pain at injection site#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	07JAN2021	1/5	1	Yes		NA	R (11JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1170 11701197	GASTR	Nausea/ Queeziness	1	03SEP2020	1/7	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	05SEP2020	3/5	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site erythema/ Injection Site Redness#	3	05JAN2021	1/4	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1170 11701198	GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	1/7	2	Yes		NA	R (09SEP2020)	N/N
		Injection site swelling/ Injection Site Swelling	1	03SEP2020	1/7	2	Yes		NA	R (09SEP2020)	N/N
	GASTR	Nausea/ Queeziness	1	06SEP2020	4/3	1	Yes		NA	R (08SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	06SEP2020	4/3	1	Yes		NA	R (08SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		Injection site erythema/ Injection Site Redness	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	24SEP2020	1/17	1	Yes		NA	R (10OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1170 11701200	GENRL	Injection site swelling/ Injection Site Swelling	2	24SEP2020	1/5	1	Yes		NA	R (28SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
	NERV	Headache/ Headache	1	06SEP2020	4/1	1	Yes		NA	R (06SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	1/15	1	Yes		NA	R (08OCT2020)	N/N
>55/ C4591001 1170 11701202	GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	1/1	1	Yes		NA	R (03SEP2020)	N/N
>55/ C4591001 1170 11701214	GENRL	Injection site pain/ Pain at injection site#	3	02FEB2021	2/3	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1170 11701217	INJ&P	Limb injury/ Wound of left lower leg	1	12SEP2020	5/19	3	No	O	NA/TC	R (30SEP2020)	N/N
>55/ C4591001	BLOOD	Neutropenia/ Neutropenia	2	01OCT2020	3/32	3	No	O	NA/TC	R (01NOV2020)	Y/N
		Thrombocytopenia/ Thrombocytopenia	2	01OCT2020	3/32	2	No	O	NA	R (01NOV2020)	Y/N
	INFEC	Cellulitis/ Cellulitis of left lower leg	2	01OCT2020	3/32	3	No	O	NA/TC/TCN	R (01NOV2020)	Y/N
>55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701218											
>55/ C4591001 1170 11701219	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
>55/ C4591001 1170 11701220	GENRL	Chills/ Chills#	4	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
		Pyrexia/ Fever#	4	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
>55/ C4591001 1170 11701238	GENRL	Injection site pain/ Pain at injection site	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Pyrexia/ Fever	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
>55/ C4591001 1170 11701239	GENRL	Injection site pain/ Pain at injection site#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
	GENRL	Pyrexia/ fever#	4	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
	NERV	Headache/ Headache#	4	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
>55/ C4591001	GENRL	Chills/ Chills	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701240	NERV	Headache/ Headache	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
		Injection site pain/ Pain at Injection Site	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1170 11701242	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ Headache	1	22SEP2020	14/4	1	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Injection site erythema/ Injection Site Redness	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ Injection Site Soreness	2	28SEP2020	1/3	2	Yes		NA/TC	R (30SEP2020)	N/N
		Injection site pain/ Pain at Injection Site	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
		Injection site swelling/ Injection Site Swelling	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Malaise/ Malaise	2	29SEP2020	2/2	2	Yes		NA/TC	R (30SEP2020)	N/N
		Pyrexia/ Fever	2	29SEP2020	2/2	2	Yes		NA/TC	R (30SEP2020)	N/N
	NERV	Headache/ Headache	2	29SEP2020	2/2	2	Yes		NA/TC	R (30SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1170 11701246	GENRL	Chills/ Chills	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ Injection Site Tenderness	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
>55/ C4591001 1170 11701247	GENRL	Injection site pain/ Injection Site Pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Chills/ Chills#	3	11FEB2021	22/2	1	Yes		NA	R (12FEB2021)	N/N
		Fatigue/ Fatigue#	3	11FEB2021	22/2	1	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1170 11701248	GENRL	Fatigue/ Fatigue#	4	01FEB2021	1/5	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1170 11701254	GENRL	Injection site pain/ Injection Site Pain	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Chills/ Chills	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		Fatigue/ Fatigue	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Arthralgia/ Joint Pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		Myalgia/ Muscle Pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	NERV	Headache/ Headache	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1170 11701265	GENRL	Injection site pain/ Injection Site Pain#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1170 11701266	GENRL	Fatigue/ Fatigue	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site erythema/ Injection Site Redness	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		Injection site pain/ Pain at injection site	1	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	EAR	Vertigo/ Vertigo	2	14OCT2020	15/15	1	No	O	NA	R (28OCT2020)	N/N
>55/ C4591001	GENRL	Fatigue/ Fatigue	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1170 11701267	MUSC	Arthralgia/ Joint Ache	1	12SEP2020	3/3	1	Yes	NA/TC		R (14SEP2020)	N/N	
>55/ C4591001 1170 11701270		Myalgia/ Myalgias	1	12SEP2020	3/3	1	Yes	NA/TC		R (14SEP2020)	N/N	
>55/ C4591001 1170 11701272	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/2	1	Yes	NA		R (11SEP2020)	N/N	
>55/ C4591001 1170 11701273	GENRL	Injection site pain/ Injection Site Pain#	3	06JAN2021	1/2	1	Yes	NA		R (07JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	27JAN2021	2/2	1	Yes	NA		R (28JAN2021)	N/N	
		Injection site pain/ pain at injection site#	4	27JAN2021	2/2	1	Yes	NA		R (28JAN2021)	N/N	
>55/ C4591001 1170 11701275	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/2	1	Yes	NA		R (11SEP2020)	N/N	
>55/ C4591001 1170 11701276	GENRL	Injection site pain/ Injection Site Pain#	3	21JAN2021	1/3	1	Yes	NA		R (23JAN2021)	N/N	
>55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/2	1	Yes	NA		R (11SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701277	GENRL	Fatigue/ Fatigue#	4	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
		Injection site erythema/ Injection site redness#	4	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
>55/ C4591001 1170 11701278	GENRL	Injection site pain/ Injection Site Pain	2	01OCT2020	1/5	1	Yes		NA/TC	R (05OCT2020)	N/N
	GENRL	Chills/ Chills	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		Fatigue/ Fatigue	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		Malaise/ Malaise	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		Pyrexia/ Fever	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
>55/ C4591001 1170 11701294	NERV	Headache/ Headache	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		Pyrexia/ Fever	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
	NERV	Headache/ Headache	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701295	GENRL	Fatigue/ Fatigue	2	02OCT2020	1/4	1	Yes		NA	R (05OCT2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	02OCT2020	1/4	1	Yes		NA	R (05OCT2020)	N/N
	GENRL	Chills/ Chills	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
		Pyrexia/ Fever	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
>55/ C4591001 1170 11701299	GENRL	Fatigue/ Fatigue#	3	29DEC2020	2/2	1	Yes		NA	R (30DEC2020)	N/N
>55/ C4591001 1170 11701301	GENRL	Fatigue/ Fatigue#	3	18JAN2021	1/2	1	Yes		NA	RS (19JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1170 11701305	GENRL	Fatigue/ Fatigue#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1170 11701309	MUSC	Pyrexia/ Fever#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
		Arthralgia/ Generalized Joint Pain#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
	NERV	Headache/ Intermittent Headache	1	14SEP2020	4/8	1	Yes		NA	R (21SEP2020)	N/N
>55/ C4591001 1170 11701327	GENRL	Injection site pain/ Injection Site Pain	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1170 11701329	GENRL	Injection site erythema/ Injection Site Redness	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001 1170 11701330†	MUSC	Injection site pain/ Pain at Injection Site	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		Injection site swelling/ Injection Site Swelling	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		Myalgia/ Generalized Muscle Pain	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
INFECTION	Conjunctivitis/ Conjunctivitis	1	06OCT2020	21/39	1	No	O	NA/TC	R (13NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1170 11701331	GENRL	Injection site pain/ Injection at pain site#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
>55/ C4591001 1170 11701333	GENRL	Injection site pain/ Injection Site Pain	1	16SEP2020	1/5	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	19SEP2020	4/2	1	Yes		NA	R (20SEP2020)	N/N
>55/ C4591001 1170 11701335	GENRL	Injection site pain/ Injection Site Pain	1	17SEP2020	2/4	1	Yes		NA	R (20SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	23SEP2020	8/3	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ Headache#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
>55/ C4591001 1170 11701336	GENRL	Injection site pain/ Pain at injection Site	1	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1170 11701339	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	2/3	1	Yes		NA	R (30JAN2021)	N/N
		Injection site pain/ Left Arm Injection Site Soreness#	3	28JAN2021	2/3	2	Yes		NA	R (30JAN2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ Pain at injection site#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701345† >55/ C4591001 1170 11701353†	GENRL	Fatigue/ Fatigue#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
>55/ C4591001 1170 11701356	GENRL	Injection site pain/ Pain at injection site#	4	01FEB2021	1/5	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1170 11701356	GENRL	Injection site pain/ Injection Site Pain	1	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N
>55/ C4591001 1170 11701363	GENRL	Injection site pain/ pain at injection site#	3	17DEC2020	2/3	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Chills/ Chills#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
		Fatigue/ Fatigue#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
		Myalgia/ Generalized Muscle Pain#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
	NERV	Headache/ Headache#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pyrexia/ Fever#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
>55/ C4591001 1170 11701367	GENRL	Injection site bruising/ Injection Site Bruise#	3	06JAN2021	2/16	2	Yes		NA	R (21JAN2021)	N/N
	GENRL	Pyrexia/ fever#	4	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001 1170 11701368	GENRL	Injection site pain/ Injection Site Pain	1	22SEP2020	1/6	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	24SEP2020	3/6	1	Yes		NA	R (29SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
>55/ C4591001 1170 11701369	GENRL	Fatigue/ Fatigue#	4	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
>55/ C4591001 1170 11701371	GENRL	Fatigue/ Fatigue	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
	NERV	Headache/ Headache	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Pyrexia/ Fever#	4	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1170 11701409†	GENRL	Injection site pain/ Injection Site Pain#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
>55/ C4591001 1170 11701448	GENRL	Chills/ Chills	1	28OCT2020	3/2	1	Yes		NA	R (29OCT2020)	N/N
		Fatigue/ Fatigue	1	28OCT2020	3/3	1	Yes		NA	R (30OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1171 11711015	GENRL	Chills/ Chills	1	13AUG2020	1/2	1	Yes		NA	R (14AUG2020)	N/N
>55/ C4591001 1171 11711040	GENRL	Injection site pain/ Injection Site Pain [Left Arm Deltoid]	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001	GASTR	Intestinal ulcer perforation/ Perforated Intestinal marginated Ulcer#	3	31JAN2021	13/1	3	No	O	NA/TCN	R (31JAN2021)	Y/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1171 11711045 >55/ C4591001 1171 11711049	INJ&P	Fall/ Fall	2	25SEP2020	18/1	2	No	O	NA	R (25SEP2020)	N/N	
>55/ C4591001 1171 11711064	GENRL	Fibula fracture/ Fibula Fracture [Right] Fatigue/ Fatigue	2	25SEP2020	18/78	2	No	O	NA/TC	R (11DEC2020)	N/N	
>55/ C4591001 1171 11711102	RESP	Oropharyngeal pain/ Sore Throat	2	26SEP2020	13/3	2	No	O	NA/TC	R (28SEP2020)	N/N	
>55/ C4591001 1171 11711107	GENRL	Injection site pain/ Soreness around injection site	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N	
>55/ C4591001 1171 11711165	NERV	Pain/ Body aches (generalized) Headache/ Headache	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N	
>55/ C4591001 1171 11711165	INJ&P	Ligament sprain/ Lumbar Ligament Sprain	2	15JAN2021	115/16	1	No	O	NA/TC	R (30JAN2021)	N/N	
>55/ C4591001	GENRL	Pyrexia/ Low grade fever	2	23SEP2020	1/3	1	Yes		NA/TC	R (25SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1171 11711180	MUSC	Myalgia/ Myalgia	2	23SEP2020	1/3	1	Yes		NA/TC	R (25SEP2020)	N/N
>55/ C4591001 1171 11711182	GENRL	Injection site pain/ Injection Pain	1	03SEP2020	2/4	1	Yes		NA	R (06SEP2020)	N/N
>55/ C4591001 1171 11711188	NERV	Headache/ Headache	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
>55/ C4591001 1171 11711188	GENRL	Fatigue/ Fatigue	1	04SEP2020	3/3	1	Yes		NA	R (06SEP2020)	N/N
>55/ C4591001 1171 11711193	MUSC	Injection site pain/ Left Arm pain ( At the injection site )	1	04SEP2020	3/3	1	Yes		NA	R (06SEP2020)	N/N
>55/ C4591001 1171 11711193	MUSC	Myalgia/ Myalgia	1	04SEP2020	3/3	1	Yes		NA	R (06SEP2020)	N/N
>55/ C4591001 1171 11711193	INJ&P	Hand fracture/ Right First Metacarpal Fracture	2	04DEC2020	68/1	1	No	O	NA/TC/TCN	R (04DEC2020)	N/N
>55/ C4591001 1171 11711201	MUSC	Road traffic accident/ Dirt bike accident	2	04DEC2020	68/1	2	No	O	NA	R (04DEC2020)	N/N
>55/ C4591001 1171 11711201	MUSC	Pain in extremity/ Arm Pain [Left]	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1171 11711201	NERV	Headache/ Headache	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1171 11711208	METAB	Hyperlipidaemia/ Worsening of hyperlipidemia	2	21OCT2020	22/26	1	No	O	NA/TC	R (15NOV2020)	N/N	
		Type 2 diabetes mellitus/ Worsening of diabetes type II	2	21OCT2020	22/26	1	No	O	NA/TC	R (15NOV2020)	N/N	
		Injection site pain/ Injection site soreness	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N	
		Fatigue/ Fatigue	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N	
		Nausea/ Nausea	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N	
		Fatigue/ Fatigue	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N	
		Diarrhoea/ Diarrhea	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N	
		Injection site pain/ Arm pain ( at the injection site )	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N	
		Blood glucose fluctuation/ Worsening Blood Sugar Fluctuation	2	28SEP2020	1/57	1	No	O	NA	R (23NOV2020)	N/N	
		Pain in extremity/ Pain in Arm [Left]	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1171 11711243 >55/ C4591001	GENRL	Pyrexia/ Fever#	4	13JAN2021	2/1	1	Yes		NA	R (13JAN2021)	N/N
1171 11711253 >55/ C4591001	GENRL	Injection site pain/ Left Arm Pain (at the inject site )	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
1171 11711276 >55/ C4591001	MUSC	Myalgia/ Muscle aches, generalized	1	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
1171 11711302	MUSC	Myalgia/ Muscle aches, generalized	2	27OCT2020	2/2	2	Yes		NA/TC	R (28OCT2020)	N/N
>55/ C4591001 1174 11741001	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		Pyrexia/ Fever	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	NERV	Headache/ Headache	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
>55/ C4591001 1174 11741007	GENRL	Chills/ Chills#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	MUSC	Pain in extremity/ Left arm soreness#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1174 11741009	NERV	Headache/ Headache#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Pain/ Generalized Aches and pain#	3	18DEC2020	2/1	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Chills/ Chills#	4	06JAN2021	2/1	1	Yes		NA	R (06JAN2021)	N/N
>55/ C4591001 1174 11741010		Pain/ Generalized Aches and pain#	4	06JAN2021	2/1	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Injection site nodule/ Injection site nodule right arm	1	02SEP2020	2/3	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Chills/ Chills	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Injection site nodule/ Golf ball sized injection site nodule right deltoid	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Pain/ Generalized aches	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C4591001 1174 11741012	MUSC	Pain in extremity/ Left arm soreness#	3	22DEC2020	2/1	1	Yes		NA/TC	R (22DEC2020)	N/N
	MUSC	Myalgia/ Myalgia#	4	12JAN2021	2/2	1	Yes		NA/TC	R (13JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1174 11741014	RESP	Nasal congestion/ Nasal congestion#	4	12JAN2021	2/2	1	Yes		NA/TC	R (13JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N	
>55/ C4591001 1174 11741017	MUSC	Pain in extremity/ Pain in right arm#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N	
	GENRL	Chills/ Chills#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N	
>55/ C4591001 1174 11741018		Pain/ Body aches#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N	
		Pyrexia/ Fever#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N	
	NERV	Headache/ Headache#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N	
	INFEC	Herpes zoster/ Shingles#	4	14JAN2021	4/C	1	No	O	NA/TC	N	N/N	
	GENRL	Chills/ Chills	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N	
>55/ C4591001		Injection site pain/ Pain at injection site left arm	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N	
		Pain/ Aching	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N	
>55/ C4591001	EAR	Tinnitus/ Bilateral Tinnitus	1	13SEP2020	11/C	1	No	O	NA	N	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1174 11741022 >55/ C4591001 1174 11741035	GENRL	Chills/ Chills	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Pyrexia/ Fever	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	NERV	Headache/ Headache	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
>55/ C4591001 1174 11741037	INFEC	Post procedural infection/ Abdominal Post Surgical Infection	2	29DEC2020	93/17	1	No	O	NA/TCN	R (14JAN2021)	N/N
	MUSC	Pain in extremity/ Left arm soreness#	4	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
>55/ C4591001 1174 11741040	GENRL	Fatigue/ Fatigue	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Pain in extremity/ Left arm soreness	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Pain in extremity/ Right arm soreness	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
>55/ C4591001 1174 11741042	RENAL	Hydronephrosis/ Hydronephrosis	1	02OCT2020	17/5	2	No	O	NA/TC/TCN	R (06OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1174 11741044	GENRL	Nephrolithiasis/ nephrolithiasis	1	02OCT2020	17/5	3	No	O	NA/TC/TCN	R (06OCT2020)	Y/N	
		Chills/ Chills#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N	
	MUSC	Pain in extremity/ Soreness Left arm#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N	
>55/ C4591001 1174 11741048	GENRL	Pain/ Generalized aches#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N	
	MUSC	Pyrexia/ Fever#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N	
		Pain in extremity/ Left arm soreness#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N	
>55/ C4591001 1174 11741059	NERV	Headache/ Headache#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N	
	GENRL	Pyrexia/ Fever	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N	
>55/ C4591001 1174 11741069	SKIN	Rash/ Rash left upper arm	1	22SEP2020	1/4	1	No	O	NA	R (25SEP2020)	N/N	
	RESP	Oropharyngeal pain/ SORE THROAT, MILD INTERMITTENT	1	14AUG2020	3/11	1	No	O	NA	R (24AUG2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1177 11771006 >55/ C4591001 1177 11771012	RESP	Pulmonary embolism/ Right Lower Lobe Pulmonary Artery Embolus	2	01OCT2020	29/C	2	No	O	NA/TC	N	N/N
1177 11771012	VASC	Aortic aneurysm/ Aortic Aneurysm	2	01OCT2020	29/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1177 11771052	GENRL	Pain/ Body Aches#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1177 11771055	EAR	Tinnitus/ TINNITUS	2	08SEP2020	1/4	1	No	O	NA	R (11SEP2020)	N/N
1177 11771055	GENRL	Injection site pain/ MUSCLE PAIN AT INJECTION SITE	2	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1177 11771063	NEOPL	Malignant melanoma/ MELANOMA, Upper Back	2	29SEP2020	22/109	2	No	O	NA/TCN	R (15JAN2021)	N/N
>55/ C4591001 1177 11771069	MUSC	Myalgia/ MUSCLE PAIN, BOTH ARMS	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1177 11771089	GENRL	Injection site pain/ Injection Site Pain	2	09SEP2020	1/3	2	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	INJ&P	Muscle strain/ Abdominal Strain#	2	20NOV2020	9/C	1	No	O	NA	N	N/N	
>55/ C4591001 1177 11771115	GENRL	Injection site pain/ Injection Site Pain	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N	
	GENRL	Chills/ Chills	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N	
>55/ C4591001 1177 11771143	GENRL	Pyrexia/ FEVER	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
>55/ C4591001 1177 11771164	VASC	Aortic aneurysm/ Aortic Root Aneurysm	2	29NOV2020	75/C	1	No	O	NA/TC	RG	N/N	
	GASTR	Oesophageal ulcer/ Esophageal Ulcer	2	05JAN2021	112/C	2	No	O	NA	RG	N/N	
>55/ C4591001 1177 11771178	INJ&P	Fall/ MECHANICAL FALL	1	03SEP2020	8/1	3	No	O	NA	R (03SEP2020)	N/N	
		Spinal compression fracture/ LUMBAR COMPRESSION FRACTURE, L1	1	03SEP2020	8/60	2	No	O	NA/TC	R (01NOV2020)	N/N	
>55/ C4591001 1177 11771204	NEOPL	Bladder cancer/ Bladder Cancer	2	24OCT2020	34/C	3	No	O	NA/TC/TCN	RG	Y/N	
>55/ C4591001	INFEC	Mastoiditis/ Mastoiditis	2	01NOV2020	40/17	2	No	O	NA/TC	R (17NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1177 11771253 >55/ C4591001 1177 11771299	GENRL	Pyrexia/ Fever	1	05SEP2020	1/2	2	Yes		NA	R (06SEP2020)	N/N
>55/ C4591001 1177 11771317	NEOPL	Breast cancer stage I/ Breast Cancer, Stage 1	2	30NOV2020	62/C	2	No	O	NA/TCN	RG	Y/N
>55/ C4591001 1177 11771353	MUSC	Pain in extremity/ Pain, Left toe	1	14SEP2020	1/3	2	No	O	NA	R (16SEP2020)	N/N
>55/ C4591001 1177 11771370	GENRL	Chills/ Chills	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
>55/ C4591001 1177 11771380	GASTR	Aphthous ulcer/ Aphthous Ulcers	1	19SEP2020	3/52	2	Yes		NA/TC	R (09NOV2020)	N/N
>55/ C4591001 1177 11771421	GENRL	Fatigue/ Fatigue	2	09OCT2020	2/10	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1177 11771431	GENRL	Pain/ Generalized Body Aches	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
>55/ C4591001 1177 11771448	GASTR	Diarrhoea/ DIARRHEA	1	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Asthenia/ WEAKNESS	1	25SEP2020	1/1	2	Yes		NA	R (25SEP2020)	N/N
	SKIN	Cold sweat/ COLD SWEATS	1	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN, LEFT ARM	1	27SEP2020	3/3	1	Yes		NA	R (29SEP2020)	N/N
	GENRL	Pyrexia/ FEVER	1	28SEP2020	4/7	1	Yes		NA/TC	R (04OCT2020)	N/N
	NERV	Headache/ HEADACHE	1	28SEP2020	4/7	1	Yes		NA/TC	R (04OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain, Left Arm	2	16OCT2020	1/17	1	Yes		NA	R (01NOV2020)	N/N
>55/ C4591001 1177 11771457	GENRL	Injection site pain/ Injection Site Pain	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
>55/ C4591001 1177 11771508	INJ&P	Fall/ Fall	1	25OCT2020	12/1	2	No	O	NA/TCN	R (25OCT2020)	N/N
		Wrist fracture/ Fractured Right Wrist	1	25OCT2020	12/C	2	No	O	NA/TCN	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1177 11771527	GENRL	Injection site pain/ INJECTION SITE MUSCLE PAIN	1	19OCT2020	1/2	2	Yes		NA/TC	R (20OCT2020)	N/N	
		Injection site swelling/ SWELLING AT INJECTION SITE	1	19OCT2020	1/4	1	Yes		NA/TC	R (22OCT2020)	N/N	
	GASTR	Abdominal pain/ ABDOMINAL PAIN	1	31OCT2020	13/2	1	No	O	NA	R (01NOV2020)	N/N	
		Nausea/ NAUSEA	1	31OCT2020	13/2	1	No	O	NA	R (01NOV2020)	N/N	
>55/ C4591001 1177 11771536	GENRL	Pyrexia/ Fever	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N	
>55/ C4591001 1178 11781002	GENRL	Fatigue/ Fatigue	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N	
		Injection site pain/ Injection site muscle soreness left arm	1	22AUG2020	2/3	1	Yes		NA	R (24AUG2020)	N/N	
	INV	Body temperature increased/ increased temperature	1	22AUG2020	2/2	2	Yes		NA	R (23AUG2020)	N/N	
>55/ C4591001 1178 11781003	GENRL	Injection site pain/ Injection site tenderness#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N	
>55/ C4591001 1178 11781004	NERV	Headache/ headache#	3	23DEC2020	2/1	1	Yes		NA	R (23DEC2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Malaise/ malaise#	4	13JAN2021	2/1	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	4	13JAN2021	2/1	1	Yes		NA/TC	R (13JAN2021)	N/N
	NERV	Dizziness/ dizziness#	4	13JAN2021	2/1	2	Yes		NA	R (13JAN2021)	N/N
	MUSC	Bursitis/ right knee bursitis#	4	18JAN2021	7/20	2	No	O	NA/TC	R (06FEB2021)	N/N
>55/ C4591001 1178 11781005	EAR	Vertigo/ vertigo-intermittent	1	30AUG2020	7/24	2	Yes		NA/TCN	R (22SEP2020)	N/N
>55/ C4591001 1178 11781006	GENRL	Injection site pain/ injection site soreness	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Injection site erythema/ redness at injection site, left arm	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ soreness at injection site, left arm	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		Malaise/ malaise	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C4591001 1178 11781007	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/3	1	Yes		NA/TC	R (17SEP2020)	N/N
	MUSC	Myalgia/ Generalized myalgia	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1178 11781008	GENRL	Fatigue/ Fatigue#	4	08FEB2021	1/2	2	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1178 11781009	GENRL	Injection site pain/ soreness at injection site#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
>55/ C4591001 1178 11781011	GENRL	Fatigue/ intermittent fatigue	1	26AUG2020	3/7	1	Yes		NA	R (01SEP2020)	N/N
	RESP	Upper-airway cough syndrome/ post-nasal drip (intermittent)	1	27AUG2020	4/5	1	Yes		NA	R (31AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
>55/ C4591001 1178 11781012	MUSC	Osteoarthritis/ worsening of osteoarthritis, right hip	1	08SEP2020	16/108	3	No	O	NA/TCN	R (24DEC2020)	Y/N
>55/ C4591001 1178 11781015	GENRL	Injection site pain/ injection site tenderness	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
	NERV	Transient global amnesia/ transient global amnesia	2	10OCT2020	26/1	3	No	O	NA	R (10OCT2020)	Y/N
	VASC	Aortic dilatation/ Ascending aorta ectasia	2	10OCT2020	26/C	1	No	O	NA	N	N/N
	CARD	Left ventricular dysfunction/ Diastolic dysfunction of the left ventricle	2	11OCT2020	27/C	1	No	O	NA	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1178 11781017	NERV	Headache/ headache	1	25AUG2020	1/2	1	Yes		NA/TC	R (26AUG2020)	N/N
	INFEC	Herpes zoster/ shingles outbreak	1	28AUG2020	4/8	1	Yes		NA	R (04SEP2020)	N/N
	NERV	Headache/ headache	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N
	NERV	Headache/ headache#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Injection site pain/ Left arm soreness (injection site)#	3	21JAN2021	3/3	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Chills/ chills#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
		Fatigue/ fatigue#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	MUSC	Pain in extremity/ Arm soreness#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1178 11781021	GENRL	Fatigue/ fatigue	1	26AUG2020	1/2	2	Yes		NA	R (27AUG2020)	N/N
		Injection site pain/ injection site tenderness	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Injection site pain/ Injection site tenderness	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	16SEP2020	2/2	1	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	01OCT2020	17/1	1	No	O	NA	R (01OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	CARD	Angina pectoris/ angina pectoris	2	20OCT2020	36/4	1	No	O	NA	R (23OCT2020)	N/N
>55/ C4591001 1178 11781024	GENRL	Injection site bruising/ bruising at injection site	2	16SEP2020	1/4	1	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ tenderness at injection site	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001 1178 11781025	RENAL	Nephrolithiasis/ kidney stones	2	19SEP2020	4/5	3	No	O	NA/TC	R (23SEP2020)	Y/N
	INFEC	Pyelonephritis/ Pyelonephritis	2	03OCT2020	18/28	2	No	O	NA/TC	R (30OCT2020)	Y/N
	RENAL	Nephrolithiasis/ Kidney stone, worsening	2	03OCT2020	18/14	3	No	O	NA/TC	R (16OCT2020)	N/N
>55/ C4591001 1178 11781026	SKIN	Pruritus/ generalized itching#	4	11FEB2021	3/2	1	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1178 11781027	GASTR	Toothache/ generalized teeth ache	1	27AUG2020	2/3	1	No	O	NA	R (29AUG2020)	N/N
	GENRL	Pain/ generalized body ache	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	NERV	Headache/ headache	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1178 11781028	NERV	Pain/ Generalized body ache	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		Headache/ Headache	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001 1178 11781028	GENRL	Injection site pain/ Left deltoid soreness at injection site	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C4591001 1178 11781031	GENRL	Chills/ chills#	4	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
>55/ C4591001 1178 11781032	GENRL	Fatigue/ fatigue#	4	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
		Pain/ body aches#	4	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
		Injection site pain/ Tenderness at injection site	2	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1178 11781033	GENRL	Fatigue/ Fatigue	2	18SEP2020	3/2	1	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1178 11781033	INJ&P	Contusion/ Bruising - bilateral forearms	1	30AUG2020	4/131	1	No	O	NA	R (07JAN2021)	N/N
>55/ C4591001 1178 11781035	INJ&P	Contusion/ bruising, bilateral upper extremities	1	03SEP2020	8/22	1	No	O	NA	R (24SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site tenderness	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1178 11781039	SKIN	Acne/ whiteheads, bilateral ears	1	11SEP2020	15/34	1	No	O	NA	R (14OCT2020)	N/N
	GENRL	Injection site discomfort/ discomfort at injection site	2	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
	MUSC	Arthralgia/ right shoulder pain	2	21OCT2020	36/3	1	No	O	NA/TC	R (23OCT2020)	N/N
>55/ C4591001 1178 11781047	PSYCH	Libido increased/ Increased Libido	1	10SEP2020	11/29	1	No	O	NA	R (08OCT2020)	N/N
>55/ C4591001 1178 11781048	GASTR	Salivary gland calculus/ Sialolithiasis	1	20SEP2020	21/54	2	No	O	NA/TC	R (12NOV2020)	Y/N
	INFEC	Post procedural infection/ Post operative infection (sialolithiasis removal)	2	18NOV2020	59/12	3	No	O	NA/TC	R (29NOV2020)	Y/N
>55/ C4591001 1178 11781049	GENRL	Injection site pruritus/ Itching at injection site (left arm)#	4	11FEB2021	4/3	1	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1178 11781057	GASTR	Diarrhoea/ diarrhea	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
	GENRL	Injection site pain/ injection site tenderness, left arm	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Chills/ chills	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N	
	GENRL	Chills/ chills	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
		Fatigue/ fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
		Pain/ generalized body ache	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N	
		Pyrexia/ Fever	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
>55/ C4591001 1178 11781059	GENRL	Injection site pain/ Injection Site Soreness	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N	
	GENRL	Chills/ Chills	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
>55/ C4591001 1178 11781064	GENRL	Injection site pain/ Injection site soreness	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N	
		Injection site swelling/ Injection site swelling	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N	
		Injection site swelling/ Injection site swelling	2	22SEP2020	1/9	2	Yes		NA	R (30SEP2020)	N/N	
	GENRL	Pyrexia/ Fever	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
>55/ C4591001	GENRL	Injection site pain/ injection site soreness#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1178 11781066 >55/ C4591001	GENRL	Injection site pain/ pain at injection site	1	02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N
1178 11781081	GENRL	Fatigue/ fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	SKIN	Night sweats/ night sweats	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001	NEOPL	Basal cell carcinoma/ Basal cell carcinoma (nose)	2	20OCT2020	28/C	2	No	O	NA	N	N/N
1178 11781086 >55/ C4591001	GENRL	Injection site pain/ injection site soreness#	3	22JAN2021	2/1	1	Yes		NA	R (22JAN2021)	N/N
1178 11781091	GENRL	Injection site erythema/ erythema at injection site#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
		Injection site pain/ tenderness at injection site#	4	09FEB2021	1/4	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
	INV	Body temperature increased/ elevated temperature#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001	GASTR	Diarrhoea/ loose stools	1	08SEP2020	6/4	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1178 11781093 >55/ C4591001 1178 11781099	GENRL	Injection site pain/ Soreness at injection site	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Pain/ generalized body ache	2	24SEP2020	1/2	2	Yes		NA/TC	R (25SEP2020)	N/N
		Pyrexia/ fever	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1178 11781101	MUSC	Osteoarthritis/ osteoarthritis	1	14SEP2020	11/C	1	No	O	NA	N	N/N
	GENRL	Fatigue/ fatigue#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
		Injection site pain/ injection site tenderness#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
>55/ C4591001 1178 11781102	GENRL	Chills/ chills#	4	08FEB2021	1/1	1	Yes		NA	R (08FEB2021)	N/N
	MUSC	Plantar fasciitis/ plantar fasciitis, left foot#	4	19FEB2021	12/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1178 11781103	GENRL	Injection site pain/ Left arm soreness (injection site)	1	04SEP2020	1/4	2	Yes		NA	R (07SEP2020)	N/N
	SKIN	Urticaria/ Urticaria	1	05SEP2020	2/3	2	Yes		NA/TC	R (07SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site soreness	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	MUSC	Myalgia/ Generalized muscle ache	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1178 11781108	GENRL	Injection site pain/ injection site pain, left arm	1	05SEP2020	2/1	2	Yes		NA/TC	R (05SEP2020)	N/N
>55/ C4591001 1178 11781109	GENRL	Injection site pain/ Pain at injection site	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1178 11781111	GENRL	Injection site pain/ injection site soreness#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
>55/ C4591001 1178 11781112	EYE	Vitreous floaters/ eye floaters#	3	01FEB2021	6/C	2	No	O	NA	N	N/N
	GENRL	Fatigue/ fatigue#	4	23FEB2021	1/1	2	Yes		NA	R (23FEB2021)	N/N
	GENRL	Feeling abnormal/ brain fog#	4	24FEB2021	2/1	2	Yes		NA	R (24FEB2021)	N/N
		Pain/ generalized body aches#	4	24FEB2021	2/1	2	Yes		NA/TC	R (24FEB2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ injection site tenderness#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1178 11781115	GASTR	Nausea/ nausea#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N	
	GENRL	Chills/ chills#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N	
		Pain/ body aches#	4	09FEB2021	2/1	1	Yes		NA/TC	R (09FEB2021)	N/N	
>55/ C4591001 1178 11781122	NEOPL	Basal cell carcinoma/ Basal Cell Carcinoma (face)	2	15OCT2020	18/15	2	No	O	NA	R (29OCT2020)	N/N	
	CARD	Atrial fibrillation/ worsening of paroxysmal atrial fibrillation	2	14JAN2021	109/22	2	No	O	NA/TCN	R (04FEB2021)	Y/N	
	GENRL	Injection site pain/ tenderness at injection site#	3	22JAN2021	4/8	1	Yes		NA/TC	R (29JAN2021)	N/N	
	GASTR	Gastroesophageal reflux disease/ GERD#	3	04FEB2021	17/C	1	No	O	NA/TC	N	N/N	
	GASTR	Intestinal obstruction/ intestinal obstruction#	3	09FEB2021	22/11	3	No	O	NA	R (19FEB2021)	Y/N	
>55/ C4591001 1178 11781123	GASTR	Abdominal distension/ bloating, abdominal	1	23SEP2020	16/3	1	No	O	NA	R (25SEP2020)	N/N	
>55/ C4591001 1178 11781125	GENRL	Pyrexia/ fever	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1178 11781126	MUSC	Myalgia/ myalgias	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Injection site pain/ injection site tenderness#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
>55/ C4591001 1178 11781132	INJ&P	Malaise/ malaise#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
		Wrist fracture/ Fracture left wrist	2	09OCT2020	11/56	2	No	O	NA/TC/TCN	R (03DEC2020)	N/N
>55/ C4591001 1178 11781134	GENRL	Injection site pain/ pain at injection site	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1178 11781136	MUSC	Myalgia/ Diffuse myalgias	2	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
>55/ C4591001 1178 11781138	RENAL	Nocturia/ nocturia	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	CARD	Coronary artery disease/ vascular disease (coronary artery disease)	2	08OCT2020	10/C	3	No	O	NA/TC	N	N/N
		Myocardial infarction/ Myocardial infarction	2	08OCT2020	10/12	3	No	O	NA	R (19OCT2020)	Y/N
	GENRL	Pain/ body aches#	4	23FEB2021	2/C	1	Yes		NA	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1178 11781139	GENRL	Injection site pain/ soreness at injection site#	3	18JAN2021	1/5	1	Yes		NA/TC	R (22JAN2021)	N/N
	GENRL	Injection site pain/ injection site soreness#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	NERV	Headache/ worsening headache#	4	09FEB2021	2/1	1	Yes		NA/TC	R (09FEB2021)	N/N
>55/ C4591001 1178 11781140	GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	1/6	1	Yes		NA	R (15SEP2020)	N/N
	INJ&P	Wrist fracture/ Left wrist fracture	2	15OCT2020	17/43	2	No	O	NA/TC/TCN	R (26NOV2020)	N/N
>55/ C4591001 1178 11781143	GENRL	Malaise/ malaise	1	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Injection site soreness	2	01OCT2020	2/4	1	Yes		NA	R (04OCT2020)	N/N
		Malaise/ Malaise	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
>55/ C4591001 1178 11781146	GENRL	Injection site pain/ injection site pain	1	10SEP2020	1/5	2	Yes		NA	R (14SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	11SEP2020	2/3	2	Yes		NA	R (13SEP2020)	N/N
		Pyrexia/ fever	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1178 11781147	MUSC	Myalgia/ generalized muscle ache	1	11SEP2020	2/3	1	Yes		NA/TC	R (13SEP2020)	N/N
	NERV	Headache/ headache	1	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Chills/ chills	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
		Pyrexia/ fever	2	01OCT2020	1/3	1	Yes		NA/TC	R (03OCT2020)	N/N
	MUSC	Myalgia/ generalized muscle ache	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ headache	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
	RESP	Sneezing/ sneezing	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
	VASC	Hypertension/ exacerbation of hypertension	1	28SEP2020	19/23	1	No	O	NA/TC	R (20OCT2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ soreness at injection site#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
>55/ C4591001 1178 11781148	GENRL	Injection site pain/ injection site pain	1	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
GENRL	Injection site pain/ Tenderness at injection site	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N	
NERV	Headache/ Headache	2	03OCT2020	2/1	2	Yes		NA	R (03OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1178 11781151	GENRL	Injection site pain/ injection site tenderness	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Injection site pain/ injection site tenderness#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
>55/ C4591001 1178 11781157	GENRL	Injection site pain/ Pain at injection site	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
>55/ C4591001 1178 11781158	GENRL	Pyrexia/ Fever	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Chills/ Chills	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		Injection site pain/ Pain at injection site	2	01OCT2020	2/5	1	Yes		NA	R (05OCT2020)	N/N
>55/ C4591001 1178 11781160	GENRL	Injection site pain/ tenderness at injection site	1	18SEP2020	8/5	1	Yes		NA	R (22SEP2020)	N/N
>55/ C4591001 1178 11781164	BLOOD	Lymphadenopathy/ lymphadenopathy, right axilla	2	14OCT2020	10/8	1	Yes		NA	R (21OCT2020)	N/N
	GENRL	Injection site pain/ injection site tenderness#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001	MUSC	Arthralgia/ Left hip pain	2	20OCT2020	16/43	1	No	O	NA/TC	R (01DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1178 11781166	INJ&P	Skin laceration/ Laceration, Left lower leg	2	29OCT2020	25/33	2	No	O	NA/TC	R (30NOV2020)	N/N	
>55/ C4591001 1178 11781167	HEPAT	Cholecystitis/ cholecystitis	2	09OCT2020	5/4	3	No	O	NA/TC/TCN	R (12OCT2020)	Y/N	
		Cholelithiasis/ cholelithiasis (gallstones)	2	09OCT2020	5/3	3	No	O	NA/TC/TCN	R (11OCT2020)	N/N	
>55/ C4591001 1178 11781173	GENRL	Injection site pain/ Tenderness at injection site	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N	
	GENRL	Chills/ chills	1	06OCT2020	22/2	1	Yes		NA	R (07OCT2020)	N/N	
		Injection site pain/ Tenderness at injection site	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N	
	GASTR	Abdominal pain/ intermittent Right abdominal pain	2	17OCT2020	12/51	1	No	O	NA	R (06DEC2020)	N/N	
>55/ C4591001 1178 11781176	RENAL	Urine odour abnormal/ urine odor	1	19SEP2020	5/55	1	No	O	NA	R (12NOV2020)	N/N	
>55/ C4591001 1178 11781177	GENRL	Chills/ chills#	4	09FEB2021	1/1	2	Yes		NA	R (09FEB2021)	N/N	
		Injection site pain/ injection site pain#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1178 11781178	NERV	Pain/ generalized body aches#	4	09FEB2021	1/2	2	Yes		NA/TC	R (10FEB2021)	N/N
		Headache/ headache#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
	GENRL	Pyrexia/ fever#	4	10FEB2021	2/1	1	Yes		NA/TC	R (10FEB2021)	N/N
	GENRL	Injection site pain/ Tenderness at injection site	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Malaise/ generalized malaise	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Pain/ Body aches	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	23DEC2020	1/3	1	Yes		NA	R (25DEC2020)	N/N
	GENRL	Injection site pain/ Soreness of injection site	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
GENRL	Injection site pain/ Tenderness at injection site	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1178 11781196	GENRL	Fatigue/ Fatigue	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ Soreness at injection site - Left arm	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		Injection site pain/ soreness at injection site, left arm	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
>55/ C4591001 1178 11781199	GENRL	Fatigue/ Fatigue	2	07OCT2020	1/8	1	Yes		NA	R (14OCT2020)	N/N
	NERV	Headache/ Headache	2	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Chills/ chills#	4	23FEB2021	2/1	2	Yes		NA/TC	R (23FEB2021)	N/N
	NERV	Syncope/ syncope#	4	23FEB2021	2/1	2	Yes		NA	R (23FEB2021)	N/N
>55/ C4591001 1178 11781201	GENRL	Injection site pain/ injection site soreness#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N
>55/ C4591001 1178 11781202	GENRL	Injection site pain/ injection site tenderness#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1178 11781203	GENRL	Chills/ chills#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ headache#	4	10FEB2021	2/1	1	Yes		NA/TC	R (10FEB2021)	N/N
	VASC	Flushing/ Flushing (face/cheeks)#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1178 11781205	GENRL	Injection site pain/ injection site tenderness	1	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N
	SKIN	Rash/ generalized upper body rash	2	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N
>55/ C4591001 1178 11781206	GENRL	Injection site pain/ injection site soreness#	3	21JAN2021	1/5	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Malaise/ malaise#	3	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
>55/ C4591001 1178 11781212	GENRL	Injection site pain/ tenderness at injection site	1	18SEP2020	1/6	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Injection site swelling/ swelling, injection site	1	18SEP2020	1/6	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Intervertebral disc degeneration/ exacerbation of degenerative disc disease	2	28OCT2020	20/24	2	No	O	NA/TC	R (20NOV2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ Tenderness at injection site	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N



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1178 11781215	GENRL	Chills/ chills	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
>55/ C4591001 1178 11781225	GENRL	Injection site pain/ left deltoid soreness at site of injection	1	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C4591001 1178 11781229	GENRL	Injection site pain/ pain at injection site	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
>55/ C4591001 1178 11781229	GENRL	Injection site pain/ injection site soreness	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
>55/ C4591001 1178 11781232	MUSC	Rotator cuff syndrome/ Rotator cuff tear	2	14OCT2020	2/23	2	No	O	NA/TCN	R (05NOV2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site#	3	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
	NERV	Carpal tunnel syndrome/ left carpal tunnel syndrome#	3	02FEB2021	13/1	2	No	O	NA	R (02FEB2021)	N/N
	GENRL	Chills/ chills#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
		Fatigue/ fatigue#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
		Pyrexia/ fever#	4	10FEB2021	2/1	2	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ headache#	4	10FEB2021	2/1	1	Yes		NA/TC	R (10FEB2021)	N/N

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>55/ C4591001 1178 11781235	GENRL	Injection site pain/ Pain at injection site.	1	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C4591001 1178 11781238	GENRL	Injection site pain/ soreness at injection site#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	INJ&P	Foot fracture/ Right hallux fracture#	3	11FEB2021	17/C	1	No	O	NA/TC/TCN	N	N/N
>55/ C4591001 1178 11781241	REPRO	Prostatomegaly/ Exacerbation of enlarged prostate	1	05OCT2020	13/C	2	No	O	NA	N	N/N
	GENRL	Injection site pain/ Injection site tenderness.	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
>55/ C4591001 1178 11781242	VASC	Hypertension/ hypertension	1	09OCT2020	17/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1178 11781252	GENRL	Injection site pain/ tenderness at injection site	1	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1178 11781255	GENRL	Nodule/ Nodule/lump left arm below injection site.	1	12OCT2020	18/5	1	Yes		NA	R (16OCT2020)	N/N
>55/ C4591001	MUSC	Muscular weakness/ Decreased strength in both arms.	1	01OCT2020	7/15	1	No	O	NA	R (15OCT2020)	N/N

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1178 11781256 >55/ C4591001 1178 11781259	GASTR	Nausea/ nausea	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
1178 11781259 >55/ C4591001 1178 11781261	GENRL	Chills/ chills	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
1178 11781261 >55/ C4591001 1178 11781264	GENRL	Injection site pain/ Left deltoid soreness at site of injection.	1	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
1178 11781264 >55/ C4591001 1178 11781265	GENRL	Injection site pain/ soreness at injection site	2	17OCT2020	2/3	1	Yes		NA/TC	R (19OCT2020)	N/N
1178 11781265 >55/ C4591001 1178 11781266	GENRL	Injection site pain/ injection site pain#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
1178 11781266 >55/ C4591001 1178 11781267	GENRL	Fatigue/ fatigue#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
1178 11781267 >55/ C4591001 1178 11781268	GENRL	Axillary pain/ right axillary tenderness	2	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N
1178 11781268 >55/ C4591001 1178 11781269	ENDO	Thyroid mass/ worsening of right thyroid nodule	2	28OCT2020	9/50	2	No	O	NA	R (16DEC2020)	N/N
1178 11781269 >55/ C4591001 1178 11781270	GENRL	Injection site pain/ soreness at injection site (left deltoid)#	3	04JAN2021	1/2	1	Yes		NA/TC	R (05JAN2021)	N/N

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>55/ C4591001 1178 11781274	NERV	Headache/ Headache#	3	05JAN2021	2/1	1	Yes		NA/TC	R (05JAN2021)	N/N
	GENRL	Injection site pain/ tenderness at injection site#	4	25JAN2021	1/C	1	Yes		NA	N	N/N
	GASTR	Diarrhoea/ Diarrhea	1	02OCT2020	2/2	2	Yes		NA	R (03OCT2020)	N/N
	GENRL	Chills/ Chills	1	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	02OCT2020	2/2	2	Yes		NA	R (03OCT2020)	N/N
	REPRO	Pelvic pain/ pelvic pain	1	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
	MUSC	Arthralgia/ joint pain	2	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
>55/ C4591001 1178 11781278	NERV	Headache/ headache	2	23OCT2020	1/2	1	Yes		NA/TC	R (24OCT2020)	N/N
	GENRL	Chills/ chills	2	24OCT2020	2/1	1	Yes		NA/TC	R (24OCT2020)	N/N
	GENRL	Injection site pain/ pain beyond injection site	1	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	23OCT2020	1/1	1	Yes		NA	R (23OCT2020)	N/Y
>55/ C4591001 1178 11781280	GENRL	Pyrexia/ fever#	3	27JAN2021	2/1	2	Yes		NA/TC	R (27JAN2021)	N/N

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	GENRL	Injection site pain/ soreness at injection site#	4	02MAR2021	1/C	2	Yes		NA	N	N/N
		Pyrexia/ fever#	4	02MAR2021	1/C	1	Yes		NA/TC	N	N/N
	MUSC	Myalgia/ myalgia#	4	03MAR2021	2/C	2	Yes		NA	N	N/N
	NERV	Headache/ headache#	4	03MAR2021	2/C	2	Yes		NA	N	N/N
>55/ C4591001 1178 11781281	GENRL	Injection site pain/ injection site tenderness#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N
>55/ C4591001 1178 11781287	INJ&P	Facial bones fracture/ facial fracture#	2	28FEB2021	125/5	2	No	O	NA/TCN	R (04MAR2021)	N/N
		Skin laceration/ lacerations#	2	28FEB2021	125/5	2	No	O	NA	R (04MAR2021)	N/N
	RENAL	Nephrolithiasis/ Nephrolithiasis#	2	28FEB2021	125/3	2	No	O	NA	R (02MAR2021)	Y/N
>55/ C4591001 1178 11781289	GENRL	Fatigue/ Fatigue#	3	16DEC2020	1/1	1	Yes		NA	R (16DEC2020)	N/N
		Injection site pain/ soreness at injection site#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N
>55/ C4591001 1178 11781292	GENRL	Injection site pain/ soreness at injection site#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1178 11781293	GENRL	Injection site pain/ injection site soreness	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
	METAB	Gout/ Gout (right great toe)	2	14NOV2020	18/7	2	No	O	NA/TC	R (20NOV2020)	N/N
	GASTR	Small intestinal obstruction/ small bowel obstruction	2	14DEC2020	48/4	3	No	O	NA	R (17DEC2020)	Y/N
>55/ C4591001 1178 11781294	MUSC	Myalgia/ Myalgias intermittent	1	09OCT2020	2/14	1	Yes		NA/TC	R (22OCT2020)	N/N
	NERV	Headache/ Headache	2	29OCT2020	2/1	1	Yes		NA/TC	R (29OCT2020)	N/N
>55/ C4591001 1178 11781297	GENRL	Injection site pain/ Injection site tenderness, right arm	1	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/Y
	RESP	Epistaxis/ epistaxis	1	20OCT2020	7/1	1	No	O	NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N
>55/ C4591001 1178 11781302	GENRL	Fatigue/ fatigue#	3	25JAN2021	1/3	3	Yes		NA	R (27JAN2021)	N/N
	METAB	Decreased appetite/ Decreased appetite#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Pain in extremity/ upper and lower arm pain, left arm#	3	25JAN2021	1/2	2	Yes		NA	R (26JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Arthralgia/ Left wrist pain#	3	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N	
	GENRL	Pyrexia/ fever#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N	
	MUSC	Myalgia/ myalgia#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N	
	GASTR	Diarrhoea/ diarrhea#	4	24FEB2021	3/2	2	Yes		NA	R (25FEB2021)	N/N	
		Dyspepsia/ heartburn#	4	24FEB2021	3/2	1	Yes		NA/TC	R (25FEB2021)	N/N	
	SKIN	Skin lesion/ Skin lesions, punctate erythematous (left forearm)#	4	25FEB2021	4/3	1	Yes		NA	R (27FEB2021)	N/N	
>55/ C4591001 1178 11781303	GENRL	Chills/ chills	1	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N	
		Fatigue/ fatigue	1	16OCT2020	2/2	2	Yes		NA	R (17OCT2020)	N/N	
>55/ C4591001 1178 11781306	GENRL	Injection site pain/ Soreness at injection site	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N	
>55/ C4591001 1178 11781308	GENRL	Fatigue/ fatigue#	4	25FEB2021	2/3	3	Yes		NA	R (27FEB2021)	N/N	
		Injection site pain/ Injection site tenderness#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N	
>55/ C4591001	INFEC	Acarodermatitis/ Scabies	2	04DEC2020	24/2	2	No	O	NA/TC	R (05DEC2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1178 11781315		Cellulitis/ cellulitis, bilateral arms	2	04DEC2020	24/32	2	No	O	NA/TC	R (04JAN2021)	N/N
	INJ&P	Limb injury/ Right hand wound	2	11DEC2020	31/25	3	No	O	NA	R (04JAN2021)	N/N
	PSYCH	Delusion of parasitosis/ delusional parasitosis#	2	21DEC2020	41/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1179 11791001	GENRL	Chills/ CHILLS#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Fatigue/ TIREDNESS#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
>55/ C4591001 1179 11791012	GENRL	Fatigue/ Fatigue#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1179 11791013	GENRL	Chills/ Chills#	4	03FEB2021	1/3	1	Yes		NA/TC	R (05FEB2021)	N/N
		Injection site pain/ Injection site soreness#	4	03FEB2021	1/3	1	Yes		NA/TC	R (05FEB2021)	N/N
>55/ C4591001	GENRL	Chills/ Chills#	4	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1179 11791027		Injection site pain/ Injection site soreness#	4	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1179 11791028	GENRL	Chills/ Chills#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Fatigue/ Fatigue#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
>55/ C4591001 1179 11791029	GENRL	Injection site pain/ Sore arm on side of injection#	4	09JAN2021	1/2	1	Yes		NA	R (10JAN2021)	N/N
>55/ C4591001 1179 11791035	GENRL	Fatigue/ FATIGUE#	4	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Pain in extremity/ ARM SORENESS#	4	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N
>55/ C4591001 1179 11791038	GENRL	Injection site pain/ Injection Site Soreness#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001	GENRL	Chills/ Chills#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1179 11791047		Injection site pain/ Injection Site Soreness#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N	
>55/ C4591001 1179 11791059	GENRL	Chills/ CHILLS#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
		Pain/ BODY ACHES#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
		Pyrexia/ FEVER#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
>55/ C4591001 1179 11791062	INV	Body temperature increased/ Elevated temperature of 99.6 Fahrenheit.	1	10SEP2020	3/2	1	No	O	NA/TC	R (11SEP2020)	N/N	
	SKIN	Rash/ Rash on bilateral hands and left lower extremity.	1	10SEP2020	3/2	1	No	O	NA/TC	R (11SEP2020)	N/N	
>55/ C4591001 1179 11791078	GENRL	Fatigue/ Fatigue#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N	
		Pyrexia/ Fever of 99#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N	
	NERV	Headache/ Headache#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N	
>55/ C4591001 1179 11791096	BLOOD	Lymph node pain/ Soreness in lymph node under arm on side of injection.#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1179 11791121	GENRL	Injection site pain/ Injection Site Soreness#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
>55/ C4591001 1179 11791129	GENRL	Chills/ Chills	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N
>55/ C4591001 1179 11791135	GENRL	Injection site pain/ Injection Site Soreness#	4	03FEB2021	1/2	1	Yes		NA/TC	R (04FEB2021)	N/N
	NERV	Somnolence/ Drowsiness#	4	03FEB2021	1/2	1	Yes		NA/TC	R (04FEB2021)	N/N
>55/ C4591001 1179 11791140	MUSC	Myalgia/ Myalgia	2	12NOV2020	1/3	1	Yes		NA/TC	R (14NOV2020)	N/N
>55/ C4591001 1179 11791141	GENRL	Chills/ Chills#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1179 11791142	MUSC	Myalgia/ Myalgia	2	12NOV2020	1/3	1	Yes		NA/TC	R (14NOV2020)	N/N
>55/ C4591001	GENRL	Vaccination site pain/ Pain at the injection site left after vaccination #3#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1185 11851004	NERV	Somnolence/ Drowsiness#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N	
>55/ C4591001 1185 11851007	GENRL	Fatigue/ Fatigue#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N	
>55/ C4591001 1185 11851019	GASTR	Diarrhoea/ Diarrhea#	4	20FEB2021	5/4	1	Yes		NA	R (23FEB2021)	N/N	
>55/ C4591001 1185 11851031	VASC	Hypertension/ art. hypertension	1	12NOV2020	17/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1185 11851045	INFEC	Hordeolum/ stye right eye	1	16NOV2020	21/16	1	No	O	NA	R (01DEC2020)	N/N	
>55/ C4591001 1185 11851047	NERV	Paraesthesia/ A feeling of electric sensation for about 2 minutes#	3	09FEB2021	1/1	1	Yes		NA	R (09FEB2021)	N/N	
>55/ C4591001 1185 11851047	VASC	Hypertension/ Hypertension	2	15DEC2020	27/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1194 11941001	GENRL	Injection site pain/ Pain at injection site#	3	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1194 11941002	GENRL	Injection site pain/ Pain at injection site#	3	11JAN2021	1/3	2	Yes		NA	R (13JAN2021)	N/N
	BLOOD	Lymphadenopathy/ enlarged lymph nodes (right axillar)#	4	02FEB2021	2/12	2	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1194 11941007	GENRL	Injection site pain/ Pain at injection site#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Injection site pain/ Pain on injection site#	4	05FEB2021	2/4	2	Yes		NA	R (08FEB2021)	N/N
	NERV	Headache/ Headache#	4	05FEB2021	2/4	2	Yes		NA	R (08FEB2021)	N/N
>55/ C4591001 1194 11941017	GENRL	Injection site pain/ Pain at injection site#	3	27FEB2021	2/3	1	Yes		NA	R (01MAR2021)	N/N
>55/ C4591001 1194 11941018	GENRL	Injection site pain/ Pain at injection site#	3	25JAN2021	1/3	2	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001 1194 11941027	GENRL	Injection site pain/ Pain at injection site#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
>55/ C4591001 1194 11941028	GENRL	Injection site pain/ Pain at injection site#	3	13JAN2021	1/33	1	Yes		NA	R (14FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue#	4	03FEB2021	1/3	2	Yes		NA	R (05FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	03FEB2021	1/3	2	Yes		NA	R (05FEB2021)	N/N
		Injection site swelling/ Swelling at injection site#	4	03FEB2021	1/3	2	Yes		NA	R (05FEB2021)	N/N
	NERV	Headache/ Headache#	4	03FEB2021	1/3	2	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1194 11941060	GASTR	Aphthous ulcer/ aphthous ulcer	2	09NOV2020	1/3	1	No	O	NA	R (11NOV2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	11JAN2021	1/3	2	Yes		NA	R (13JAN2021)	N/N
>55/ C4591001 1194 11941063	GENRL	Injection site pain/ Pain at injection site#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
>55/ C4591001 1194 11941064	GENRL	Injection site pain/ Pain at injection site#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ Headache#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1194 11941068	GENRL	Injection site pain/ Pain at injection site#	3	13JAN2021	2/4	2	Yes		NA	R (16JAN2021)	N/N
	NERV	Headache/ Headache#	3	16JAN2021	5/1	2	Yes		NA	R (16JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue#	4	03FEB2021	2/6	2	Yes		NA	R (08FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	03FEB2021	2/3	2	Yes		NA	R (05FEB2021)	N/N
	NERV	Headache/ Headache#	4	03FEB2021	2/6	2	Yes		NA	R (08FEB2021)	N/N
>55/ C4591001 1194 11941075	GENRL	Injection site pain/ Pain at injection site#	3	22JAN2021	2/3	2	Yes		NA	R (24JAN2021)	N/N
	MUSC	Arthralgia/ arthralgia (right hip)#	4	08MAR2021	26/C	2	No	O	NA	N	N/N
>55/ C4591001 1194 11941077	GENRL	Fatigue/ Fatigue#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
		Injection site pain/ Pain at injection site#	3	27JAN2021	1/2	2	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1194 11941079	GENRL	Injection site pain/ Pain at injection site#	3	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
>55/ C4591001 1194 11941084	GENRL	Injection site pain/ Pain at injection site#	3	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
>55/ C4591001 1194 11941094	GENRL	Fatigue/ Fatigue#	3	19JAN2021	2/3	1	Yes		NA	R (21JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Injection site pain/ Pain at injection site#	3	19JAN2021	2/3	1	Yes		NA	R (21JAN2021)	N/N
		Headache/ Headache#	3	19JAN2021	2/3	2	Yes		NA/TC	R (21JAN2021)	N/N
>55/ C4591001 1194 11941095	GENRL	Injection site pain/ Pain at injection site#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
>55/ C4591001 1195 11951006	NEOPL	Adenocarcinoma pancreas/ Adenocarcinoma Pancreas	2	11DEC2020	39/C	2	No	O	NA	RG	Y/N
	HEPAT	Hepatic cyst/ Liver cyst	2	05JAN2021	64/C	1	No	O	NA	N	N/N
	INFEC	Escherichia sepsis/ Escherichia coli sepsis	2	07JAN2021	66/3	2	No	O	NA/TC	R (09JAN2021)	N/N
	CARD	Tachycardia/ Tachycardia	2	21JAN2021	80/8	1	No	O	NA/TC	R (28JAN2021)	N/N
	GENRL	Oedema peripheral/ leg oedema#	2	FEB2021	91/	1	No	O	NA/TC	R (08FEB2021)	N/N
	SKIN	Decubitus ulcer/ Decubitus ulcer left heel#	2	FEB2021	91/C	2	No	O	NA/TCN	RG	N/N
	GENRL	Impaired healing/ post operative wound healing disturbance#	2	11FEB2021	101/6	2	No	O	NA	R (16FEB2021)	Y/N
>55/ C4591001 1195 11951011	MUSC	Myalgia/ muscular pain ( sore muscles)	1	27OCT2020	13/1	1	No	O	NA	R (27OCT2020)	N/N
	GENRL	Injection site pain/ Pain injection site#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1195 11951012	NERV	Headache/ Headache#	4	17FEB2021	2/1	2	Yes		NA/TC	R (17FEB2021)	N/N
	GENRL	Chills/ Chills#	4	09FEB2021	2/2	2	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1195 11951014	NERV	Headache/ Headache#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
	MUSC	Osteoarthritis/ rhisarthrosis thumb right	2	17NOV2020	13/90	2	No	O	NA	R (14FEB2021)	Y/N
>55/ C4591001 1195 11951016	GASTR	Diarrhoea/ Diarrhea	1	22OCT2020	8/1	1	No	O	NA	R (22OCT2020)	N/N
>55/ C4591001 1195 11951025	GENRL	Injection site erythema/ Redness injection site#	4	18FEB2021	2/3	1	Yes		NA/TC	R (20FEB2021)	N/N
>55/ C4591001 1195 11951031	MUSC	Pain in extremity/ Limb pain#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1195 11951037	NERV	Headache/ Headache#	4	11FEB2021	2/1	2	Yes		NA	R (11FEB2021)	N/N
	GASTR	Nausea/ Nausea	2	01DEC2020	26/9	1	No	O	NA/TC	R (09DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1195 11951044	GASTR	Diarrhoea/ Diarrhoe (fatty food)	1	24OCT2020	9/1	1	No	O	NA	R (24OCT2020)	N/N
>55/ C4591001 1195 11951059	GENRL	Chills/ Chills#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Chills/ Chills#	4	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	18FEB2021	1/2	2	Yes		NA/TC	R (19FEB2021)	N/N
	CARD	Arrhythmia/ absolute arrhythmia#	4	25FEB2021	8/C	2	No	O	NA	RG	Y/N
>55/ C4591001 1195 11951110	NERV	Vith nerve paralysis/ paralysis of Nervus abducens right eye	2	04DEC2020	27/11	1	No	O	NA	R (14DEC2020)	N/N
	GENRL	Chills/ Chills#	3	10FEB2021	23/2	2	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	11FEB2021	2/1	2	Yes		NA/TC	R (11FEB2021)	N/N
>55/ C4591001 1195 11951112	GENRL	Chills/ Chills#	3	30JAN2021	2/1	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Chills/ Chills#	4	20FEB2021	2/1	2	Yes		NA	R (20FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache#	4	20FEB2021	2/2	3	Yes		NA	R (21FEB2021)	N/N
>55/ C4591001 1195 11951121	MUSC	Foot deformity/ flat splayfoot left and right side#	3	07FEB2021	12/C	1	No	O	NA	RG	N/N
>55/ C4591001 1195 11951122	MUSC	Tendonitis/ tendinitis left feet	2	05DEC2020	25/7	1	No	O	NA	R (11DEC2020)	N/N
>55/ C4591001 1195 11951125	CARD	Cardiovascular disorder/ circulatory dysregulation	2	25NOV2020	15/1	1	No	O	NA	R (25NOV2020)	N/N
>55/ C4591001 1195 11951126	MUSC	Osteoarthritis/ Arthrosis shoulder right	2	25JAN2021	76/C	1	No	O	NA	RG	N/N
>55/ C4591001 1195 11951131	GASTR	Umbilical hernia/ umbilical hernia	2	24NOV2020	18/10	1	No	O	NA	R (03DEC2020)	Y/N
	GENRL	Injection site pain/ Pain injection side#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ Headache#	3	26JAN2021	1/3	2	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Chills/ Chills#	4	16FEB2021	1/2	2	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	17FEB2021	2/1	2	Yes		NA/TC	R (17FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1195 11951132	NEOPL	Lymphoma/ Lymphoma	2	30DEC2020	54/63	2	No	O	NA	R (02MAR2021)	Y/N	
>55/ C4591001 1195 11951133	MUSC	Intervertebral disc protrusion/ intervertebral disc protusion cervical spine	2	08NOV2020	2/C	2	No	O	NA	RG	N/N	
>55/ C4591001 1195 11951151	GENRL	Injection site erythema/ Redness injection site#	3	19FEB2021	1/7	2	Yes		NA	R (25FEB2021)	N/N	
	NERV	Headache/ Headache#	3	20FEB2021	2/1	2	Yes		NA	R (20FEB2021)	N/N	
	GENRL	Chills/ Chills#	4	12MAR2021	2/2	2	Yes		NA	R (13MAR2021)	N/N	
	NERV	Headache/ Headache#	4	12MAR2021	2/2	2	Yes		NA	R (13MAR2021)	N/N	
>55/ C4591001 1197 11971006	MUSC	Osteoarthritis/ worsening of activated arthrosis	1	17OCT2020	3/3	2	No	CD	NA/TC	R (19OCT2020)	N/N	
>55/ C4591001 1197 11971012	GENRL	Peripheral swelling/ arm swelling#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N	
>55/ C4591001 1197 11971016	EYE	Conjunctival haemorrhage/ Hyposphagma left	1	17OCT2020	2/4	1	No	CD	NA	R (20OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1197 11971021	GENRL	Chills/ chills#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Injection site pain/ Pain Injection Region Right Arm#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	20FEB2021	3/2	1	Yes		NA	R (21FEB2021)	N/N
>55/ C4591001 1197 11971023		Vomiting/ vomiting#	4	20FEB2021	3/2	1	Yes		NA	R (21FEB2021)	N/N
	GENRL	Chills/ Chills#	3	05FEB2021	1/3	2	Yes		NA	R (07FEB2021)	N/N
		Injection site pain/ Pain at injection side#	3	05FEB2021	1/2	2	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1197 11971024	MUSC	Arthralgia/ Generalized Arthralgia#	3	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	3	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection side left arm#	3	03FEB2021	1/4	2	Yes		NA	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	3	05FEB2021	3/1	2	Yes		NA/TC	R (05FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	06FEB2021	4/3	1	Yes		NA	R (08FEB2021)	N/N
	MUSC	Arthralgia/ Generalized Arthralgia#	3	07FEB2021	5/3	2	Yes		NA	R (09FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1197 11971030	GENRL	Injection site pain/ pain at injection site#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
>55/ C4591001 1197 11971033	MUSC	Pain in extremity/ arm pain#	2	28JAN2021	85/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
>55/ C4591001 1197 11971044	VASC	Hypertension/ hypertension, worsening	2	20NOV2020	16/11	2	No	O	NA/TC	R (30NOV2020)	N/N
	GENRL	Injection site pain/ Pain Injection Region left Arm#	3	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N
	GENRL	Chills/ Chills#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Chills/ chills#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
		Pyrexia/ fever#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
	NERV	Headache/ headache#	4	19FEB2021	2/1	2	Yes		NA	R (19FEB2021)	N/N
>55/ C4591001 1197 11971046	GENRL	Injection site pain/ pain at injection site#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
>55/ C4591001	VASC	Hypertension/ worsening hypertension	1	20OCT2020	4/11	1	No	O	NA	R (30OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1197 11971047 >55/ C4591001	GENRL	Pyrexia/ fever#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
1197 11971049	MUSC	Arthralgia/ generalized arthralgia#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
>55/ C4591001	EYE	Cataract/ cataract left eye	1	05NOV2020	20/C	1	No	O	NA	N	N/N
1197 11971051 >55/ C4591001	GENRL	Injection site pain/ muscle pain at injection site#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
1197 11971052	GENRL	Injection site pain/ pain at injection site#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
	NERV	Headache/ headache#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
	MUSC	Arthralgia/ Generalized joint pain#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
>55/ C4591001	MUSC	Pain in extremity/ Arm Pain left Side#	3	03FEB2021	1/3	2	Yes		NA/TC	R (05FEB2021)	N/N
1197 11971054	GENRL	Fatigue/ Fatigue#	3	04FEB2021	2/1	1	Yes		NA/TC	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	3	04FEB2021	2/2	2	Yes		NA	R (05FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Pain at injection Site#	4	24FEB2021	1/3	2	Yes		NA/TC	R (26FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
	MUSC	Myalgia/ Generalized Myalgia#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
>55/ C4591001 1197 11971055	GENRL	Injection site pain/ Patin at injection site#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1197 11971056	MUSC	Pain in extremity/ Arm pain#	3	03FEB2021	1/2	2	Yes		NA	R (04FEB2021)	N/N
	MUSC	Pain in extremity/ Pain Upper Arm#	4	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
>55/ C4591001 1197 11971063	GASTR	Toothache/ dental toothache	2	08NOV2020	3/1	2	No	O	NA/TC	R (08NOV2020)	N/N
	GENRL	Injection site swelling/ swelling left arm at injection site#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
	GASTR	Nausea/ nausea#	4	20FEB2021	2/1	3	Yes		NA	R (20FEB2021)	N/N
	GENRL	Chills/ chills#	4	20FEB2021	2/1	3	Yes		NA/TC	R (20FEB2021)	N/N
		Peripheral swelling/ arm swelling#	4	20FEB2021	2/1	3	Yes		NA/TC	R (20FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1197 11971065	NERV	Pyrexia/ Fever#	4	20FEB2021	2/1	3	Yes		NA/TC	R (20FEB2021)	N/N
		Headache/ headache#	4	20FEB2021	2/1	3	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	3	30JAN2021	2/1	2	Yes		NA	R (30JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	31JAN2021	3/2	2	Yes		NA	R (01FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	20FEB2021	2/2	2	Yes		NA/TC	R (21FEB2021)	N/N
	MUSC	Injection site pain/ Pain at Injection site#	4	20FEB2021	2/2	2	Yes		NA/TC	R (21FEB2021)	N/N
		Myalgia/ Muscle Pain#	4	20FEB2021	2/2	2	Yes		NA/TC	R (21FEB2021)	N/N
NERV	Headache/ Headache#	4	20FEB2021	2/2	2	Yes		NA/TC	R (21FEB2021)	N/N	
>55/ C4591001 1197 11971072	GENRL	Injection site pain/ Pain at Injection Site#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Chills/ Chills#	4	20FEB2021	2/2	2	Yes		NA	R (21FEB2021)	N/N
		Pain/ Structure Pain#	4	20FEB2021	2/2	2	Yes		NA	R (21FEB2021)	N/N
	NERV	Pyrexia/ Feaver#	4	20FEB2021	2/2	2	Yes		NA	R (21FEB2021)	N/N
		Headache/ Headache#	4	20FEB2021	2/2	2	Yes		NA	R (21FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1197 11971074	MUSC	Pain in extremity/ Arm Pain#	3	05FEB2021	1/3	2	Yes		NA	R (07FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	3	Yes		NA	R (07FEB2021)	N/N
		Feeling cold/ Freezing#	3	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	4	26FEB2021	1/1	1	Yes		NA	R (26FEB2021)	N/Y
	GASTR	Nausea/ Nausea#	4	27FEB2021	2/1	2	Yes		NA/TC	R (27FEB2021)	N/N
		Vomiting/ Vomitting#	4	27FEB2021	2/1	2	Yes		NA	R (27FEB2021)	N/N
	SKIN	Rash/ Examthema under injection side#	4	27FEB2021	2/5	1	Yes		NA	R (03MAR2021)	N/N
>55/ C4591001 1197 11971075	GENRL	Chills/ Chills#	4	19FEB2021	1/2	2	Yes		NA	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	4	20FEB2021	2/1	1	Yes		NA/TC	R (20FEB2021)	N/N
>55/ C4591001 1197 11971081	MUSC	Myalgia/ muscle pain#	3	05FEB2021	1/4	2	Yes		NA	R (08FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	3	08FEB2021	4/3	1	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ Headache#	3	08FEB2021	4/1	2	Yes		NA	R (08FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1197 11971083	GENRL	Injection site pain/ pain injection site#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N
		Injection site pain/ pain at injection site#	4	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N
	NERV	Disturbance in attention/ Concentration disorders#	4	20FEB2021	2/2	2	Yes		NA	R (21FEB2021)	N/N
		Hypoaesthesia/ numbness#	4	20FEB2021	2/2	2	Yes		NA	R (21FEB2021)	N/N
>55/ C4591001 1197 11971084	GASTR	Haemorrhoids/ hemorrhoids	1	27OCT2020	9/9	1	No	O	NA	R (04NOV2020)	N/N
	NEOPL	Colon adenoma/ Colon adenoma	1	27OCT2020	9/1	1	No	O	NA/TCN	R (27OCT2020)	N/N
>55/ C4591001 1197 11971087	METAB	Vitamin D deficiency/ Vitamin-D-Deficiency	2	17NOV2020	11/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1197 11971091	METAB	Iron deficiency/ Worsening of Relapsing Iron Deficiency	2	15JAN2021	70/C	2	No	O	NA/TC	RG	N/N
	NERV	Headache/ Headache#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	01FEB2021	5/2	1	Yes		NA	R (02FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INFEC	Sinusitis/ sinusitis frontalis#	4	10MAR2021	20/C	2	No	O	NA/TC	N	N/N
	BLOOD	Anaemia/ Anemia#	4	12MAR2021	22/C	3	No	O	NA/TC	N	N/N
>55/ C4591001 1197 11971097	CARD	Acute myocardial infarction/ Acute Posterior Myocardial Infarction	2	03JAN2021	58/6	4	No	O	NA/TC/TCN	R (08JAN2021)	Y/N
	GENRL	Peripheral swelling/ Arm Swelling#	3	13FEB2021	1/2	1	Yes		NA	R (14FEB2021)	N/N
>55/ C4591001 1197 11971099	GENRL	Injection site pain/ pain at injection site#	3	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
>55/ C4591001 1197 11971100	GENRL	Injection site pain/ pain injection site#	4	24FEB2021	1/2	2	Yes		NA	R (25FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
	NERV	Headache/ headache#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
>55/ C4591001 1197 11971101	SURG	Tooth extraction/ tooth extraction	2	16NOV2020	10/1	2	No	O	NA/TC	R (16NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1202 12021002	GENRL	Injection site pain/ local pain at injection site#	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Malaise/ Malaise#	3	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1202 12021012	NERV	Headache/ Headache	1	06NOV2020	10/1	2	No	O	NA/TC	R (06NOV2020)	N/N
>55/ C4591001 1203 12031003	MUSC	Joint swelling/ swollen thumb joint left	1	05NOV2020	21/4	1	No	O	NA	R (08NOV2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1203 12031006	GENRL	Injection site pain/ tenderness at injection site#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1203 12031016	NERV	Headache/ headache	1	30OCT2020	12/1	2	No	O	NA/TC	R (30OCT2020)	N/N
>55/ C4591001 1203 12031017	MUSC	Myalgia/ sore muscles (lower back and upper legs)	1	07NOV2020	20/5	1	No	O	NA	R (11NOV2020)	N/N
	GENRL	Fatigue/ fatigue	1	09NOV2020	22/3	1	No	O	NA	R (11NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	RESP	Nasal congestion/ congested nose	2	24NOV2020	16/C	1	No	O	NA/TC	N	N/N
	GENRL	Injection site pain/ injection site reaction (pain)#	3	18JAN2021	1/5	2	Yes		NA	R (22JAN2021)	N/N
	NERV	Headache/ systemic injection reaction (headache)#	3	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
	NERV	Headache/ headache#	3	03FEB2021	17/4	2	No	O	NA/TC	R (06FEB2021)	N/N
	SKIN	Pruritus/ itching both back of hands#	3	05FEB2021	19/16	2	No	O	NA/TC	R (20FEB2021)	N/N
	GENRL	Chills/ systemic injection reaction chills#	4	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
		Fatigue/ systemic injection reaction fatigue#	4	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
		Injection site pain/ injection site reaction tenderness#	4	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
		Injection site swelling/ injection site reaction swelling#	4	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N
	MUSC	Musculoskeletal pain/ systemic injection reaction muscle joint pain#	4	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
	NERV	Headache/ systemic injection reaction(headache)#	4	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1203 12031018	CARD	Tachycardia/ subjective perceived tachycardia	2	25JAN2021	78/22	1	No	O	NA/TC	R (15FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1203 12031022	INFEC	Pulpitis dental/ inflammation tooth left#	2	01MAR2021	112/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1203 12031027	MUSC	Pain in extremity/ pain left foot	1	09NOV2020	21/1	2	No	O	NA/TC	R (09NOV2020)	N/N	
	MUSC	Osteoarthritis/ aggravated pain left foot (due to arthrosis)	2	10NOV2020	1/3	3	Yes		NA/TC	R (12NOV2020)	N/N	
>55/ C4591001 1203 12031028	RESP	Epistaxis/ epistaxis	2	03DEC2020	24/1	1	No	O	NA	R (03DEC2020)	N/N	
>55/ C4591001 1203 12031029	GENRL	Fatigue/ systemic vaccination reaction fatigue#	4	08FEB2021	1/2	2	Yes		NA	R (09FEB2021)	N/N	
		Injection site erythema/ injection site reaction redness#	4	08FEB2021	1/3	2	Yes		NA	R (10FEB2021)	N/N	
		Injection site pain/ injection site reaction tenderness#	4	08FEB2021	1/3	2	Yes		NA	R (10FEB2021)	N/N	
		Pyrexia/ systemic vaccination reaction fever#	4	08FEB2021	1/2	2	Yes		NA	R (09FEB2021)	N/N	
	SKIN	Skin lesion/ Skin lesion:redness and swelling left upper arm 10cm below and ventral of injection site#	4	11FEB2021	4/5	2	Yes		NA	R (15FEB2021)	N/N	
>55/ C4591001	GENRL	Injection site pain/ tenderness at injection site#	3	09FEB2021	2/3	1	Yes		NA	R (11FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1203 12031038 >55/ C4591001 1203 12031039	SKIN	Erythema/ reddening(5cm+5cm) left upper arm ( 10cm distal from injection site)	2	18NOV2020	3/5	1	Yes		NA/TC	R (22NOV2020)	N/N
>55/ C4591001 1203 12031040	GENRL	Injection site pain/ tenderness at injection site#	3	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
>55/ C4591001 1203 12031055	GENRL	Malaise/ malaise# Injection site pain/ tenderness at injection site#	3	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
>55/ C4591001 1203 12031061	GENRL	Injection site pain/ tenderness at injection site#	3	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1203 12031061	GENRL	Injection site pain/ pain at injection site#	3	12FEB2021	1/4	1	Yes		NA	R (15FEB2021)	N/N
>55/ C4591001 1204 12041003	GENRL	Pyrexia/ mild fever	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
>55/ C4591001 1204 12041007	GENRL	Pyrexia/ fever, 101.1F	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1204 12041014	GENRL	Fatigue/ Mild Fatigue	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N
>55/ C4591001 1204 12041028	GENRL	Injection site pain/ left arm soreness (injection site)#	3	15JAN2021	1/3	1	Yes		NA	R (17JAN2021)	N/N
>55/ C4591001 1204 12041032	GENRL	Feeling hot/ feeling warm post vaccine #2 administration	2	24SEP2020	1/3	1	Yes		NA/TC	R (26SEP2020)	N/N
	MUSC	Pain in extremity/ left arm pain	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1204 12041035	NERV	Headache/ Headache	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1204 12041037	MUSC	Pain in extremity/ arm tenderness moderate, no fevers	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
>55/ C4591001 1204 12041042	GENRL	Injection site pain/ Pain at injection site	1	04SEP2020	1/4	2	Yes		NA/TC	R (07SEP2020)	N/N
	NERV	Dizziness/ Dizziness	2	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/Y
	GENRL	Fatigue/ fatigue	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Pain in extremity/ right arm pain	2	26SEP2020	2/4	1	Yes		NA/TC	R (29SEP2020)	N/N
>55/ C4591001 1204 12041053	MUSC	Arthritis/ Arthritis, first joint of fingers bilateral	2	15JAN2021	109/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001 1204 12041054	GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Pyrexia/ Low grade fever, 101	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C4591001 1204 12041068	GENRL	Injection site pain/ Injection site pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	METAB	Decreased appetite/ loss of appetite	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1204 12041069	MUSC	Pain in extremity/ left arm pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1204 12041104	NERV	Headache/ Headache	1	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ left arm pain (vac#2 injection site)	2	06OCT2020	1/4	1	Yes		NA	R (09OCT2020)	N/N
	NERV	Headache/ headache	2	07OCT2020	2/4	1	Yes		NA/TC	R (10OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1204 12041106	GENRL	Injection site pain/ left arm soreness (vac #2 injection site)	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Pyrexia/ low grade fever, 100.0	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
>55/ C4591001 1204 12041109	GENRL	Injection site pain/ left arm soreness (injection site)#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ Headache#	4	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N
>55/ C4591001 1204 12041115	GASTR	Nausea/ Nausea	1	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Mild soreness at injection site	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ left arm soreness (injection site)#	3	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
>55/ C4591001 1204 12041126	GASTR	Diarrhoea/ non-bloody diarrhea	1	20SEP2020	3/5	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	23SEP2020	6/3	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1204 12041142	GENRL	Injection site pain/ left arm soreness (injection site)#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1204 12041146	GENRL	Injection site pain/ left arm soreness at injection site#	3	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
>55/ C4591001 1204 12041162†	GENRL	Injection site pain/ left arm pain (injection site)	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ Low grade fever 100.6 F	1	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
>55/ C4591001 1204 12041166	MUSC	Myalgia/ Generalized muscle aches	1	26SEP2020	2/4	1	Yes		NA	R (29SEP2020)	N/N
	NERV	Headache/ Headache	1	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
>55/ C4591001 1204 12041169	GENRL	Injection site pain/ Muscle tenderness at injection site	1	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/N
	NERV	Headache/ Headache	1	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1204 12041175	GENRL	Injection site pain/ left arm soreness (injection site)#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Chills/ chills#	3	14JAN2021	2/2	1	Yes		NA/TC	R (15JAN2021)	N/N
		Fatigue/ fatigue#	3	14JAN2021	2/2	1	Yes		NA/TC	R (15JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1204 12041196	GENRL	Injection site pain/ Pain in right arm at injection site	2	29OCT2020	1/4	1	Yes		NA	R (01NOV2020)	N/N
>55/ C4591001 1204 12041212	GENRL	Chills/ Chills	2	31OCT2020	2/3	1	Yes		NA	R (02NOV2020)	N/N
		Pyrexia/ Low grade fever, 101.0	2	31OCT2020	2/3	1	Yes		NA	R (02NOV2020)	N/N
>55/ C4591001 1204 12041213	GENRL	Injection site pain/ Injection site pain (vac 1 site)	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
>55/ C4591001 1204 12041219	GENRL	Pyrexia/ mild fever, body temperature 99.1	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
	VASC	Flushing/ Feeling flushed, generalized	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
		Injection site pain/ Muscle tenderness at injection site	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
	NERV	Headache/ Headache	1	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
	GENRL	Pyrexia/ Low grade fever, 100.5	2	03NOV2020	2/2	2	Yes		NA/TC	R (04NOV2020)	N/N
	NERV	Headache/ Headache	2	03NOV2020	2/2	1	Yes		NA/TC	R (04NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1204 12041229	GENRL	Injection site pain/ left arm soreness (vac#1 injection site)	1	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	04NOV2020	1/2	1	Yes		NA	R (05NOV2020)	N/N
>55/ C4591001 1204 12041245	GENRL	Fatigue/ fatigue#	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
>55/ C4591001 1204 12041254	GENRL	Injection site pain/ left arm soreness (vac#1 injection site)	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N
	NERV	Headache/ Persistent Headache	2	06NOV2020	1/2	2	Yes		NA/TC	R (07NOV2020)	N/N
	GENRL	Injection site pain/ muscle tenderness at injection site	2	08NOV2020	3/6	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Injection site erythema/ erythema at injection site	2	09NOV2020	4/5	1	Yes		NA	R (13NOV2020)	N/N
		Injection site pruritus/ pruritus at injection site	2	09NOV2020	4/5	1	Yes		NA	R (13NOV2020)	N/N
		Injection site swelling/ swelling at injection site	2	09NOV2020	4/5	1	Yes		NA	R (13NOV2020)	N/N
>55/ C4591001 1204 12041266	GENRL	Fatigue/ fatigue	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1204 12041289	NERV	Pyrexia/ felt feverish	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N	
		Headache/ Headache#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N	
>55/ C4591001 1204 12041291	GENRL	Injection site pain/ left arm soreness (injection site)#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N	
	GENRL	Pyrexia/ fever	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N	
>55/ C4591001 1207 12071017	GENRL	Injection site swelling/ SWELLING AT INJECTION SITE (5 CM)#	3	19JAN2021	1/3	1	Yes		NA	R (21JAN2021)	N/N	
	GENRL	Injection site pain/ pain at injection site#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N	
>55/ C4591001 1207 12071019		Injection site swelling/ swelling at injection site (4 cm)#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N	
	MUSC	Arthralgia/ generalized joint pain#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N	
	INFEC	Tooth abscess/ dental abscess	2	03DEC2020	17/5	1	No	O	NA/TC	R (07DEC2020)	N/N	
>55/ C4591001 1207 12071020	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	19JAN2021	1/4	1	Yes		NA	R (22JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ HEADACHE#	3	19JAN2021	1/3	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1207 12071022	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	NERV	Headache/ headache#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1207 12071029	GENRL	Injection site swelling/ swelling at injection site#	3	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ PAIN AT INJECTION SITE#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
		Injection site swelling/ SWELLING AT INJECTION SITE#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN#	4	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001 1207 12071030	GENRL	Fatigue/ fatigue#	2	25FEB2021	1/3	1	Yes		NA	R (27FEB2021)	N/N
>55/ C4591001 1207 12071035	GENRL	Injection site pain/ pain at injection site#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N



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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1207 12071043	MUSC	Arthralgia/ RIGHT HIP PAIN	2	03DEC2020	10/C	1	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	10FEB2021	1/3	2	Yes		NA/TC	R (12FEB2021)	N/N
	NERV	Headache/ headache#	4	10FEB2021	1/3	2	Yes		NA/TC	R (12FEB2021)	N/N
>55/ C4591001 1207 12071055	INFEC	Pneumonia bacterial/ Bacterial Pneumonia#	2	05FEB2021	72/5	4	No	O	NA/W	F (09FEB2021)	Y/N
>55/ C4591001 1207 12071063	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
		Pyrexia/ fever 38.5 C#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
	MUSC	Myalgia/ generalized muscle pain#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
>55/ C4591001 1209 12091012	GENRL	Fatigue/ fatigue#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
		Pyrexia/ fever#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ muscle pain#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001 1209 12091014	INFEC	COVID-19/ COVID-19 Illness	2	18DEC2020	25/6	1	No	O	NA/TC	R (23DEC2020)	Y/N
>55/ C4591001 1213 12131011	GENRL	Chills/ CHILLS#	3	08JAN2021	1/2	2	Yes		NA	R (09JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	29JAN2021	1/2	3	Yes		NA	R (30JAN2021)	N/N
		Injection site pain/ PAIN AT INJECTION SITE#	4	29JAN2021	1/2	3	Yes		NA	R (30JAN2021)	N/N
	MUSC	Arthralgia/ GENERAL JOINT PAIN#	4	29JAN2021	1/2	3	Yes		NA	R (30JAN2021)	N/N
		Myalgia/ MUSCLE PAIN#	4	29JAN2021	1/2	3	Yes		NA	R (30JAN2021)	N/N
	SKIN	Hyperhidrosis/ SWEATING#	4	29JAN2021	1/2	3	Yes		NA	R (30JAN2021)	N/N
>55/ C4591001 1213 12131017	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	07JAN2021	1/1	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	27JAN2021	1/2	2	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1213 12131023	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	05FEB2021	1/6	3	Yes		NA	R (10FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1213 12131024	MUSC	Arthralgia/ JOINT PAIN#	3	06FEB2021	2/4	3	Yes		NA	R (09FEB2021)	N/N
		Myalgia/ MUSCLE PAIN#	3	06FEB2021	2/2	3	Yes		NA	R (07FEB2021)	N/N
	MUSC	Arthralgia/ JOINT PAIN#	4	25FEB2021	1/2	3	Yes		NA	R (26FEB2021)	N/N
		Myalgia/ MUSCLE PAIN#	4	25FEB2021	1/2	3	Yes		NA	R (26FEB2021)	N/N
	GENRL	Chills/ CHILLS#	3	07JAN2021	1/2	2	Yes		NA/TC	R (08JAN2021)	N/N
		Fatigue/ FATIGUE#	3	07JAN2021	1/2	2	Yes		NA/TC	R (08JAN2021)	N/N
>55/ C4591001 1213 12131030		Injection site pain/ PAIN AT INJECTION SITE#	3	07JAN2021	1/1	2	Yes		NA/TC	R (07JAN2021)	N/N
	SKIN	Hyperhidrosis/ SWEATING#	3	07JAN2021	1/2	2	Yes		NA/TC	R (08JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	27JAN2021	1/4	3	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	3	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
		Injection site pain/ PAIN AT INJECTION SITE#	3	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
	GASTR	Diarrhoea/ DIARRHEA#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N
GENRL	Chills/ CHILLS#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1213 12131045	MUSC	Fatigue/ FATIGUE#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N	
		Injection site pain/ PAIN AT INJECTION SITE#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N	
		Myalgia/ MUSCLE PAIN#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N	
		Headache/ HEADACHE#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N	
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	27JAN2021	1/2	2	Yes		NA	R (28JAN2021)	N/N	
	>55/ C4591001 1213 12131047	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	21JAN2021	1/2	3	Yes		NA	R (22JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N	
	>55/ C4591001 1213 12131048	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	25JAN2021	1/2	3	Yes		NA/TC	R (26JAN2021)	N/N	
	NERV	Headache/ HEADACHE#	4	25JAN2021	1/2	3	Yes		NA/TC	R (26JAN2021)	N/N	
>55/ C4591001	VASC	Hypertensive crisis/ Hypertensive crisis	1	24NOV2020	19/2	3	No	O	NA/TC	R (25NOV2020)	Y/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1213 12131049 >55/ C4591001 1214 12141002	GENRL	Chills/ Chill#	3	31DEC2020	1/2	2	Yes		NA	R (01JAN2021)	N/N
	MUSC	Pain in extremity/ Arm Pain#	3	31DEC2020	1/2	2	Yes		NA	R (01JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	19JAN2021	1/2	3	Yes		NA	R (20JAN2021)	N/N
>55/ C4591001 1214 12141006	INFEC	Herpes zoster/ Shingles in the right upper leg#	2	25JAN2021	70/5	1	No	O	NA/TC	R (29JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	24FEB2021	1/3	2	Yes		NA/TC	R (26FEB2021)	N/N
>55/ C4591001 1214 12141021	VASC	Hypertension/ Hypertension	1	18NOV2020	16/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1214 12141026	MUSC	Pain in extremity/ Arm Pain#	3	07JAN2021	1/2	2	Yes		NA	R (08JAN2021)	N/N
	MUSC	Pain in extremity/ Arm Pain#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001 1214 12141032	GENRL	Fatigue/ Fatigue#	4	22JAN2021	2/2	2	Yes		NA/TC	R (23JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1214 12141033	MUSC	Myalgia/ Muscle Pain#	4	22JAN2021	2/2	2	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
>55/ C4591001 1214 12141050	NERV	Headache/ Headache#	4	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
	SKIN	Rash maculo-papular/ Rash Maculo Popular	2	18DEC2020	19/20	1	No	CD	NA/TC	R (06JAN2021)	N/N
>55/ C4591001 1217 12171006	GENRL	Fatigue/ lassitude#	4	26JAN2021	1/3	1	Yes		NA/TC	R (28JAN2021)	N/N
	SKIN	Injection site pain/ Injection pain (arm pain)#	4	26JAN2021	1/3	1	Yes		NA/TC	R (28JAN2021)	N/N
SKIN		Hyperhidrosis/ sweating#	4	26JAN2021	1/3	1	Yes		NA/TC	R (28JAN2021)	N/N
>55/ C4591001 1217 12171007	GENRL	Fatigue/ fatigue#	3	20JAN2021	1/2	1	Yes		NA/TC	R (21JAN2021)	N/N
	GENRL	Injection site pain/ arm pain (injection pain)#	3	20JAN2021	1/2	1	Yes		NA/TC	R (21JAN2021)	N/N
GENRL		Fatigue/ Lassitude#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001	INFEC	Urinary tract infection/ urinary tract infection	2	15JAN2021	59/18	1	No	O	NA/TC	R (01FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1217 12171024 >55/ C4591001	GENRL	Injection site pain/ Arm Pain (Injection pain)#	3	19JAN2021	1/3	1	Yes		NA	R (21JAN2021)	N/N
1217 12171027	GENRL	Chills/ chills#	4	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
		Pyrexia/ 38 C Fever#	4	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
	MUSC	Arthralgia/ joint pain in the ankles#	4	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
>55/ C4591001	GENRL	Fatigue/ Lassitude#	4	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
1217 12171029	MUSC	Arthralgia/ joint pain in the ankles#	4	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
>55/ C4591001	GENRL	Chest pain/ Chest pain#	3	21DEC2020	4/1	1	No	O	NA/TC	R (21DEC2020)	N/N
1218 12181020	INFEC	Labyrinthitis/ Labyrinthitis#	4	18JAN2021	12/3	1	No	O	NA/TC/TCN	R (20JAN2021)	N/N
>55/ C4591001	GASTR	Nausea/ Nausea	2	08DEC2020	1/3	1	Yes		NA	R (10DEC2020)	N/N
1218 12181021	GENRL	Injection site pain/ Pain at injection site (left deltoid)	2	08DEC2020	1/3	1	Yes		NA	R (10DEC2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Pain/ body aches	2	08DEC2020	1/3	1	Yes		NA	R (10DEC2020)	N/N
		Arthralgia/ joint pain - generalized	2	08DEC2020	1/3	1	Yes		NA	R (10DEC2020)	N/N
		Headache/ Headache	2	08DEC2020	1/3	1	Yes		NA	R (10DEC2020)	N/N
>55/ C4591001 1218 12181024	SKIN	Dermatitis contact/ Contact dermatitis#	3	JAN2021	1/C	1	No	O	NA/TC	RG	N/N
	INFEC	Tinea pedis/ Tinea pedis#	3	01FEB2021	14/10	1	No	O	NA/TC	R (10FEB2021)	N/N
>55/ C4591001 1219 12191005	SKIN	Dermatitis contact/ itchy maculopapular rash, anterior neck - suspected contact dermatitis	1	05OCT2020	4/21	1	No	O	NA	R (25OCT2020)	N/N
	MUSC	Neck pain/ neck pain	2	17NOV2020	27/8	1	No	O	NA	R (24NOV2020)	N/N
>55/ C4591001 1219 12191007	NERV	Headache/ headache	2	15DEC2020	49/4	1	No	O	NA	R (18DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	INFEC	Urinary tract infection/ urinary tract infection#	4	01MAR2021	28/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1219 12191008	GENRL	Fatigue/ Fatigue	2	05DEC2020	41/C	1	No	O	NA	N	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1219 12191009	GENRL	Fatigue/ fatigue	2	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
	NERV	Headache/ headache	2	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
>55/ C4591001 1219 12191010	GENRL	Fatigue/ fatigue	2	29OCT2020	3/1	1	Yes		NA	R (29OCT2020)	N/N
	NERV	Headache/ headache	2	29OCT2020	3/1	1	Yes		NA/TC	R (29OCT2020)	N/N
>55/ C4591001 1219 12191011	GENRL	Injection site pain/ injection site soreness only with movement of left arm	1	06OCT2020	1/4	1	Yes		NA	R (09OCT2020)	N/Y
	GENRL	Injection site pain/ soreness at injection site	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/Y
	GENRL	Fatigue/ fatigue#	3	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	3	06JAN2021	1/2	1	Yes		NA/TC	R (07JAN2021)	N/N
	GENRL	Chills/ chills#	3	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
>55/ C4591001 1219 12191012	GENRL	Fatigue/ tiredness	2	01NOV2020	4/20	1	Yes		NA	R (20NOV2020)	N/N
	NERV	Paraesthesia/ intermittent fleeting paresthesias (hands/face)	2	01NOV2020	4/20	1	No	O	NA	R (20NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ injection site pain#	3	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N
>55/ C4591001 1219 12191025	GASTR	Diarrhoea/ diarrhea	2	16NOV2020	1/2	1	Yes		NA/TC	R (17NOV2020)	N/N
	GENRL	Pain/ body aches	2	16NOV2020	1/2	1	Yes		NA/TC	R (17NOV2020)	N/N
>55/ C4591001 1219 12191032	INJ&P	Skin laceration/ laceration right 4th finger from kitchen knife	2	21DEC2020	20/5	1	No	O	NA	R (25DEC2020)	N/N
>55/ C4591001 1219 12191045	NERV	Drug withdrawal headache/ Headache due to caffeine withdrawal	1	12DEC2020	19/3	2	No	O	NA/TC	R (14DEC2020)	N/N
>55/ C4591001 1219 12191060	GENRL	Fatigue/ tiredness#	3	30DEC2020	2/2	1	Yes		NA	R (31DEC2020)	N/N
		Injection site pain/ injection site pain#	3	30DEC2020	2/2	1	Yes		NA	R (31DEC2020)	N/N
>55/ C4591001 1220 12201006	INJ&P	Skin laceration/ Laceration to top of head	2	26NOV2020	22/9	1	No	O	NA/TCN	R (04DEC2020)	N/N
>55/ C4591001 1220 12201014	GENRL	Injection site pain/ soreness in arm at injection site	1	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1220 12201034	GENRL	Pain/ body aches	1	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
		Injection site pain/ soreness at injection site	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N
	GENRL	Pain/ body aches	2	02NOV2020	1/4	1	Yes		NA	R (05NOV2020)	N/N
		Injection site pain/ soreness at injection site#	3	16DEC2020	1/3	1	Yes		NA	R (18DEC2020)	N/Y
	GENRL	Injection site pain/ Soreness at injection site (left deltoid)	2	25NOV2020	2/2	1	Yes		NA	R (26NOV2020)	N/N
		MUSC	Myalgia/ occipital myalgia#	2	03FEB2021	72/C	2	No	O	NA/TC	N
	NERV	Headache/ Headache	2	07DEC2020	1/2	1	Yes		NA	R (08DEC2020)	N/N
	MUSC	Arthralgia/ R elbow pain	1	13DEC2020	14/C	1	No	O	NA	N	N/N
	GENRL	Fatigue/ fatigue	2	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Injection site pain/ Soreness at Injection Site	2	22DEC2020	2/1	1	Yes		NA	R (22DEC2020)	N/N
NERV	Hypoaesthesia/ Right hand fingertip numbness	2	21JAN2021	32/C	1	No	O	NA	N	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1220 12201055	GENRL	Injection site pain/ soreness at injection site	1	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N
	NERV	Headache/ headache#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
>55/ C4591001 1220 12201058	GENRL	Injection site pain/ soreness at injection site#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
>55/ C4591001 1220 12201060	EYE	Lacrimation increased/ watery eyes	1	24NOV2020	1/2	1	Yes		NA/TC	R (25NOV2020)	N/N
	MUSC	Myalgia/ myalgia	1	24NOV2020	1/2	1	Yes		NA/TC	R (25NOV2020)	N/N
	NERV	Headache/ headache	1	24NOV2020	1/2	1	Yes		NA/TC	R (25NOV2020)	N/N
	RESP	Nasal congestion/ nasal congestion	1	24NOV2020	1/2	1	Yes		NA/TC	R (25NOV2020)	N/N
	GENRL	Pain/ Body aches#	2	02MAR2021	2/C	1	Yes		NA	N	N/N
	NERV	Dizziness/ Dizziness#	2	02MAR2021	2/C	1	Yes		NA	N	N/N
		Headache/ headache#	2	02MAR2021	2/C	1	Yes		NA	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1221 12211001	GENRL	Chills/ Chills	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
		Injection site pain/ Injection site tenderness	2	04NOV2020	2/1	1	Yes		NA	R (04NOV2020)	N/N
>55/ C4591001 1221 12211018	INFEC	Oral herpes/ Cold Sore	2	05DEC2020	19/13	1	No	O	NA/TCN	R (17DEC2020)	N/N
>55/ C4591001 1221 12211021	METAB	Decreased appetite/ Loss of appetite	1	30OCT2020	1/2	1	Yes		NA/TCN	R (31OCT2020)	N/N
	NERV	Headache/ Headache	1	30OCT2020	1/3	1	Yes		NA/TCN	R (01NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	1	02NOV2020	4/5	2	Yes		NA	R (06NOV2020)	N/N
>55/ C4591001 1221 12211028	GENRL	Injection site pain/ Injection site pain, Left arm	1	05NOV2020	1/24	2	Yes		NA/TC	R (28NOV2020)	N/N
	SKIN	Pruritus/ Localized pruritis, left scapula, distal end	1	06NOV2020	2/14	1	Yes		NA	R (19NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	24NOV2020	1/5	2	Yes		NA	R (28NOV2020)	N/N
	GENRL	Chills/ Chills	2	25NOV2020	2/1	2	Yes		NA	R (25NOV2020)	N/N
		Fatigue/ Fatigue	2	25NOV2020	2/1	1	Yes		NA	R (25NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1221 12211039	GASTR	Nausea/ Nausea	1	17NOV2020	2/2	1	Yes		NA	R (18NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	1	17NOV2020	2/2	1	Yes		NA	R (18NOV2020)	N/N
		Injection site pain/ Injection site soreness, Right arm	1	17NOV2020	2/2	1	Yes		NA	R (18NOV2020)	N/N
	GENRL	Injection site pain/ Injections site soreness	2	07DEC2020	1/4	1	Yes		NA	R (10DEC2020)	N/N
	GENRL	Pain/ Bodyaches	2	08DEC2020	2/3	1	Yes		NA	R (10DEC2020)	N/N
>55/ C4591001 1221 12211048	GENRL	Swelling face/ Swelling of face#	4	18FEB2021	4/7	2	No	O	NA	R (24FEB2021)	N/N
	SKIN	Erythema/ Redness of face#	4	18FEB2021	4/C	2	No	O	NA	N	N/N
>55/ C4591001 1221 12211052	GENRL	Fatigue/ Fatigue	1	20NOV2020	1/4	2	Yes		NA	R (23NOV2020)	N/N
		Injection site pain/ Injection site pain	1	20NOV2020	1/3	1	Yes		NA	R (22NOV2020)	N/N
	NERV	Headache/ Headache	1	20NOV2020	1/3	2	Yes		NA	R (22NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10DEC2020	1/11	2	Yes		NA	R (20DEC2020)	N/N
		Injection site pain/ Injection site pain	2	10DEC2020	1/4	2	Yes		NA	R (13DEC2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	NERV	Headache/ Headache	2	10DEC2020	1/2	2	Yes		NA	R (11DEC2020)	N/N	
>55/ C4591001 1221 12211061	GENRL	Injection site pain/ Localized site injection soreness	1	25NOV2020	2/3	1	Yes		NA	R (27NOV2020)	N/N	
	SKIN	Rash maculo-papular/ Diffuse erythematous maculopapular rash#	2	17DEC2020	4/15	1	Yes		NA	R (31DEC2020)	N/N	
>55/ C4591001 1221 12211066	INJ&P	Tendon injury/ Right Achilles tendon injury#	3	21FEB2021	18/C	2	No	O	NA/TCN	RG	N/N	
	VASC	Venous thrombosis limb/ Right gastrocnemius vein clot#	4	04MAR2021	7/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1221 12211091	INFEC	Campylobacter infection/ Campylobacter Infection	1	22DEC2020	15/7	2	No	O	NA/TC	RS (28DEC2020)	N/N	
>55/ C4591001 1223 12231009	SKIN	Rash erythematous/ Left shoulder erythematous rash	2	20SEP2020	4/2	1	Yes		NA	R (21SEP2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N	
	NERV	Headache/ headache#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N	
>55/ C4591001 1223 12231011	GENRL	Injection site pain/ Injection Site Soreness	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills	2	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ Fever	2	18SEP2020	2/1	2	Yes		NA	R (18SEP2020)	N/N
	INV	Blood glucose increased/ Glucose Spike (350)	2	18SEP2020	2/5	3	Yes		NA	R (22SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ Headache	2	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1223 12231017	GENRL	Fatigue/ fatigue#	3	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
>55/ C4591001 1223 12231019	GENRL	Injection site erythema/ redness at injection site#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
		Injection site pain/ injection site pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	MUSC	Pain in extremity/ ARM SORENESS#	4	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
>55/ C4591001 1223 12231020	MUSC	Pain in extremity/ Right arm soreness	2	18SEP2020	1/2	1	Yes		NA/TC	R (19SEP2020)	N/N
>55/ C4591001 1223 12231021	GENRL	Injection site pain/ pain at injection site#	4	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1223 12231029	GENRL	Injection site pain/ soreness at injection site	1	29AUG2020	1/2	1	Yes		NA	R (30AUG2020)	N/N
>55/ C4591001 1223 12231032	INFEC	Urinary tract infection/ urinary tract infection	2	07NOV2020	52/37	2	No	O	NA/TC/TCN	R (13DEC2020)	N/N
	GENRL	Pyrexia/ fever 101.0 F#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
	MUSC	Myalgia/ generalized muscle aches#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
	NERV	Headache/ headache intermittent#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
>55/ C4591001 1223 12231037	SURG	Carpal tunnel decompression/ left ulner carpel tunnel surgery	2	29SEP2020	9/1	1	No	O	NA/TCN	R (29SEP2020)	N/N
>55/ C4591001 1223 12231038	GENRL	Injection site pain/ injection site pain#	3	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
>55/ C4591001 1223 12231039	GENRL	Injection site pain/ soreness at injection site#	3	25JAN2021	1/33	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
	GENRL	Pyrexia/ Fever 100.3 F#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1223 12231040	NERV	Headache/ Headache intermittent#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	MUSC	Limb discomfort/ arm discomfort	2	22SEP2020	2/4	1	Yes		NA/TC	R (25SEP2020)	N/N
	MUSC	Neck pain/ neck pain	2	22SEP2020	2/12	2	Yes		NA/TC	R (03OCT2020)	N/N
>55/ C4591001 1223 12231043	MUSC	Arthralgia/ joint pain	2	23SEP2020	3/4	1	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	22JAN2021	1/4	1	Yes		NA	R (25JAN2021)	N/N
>55/ C4591001 1223 12231049	GENRL	Injection site pain/ SORE (Pain) SHOULDER at injection site#	4	11FEB2021	1/5	1	Yes		NA	R (15FEB2021)	N/Y
	MUSC	Arthralgia/ joint pain	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	NERV	Dizziness/ lightheaded	2	22SEP2020	2/1	2	Yes		NA	R (22SEP2020)	N/N
>55/ C4591001 1223 12231056	NERV	Headache/ headache	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1223 12231058	RESP	Dyspnoea/ Shortness of breath	2	03FEB2021	134/10	2	No	O	NA/TC/TCN	RS (12FEB2021)	Y/N	
	GENRL	Injection site pain/ injection site pain#	3	02MAR2021	1/3	1	Yes		NA	R (04MAR2021)	N/N	
	GENRL	Fatigue/ fatigue#	3	03MAR2021	2/2	2	Yes		NA	R (04MAR2021)	N/N	
>55/ C4591001 1223 12231065	MUSC	Myalgia/ Myalgia	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N	
		Pain in extremity/ Left arm pain	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N	
>55/ C4591001 1223 12231078	GENRL	Pyrexia/ fever 99.9F#	4	04FEB2021	2/3	1	Yes		NA	R (06FEB2021)	N/N	
>55/ C4591001 1223 12231085	GENRL	Injection site pain/ soreness at injection site#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N	
	GENRL	Injection site pain/ injection site pain#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N	
	MUSC	Arthralgia/ Arthralgia Neck#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N	
>55/ C4591001 1223 12231091	GENRL	Pyrexia/ fever	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Pain in extremity/ sore left arm	2	21SEP2020	1/3	2	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C4591001 1223 12231096	GENRL	Injection site pain/ soreness at injection site#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1223 12231097	GASTR	Constipation/ intermittent constipation	2	28OCT2020	34/2	1	No	O	NA/TC	R (29OCT2020)	N/N
>55/ C4591001 1223 12231103	GENRL	Fatigue/ fatigue#	4	09JAN2021	1/1	1	Yes		NA	R (09JAN2021)	N/N
	MUSC	Pain in extremity/ arm soreness#	4	09JAN2021	1/1	1	Yes		NA/TC	R (09JAN2021)	N/N
	GENRL	Pain/ aches#	4	10JAN2021	2/1	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Pyrexia/ fever#	4	11JAN2021	3/1	1	Yes		NA/TC	R (11JAN2021)	N/N
>55/ C4591001 1223 12231104	GENRL	Injection site pain/ arm pain injection site pain#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1223 12231107	MUSC	Pain in extremity/ arm soreness#	4	26FEB2021	1/4	1	Yes		NA/TC	R (01MAR2021)	N/N
	GENRL	Fatigue/ fatigue#	4	27FEB2021	2/2	1	Yes		NA/TC	R (28FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1223 12231108	GENRL	Injection site pain/ pain in injection site#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	07JAN2021	2/3	1	Yes		NA	R (09JAN2021)	N/N
>55/ C4591001 1223 12231123	GENRL	Injection site pain/ injection site soreness	2	29SEP2020	1/4	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1223 12231124	GENRL	Injection site pain/ injection site pain#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	MUSC	Pain in extremity/ arm pain#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1223 12231125	GENRL	Injection site pain/ injection site pain#	3	27FEB2021	2/1	1	Yes		NA	R (27FEB2021)	N/N
>55/ C4591001 1223 12231136	GENRL	Asthenia/ generalized weakness	2	01OCT2020	1/2	2	Yes		NA	R (02OCT2020)	N/N
		Chills/ chills	2	01OCT2020	1/2	2	Yes		NA	R (02OCT2020)	N/N
	MUSC	Myalgia/ muscle aches	2	01OCT2020	1/2	2	Yes		NA	R (02OCT2020)	N/N
	NERV	Headache/ headaches	2	01OCT2020	1/2	2	Yes		NA/TC	R (02OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	INFEC	Oral herpes/ herpes lower lip lesion	2	28OCT2020	28/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1223 12231138	GENRL	Injection site pain/ injection site pain#	3	04MAR2021	2/2	1	Yes		NA/TC	R (05MAR2021)	N/N	
>55/ C4591001 1223 12231140	GASTR	Diarrhoea/ diarrhea	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N	
	GASTR	Nausea/ nausea#	4	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N	
	GENRL	Injection site pain/ pain at injection site#	4	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N	
>55/ C4591001 1223 12231142	MUSC	Pain in extremity/ left arm soreness	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
>55/ C4591001 1223 12231149	GENRL	Fatigue/ Fatigue#	3	04FEB2021	21/4	1	Yes		NA	R (07FEB2021)	N/N	
		Injection site pain/ injection site pain#	3	04FEB2021	21/4	1	Yes		NA	R (07FEB2021)	N/N	
>55/ C4591001 1223 12231156	MUSC	Pain in extremity/ left sore arm	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N	
>55/ C4591001	GENRL	Injection site pain/ injection site pain#	4	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1223 12231158 >55/ C4591001	NEOPL	Adenocarcinoma pancreas/ Pancreatic Adenocarcinoma	2	05NOV2020	36/C	3	No	O	NA/TC/TCN	N	Y/N
1223 12231159	GASTR	Enterocolitis/ Enterocolitis	2	15JAN2021	107/C	3	No	CD	NA/TC	N	Y/N
>55/ C4591001	INFEC	Diverticulitis/ progression of diverticulitis	1	29SEP2020	14/C	3	No	O	NA/TC	RG	Y/N
1223 12231182	INFEC	Abscess intestinal/ Pericolonic Abscess	2	13OCT2020	5/C	4	No	O	NA/TC/TCN	N	Y/N
>55/ C4591001	GENRL	Pyrexia/ fever	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
1223 12231193	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
1223 12231194	GENRL	Injection site pain/ injection site pain#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
>55/ C4591001	NERV	Headache/ headache#	4	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
1223 12231198	GENRL	Fatigue/ fatigue#	3	28FEB2021	4/2	1	Yes		NA	R (01MAR2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1223 12231209 >55/ C4591001	MUSC	Arthralgia/ left sided shoulder pain	1	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N
1223 12231227	MUSC	Myalgia/ myalgia	1	29OCT2020	23/2	1	Yes		NA	R (30OCT2020)	N/N
		Pain in extremity/ localized arm pain	2	29OCT2020	1/2	2	Yes		NA/TC	R (30OCT2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ injection site pain#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
1223 12231228 >55/ C4591001	MUSC	Pain in extremity/ right arm pain	2	04NOV2020	2/1	1	Yes		NA	R (04NOV2020)	N/N
1223 12231235	GENRL	Chills/ chills#	3	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N
		Pyrexia/ fever#	3	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	MUSC	Arthralgia/ knee joint ache#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ soreness at injection site#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
1223 12231255											



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ myalgias#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	GENRL	Chills/ chills#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
		Pyrexia/ low grade fever#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
>55/ C4591001 1223 12231261	MUSC	Pain in extremity/ arm soreness#	3	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
>55/ C4591001 1223 12231262	GENRL	Fatigue/ fatigue*		21OCT2020	1/2	2	Yes		NA	R (22OCT2020)	N/N
	MUSC	Pain in extremity/ arm soreness	1	22OCT2020	2/3	2	Yes		NA/TC	R (24OCT2020)	N/N
	GENRL	Chills/ chills	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N
	NERV	Headache/ headache	2	10NOV2020	2/1	1	Yes		NA/TC	R (10NOV2020)	N/N
>55/ C4591001 1223 12231266	GENRL	Chills/ chills	1	23OCT2020	1/2	2	Yes		NA	R (24OCT2020)	N/N
	MUSC	Myalgia/ myalgia	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
		Pain in extremity/ left arm soreness	1	23OCT2020	1/2	2	Yes		NA/TC	R (24OCT2020)	N/N
	NERV	Headache/ headache	1	24OCT2020	2/1	2	Yes		NA	R (24OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	NERV	Migraine/ migraines	2	23NOV2020	11/2	1	Yes		NA/TC	R (24NOV2020)	N/N	
>55/ C4591001 1224 12241004	GASTR	Diarrhoea/ Diarrhea	2	25SEP2020	26/1	1	No	O	NA	R (25SEP2020)	N/N	
>55/ C4591001 1224 12241012	INJ&P	Ankle fracture/ Lateral Malleolus Fracture - left ankle	1	19AUG2020	7/168	2	No	O	NA/TC/TCN	R (02FEB2021)	N/N	
		Fall/ FALL	1	19AUG2020	7/1	2	No	O	NA	RS (19AUG2020)	N/N	
	MUSC	Muscular weakness/ Diffuse weakness in extremities (Bilateral legs and Left arm)	1	19AUG2020	7/7	2	No	O	NA	RS (25AUG2020)	N/N	
>55/ C4591001 1224 12241020	NEOPL	Lipoma/ Worsening of benign fatty tumor#	3	22JAN2021	5/1	1	No	O	NA/TCN	R (22JAN2021)	N/N	
>55/ C4591001 1224 12241030	VASC	Hypertension/ Worsening of Hypertension	1	02SEP2020	17/C	1	No	O	NA/TC	N	N/N	
	GENRL	Chills/ Chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
		Pain/ Body aches	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
		Pyrexia/ Fever (99.5)	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
	METAB	Decreased appetite/ Loss of Appetite	2	10SEP2020	2/11	1	Yes		NA	R (20SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1224 12241033	MUSC	Arthralgia/ Hip Pain - Right	2	14SEP2020	6/11	1	No	O	NA	R (24SEP2020)	N/N	
	NERV	Lethargy/ Lethargy	2	14SEP2020	6/11	1	No	O	NA	R (24SEP2020)	N/N	
>55/ C4591001 1224 12241035	INFEC	Demodicidosis/ Demodex parasitic infestation - bilateral eyes#	4	18FEB2021	24/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1224 12241036	GENRL	Drug withdrawal syndrome/ Diarrhea - Oxycontin Withdrawal	1	04SEP2020	18/7	1	No	O	NA	R (10SEP2020)	N/N	
		Drug withdrawal syndrome/ Nausea - Oxycontin Withdrawal	1	04SEP2020	18/7	1	No	O	NA	R (10SEP2020)	N/N	
>55/ C4591001 1224 12241039	MUSC	Myalgia/ Soreness - Left Deltoid	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
	GASTR	Nausea/ Nausea	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N	
	GENRL	Chills/ Chills	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N	
		Pyrexia/ Fever - 99.5	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N	
	INJ&P	Joint dislocation/ Right hip dislocation	2	06OCT2020	29/1	2	No	O	NA/TC/TCN	R (06OCT2020)	N/N	
	MUSC	Osteoarthritis/ Chronic Degenerative Changes in Left Hip	2	06OCT2020	29/C	1	No	O	NA	N	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Osteoarthritis/ Chronic Degenerative Changes in Pubic Symphyses	2	06OCT2020	29/C	1	No	O	NA	N	N/N
		Spinal osteoarthritis/ Chronic Degenerative Changes in bilateral sacro iliac joints	2	06OCT2020	29/C	1	No	O	NA	N	N/N
>55/ C4591001 1224 12241042	GENRL	Injection site pruritus/ Pruritus around injection site	2	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ Headache	2	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
>55/ C4591001 1224 12241045	GASTR	Abdominal pain upper/ Stomach Cramps	2	28SEP2020	20/3	1	No	O	NA	R (30SEP2020)	N/N
	GENRL	Pyrexia/ Low Grade Fever	2	29SEP2020	21/2	1	No	O	NA	R (30SEP2020)	N/N
>55/ C4591001 1224 12241054	RENAL	Nephrolithiasis/ Kidney Stone	2	31DEC2020	113/8	1	No	O	NA/TC	R (07JAN2021)	N/N
>55/ C4591001 1224 12241064	INFEC	Osteomyelitis/ Osteomyelitis#	3	08FEB2021	20/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1224 12241070	MUSC	Arthralgia/ Hip Pain - right side	1	27AUG2020	4/4	1	No	O	NA	R (30AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1224 12241080	SKIN	Rash/ Rash - front and back torso	2	01JAN2021	109/32	1	No	CD	NA/TC	R (01FEB2021)	N/N	
	RENAL	Pollakiuria/ Urinary Frequency#	4	15FEB2021	13/C	2	No	O	NA	N	N/N	
>55/ C4591001 1224 12241082	INJ&P	Ligament rupture/ Medial Collateral Ligament Tear	2	28SEP2020	7/2	2	No	O	NA/TCN	R (29SEP2020)	N/N	
		Ligament rupture/ Torn Anterior Cruciate Ligament - Left	2	28SEP2020	7/2	2	No	O	NA/TC/TCN	R (29SEP2020)	N/N	
		Tibia fracture/ Medial Tibial Plateau Fracture	2	28SEP2020	7/2	2	No	O	NA/TCN	R (29SEP2020)	N/N	
>55/ C4591001 1224 12241089	BLOOD	Anaemia/ Anemia	2	20OCT2020	34/C	1	No	O	NA/TC	N	N/N	
	GENRL	Pyrexia/ Recurrent Intermittent Fever (99.9-100.4)#	4	02FEB2021	1/C	1	Yes		NA	N	N/N	
>55/ C4591001 1224 12241097	GASTR	Gastroesophageal reflux disease/ Gastroesophageal Reflux Disease	2	14DEC2020	89/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1224 12241106	VASC	Hypertension/ Worsening of Hypertension	2	02OCT2020	11/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001	INFEC	Herpes zoster/ Shingles	2	17OCT2020	27/C	2	No	O	NA/TC	N	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1224 12241107 >55/ C4591001 1224 12241109	EYE	Eye pain/ Bilateral eye pain#	4	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
1224 12241109 >55/ C4591001 1224 12241112	NERV	Headache/ Frontal headache#	4	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
1224 12241112 >55/ C4591001 1224 12241120	NERV	Dysgeusia/ Worsening of Copper Taste (in mouth)	2	21SEP2020	1/C	1	Yes		NA	N	N/N
1224 12241120 >55/ C4591001 1224 12241122	CARD	Atrial flutter/ Atrial Flutter	2	25SEP2020	5/1	2	No	O	NA	R (25SEP2020)	N/N
1224 12241122 >55/ C4591001 1224 12241122	MUSC	Myalgia/ Left deltoid soreness#	4	01FEB2021	1/18	1	No	O	NA	R (18FEB2021)	N/N
1224 12241122 >55/ C4591001 1224 12241122	INFEC	Urinary tract infection/ Urinary Tract Infection#	4	15FEB2021	15/15	2	No	O	NA/TC	R (01MAR2021)	N/N
1224 12241122 >55/ C4591001 1224 12241122	GENRL	Pyrexia/ Low Grade Fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
1224 12241122 >55/ C4591001 1224 12241122	MUSC	Myalgia/ Muscle Soreness	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
1224 12241122 >55/ C4591001 1224 12241122	NERV	Lethargy/ Lethargy	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
1224 12241122 >55/ C4591001 1224 12241122	NERV	Sinus headache/ Sinus Headache	2	24SEP2020	3/2	2	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1224 12241125	GENRL	Pyrexia/ Fever	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Lethargy/ Lethargy	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1224 12241127	INJ&P	Humerus fracture/ Broken Left Humerus#	2	17FEB2021	148/C	2	No	O	NA/TC/TCN	N	N/N
>55/ C4591001 1224 12241154	EYE	Vision blurred/ Blurry Vision	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Chills/ Cold Chills	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Pain/ Body Aches	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	2/2	3	Yes		NA/TC	R (01OCT2020)	N/N
	NERV	Lethargy/ Lethargy	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
	VASC	Flushing/ Flushed	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1226 12261023	GENRL	Pain/ Body pain#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001	NERV	Dizziness/ dizziness	2	01OCT2020	36/1	2	No	O	NA/TC	R (01OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261028	GENRL	Injection site pain/ Pain at the injection site#	3	29JAN2021	2/2	2	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	19FEB2021	2/5	1	Yes		NA/TC	R (23FEB2021)	N/N
		Pyrexia/ Fever (38 C)#	4	19FEB2021	2/1	1	Yes		NA/TC	R (19FEB2021)	N/N
>55/ C4591001 1226 12261034	VASC	Hypertension/ Worsening of systemic arterial hypertension	2	22OCT2020	57/98	3	No	O	NA/TC	R (27JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	30JAN2021	3/11	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1226 12261039	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	1/6	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1226 12261046	GENRL	Injection site pain/ Pain at the injection site#	3	03FEB2021	2/1	1	Yes		NA/TC	R (03FEB2021)	N/N
>55/ C4591001 1226 12261053	GENRL	Injection site pain/ Pain at the injection site#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	15FEB2021	1/2	1	Yes		NA/TC	R (16FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1226 12261062	NERV	Injection site pain/ pain at the injection site#	4	15FEB2021	1/2	1	Yes		NA/TC	R (16FEB2021)	N/N
		Headache/ Headache	1	17AUG2020	8/1	1	Yes		NA/TC	R (17AUG2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	10SEP2020	11/2	1	No	O	NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	29JAN2021	1/1	1	Yes		NA/TC	R (29JAN2021)	N/N
	NERV	Headache/ Headache#	3	30JAN2021	2/1	1	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N
>55/ C4591001 1226 12261077	MUSC	Myalgia/ Myalgia#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N
	RESP	Oropharyngeal discomfort/ Throat discomfort	2	22OCT2020	53/3	1	No	O	NA/TC	R (24OCT2020)	N/N
>55/ C4591001 1226 12261095	GENRL	Injection site pain/ pain at the injection site#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
	MUSC	Myalgia/ generalized myalgia#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
>55/ C4591001 1226 12261098	MUSC	Myalgia/ Myalgia#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Pain at te injection site#	4	20FEB2021	2/1	1	Yes		NA	R (20FEB2021)	N/N
>55/ C4591001 1226 12261131	INV	Body temperature increased/ Increased body temperature 37.6 C#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
>55/ C4591001 1226 12261141	GENRL	Injection site pain/ Pain at the injection site#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
>55/ C4591001 1226 12261142	GENRL	Injection site pain/ Pain at injection site#	3	30JAN2021	1/2	1	Yes		NA/TC	R (31JAN2021)	N/N
>55/ C4591001 1226 12261143	GENRL	Injection site pain/ Pain at injection site#	3	31JAN2021	2/1	2	Yes		NA/TC	R (31JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	31JAN2021	2/1	2	Yes		NA/TC	R (31JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	23FEB2021	2/2	1	Yes		NA/TC	R (24FEB2021)	N/N
		Pain/ body pain#	4	23FEB2021	2/2	1	Yes		NA/TC	R (24FEB2021)	N/N
>55/ C4591001 1226 12261145	RESP	Rhinorrhoea/ runny nose	2	03OCT2020	30/8	1	No	O	NA/TC	R (10OCT2020)	N/N
>55/ C4591001	NERV	Headache/ Headache	2	17SEP2020	15/1	1	No	O	NA/TC	R (17SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261169	GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1226 12261187	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	2/3	1	Yes		NA	R (01FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
>55/ C4591001 1226 12261195	NERV	Headache/ Headache	2	05SEP2020	2/1	2	Yes		NA/TC	R (05SEP2020)	N/N
	MUSC	Muscular weakness/ Lower limbs weakness	2	13OCT2020	40/1	1	No	O	NA/TC	R (13OCT2020)	N/N
	NERV	Tremor/ Lower limbs tremor	2	13OCT2020	40/1	1	No	O	NA/TC	R (13OCT2020)	N/N
>55/ C4591001 1226 12261209	GASTR	Nausea/ Nausea	2	09SEP2020	2/1	2	Yes		NA/TC	R (09SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	09SEP2020	2/1	2	Yes		NA/TC	R (09SEP2020)	N/N
	NERV	Headache/ Headache	2	09SEP2020	2/1	2	Yes		NA/TC	R (09SEP2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ Pain at the injection site#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12261211	GENRL	Pyrexia/ Fever 38.5 C#	4	15FEB2021	1/2	1	Yes		NA/TC	R (16FEB2021)	N/N	
>55/ C4591001 1226 12261212	GENRL	Fatigue/ tiredness#	4	15FEB2021	1/3	1	Yes		NA/TC	R (17FEB2021)	N/N	
		Injection site pain/ pain at the injection site#	4	15FEB2021	1/3	1	Yes		NA/TC	R (17FEB2021)	N/N	
>55/ C4591001 1226 12261219	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	2/11	1	Yes		NA	R (09FEB2021)	N/N	
>55/ C4591001 1226 12261221	GENRL	Injection site pain/ pain at the injection site#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N	
	NERV	Headache/ headache#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N	
>55/ C4591001 1226 12261222	GASTR	Diarrhoea/ Diarrhea	2	14SEP2020	7/2	1	Yes		NA	R (15SEP2020)	N/N	
>55/ C4591001 1226 12261224	METAB	Dyslipidaemia/ Dyslipidemia	2	15JAN2021	130/C	1	No	O	NA/TC	RG	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Vitamin D deficiency/ Vitamin D deficiency	2	15JAN2021	130/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1226 12261253	INFEC	Conjunctivitis/ conjunctivitis#	3	03FEB2021	2/2	1	Yes		NA/TC	R (04FEB2021)	N/N
>55/ C4591001 1226 12261281	GENRL	Fatigue/ Fatigue	2	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1226 12261283	GASTR	Abdominal pain upper/ stomachache	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Chills/ chills	2	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
		Fatigue/ fatigue	2	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
	GASTR	Toothache/ toothache	2	03OCT2020	24/8	1	No	O	NA/TC	R (10OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	28JAN2021	1/1	1	Yes		NA	R (28JAN2021)	N/N
	NERV	Somnolence/ Somnolence#	3	28JAN2021	1/1	1	Yes		NA	R (28JAN2021)	N/N
	INV	Body temperature increased/ Increased body temperature 37.5 C#	4	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ Pain at injection site	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261286 >55/ C4591001 1226 12261297	NERV	Headache/ Headache	1	24AUG2020	6/1	2	Yes		NA/TC	R (24AUG2020)	N/N
	GASTR	Nausea/ Nausea#	3	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
	NERV	Headache/ Headache#	3	30JAN2021	2/1	1	Yes		NA/TC	R (30JAN2021)	N/N
>55/ C4591001 1226 12261310	GENRL	Injection site swelling/ Swelling at injection site#	3	03FEB2021	1/1	2	Yes		NA/TCN	R (03FEB2021)	N/Y
>55/ C4591001 1226 12261316	GENRL	Pyrexia/ Fever	1	21AUG2020	2/1	2	Yes		NA/TC	R (21AUG2020)	N/N
	NERV	Headache/ Headache	1	21AUG2020	2/1	2	Yes		NA/TC	R (21AUG2020)	N/N
	GENRL	Pyrexia/ Fever (38.8 C)	2	11SEP2020	1/2	1	Yes		NA/TC/TCN	R (12SEP2020)	N/N
	NERV	Headache/ Headache	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
>55/ C4591001 1226 12261317	GENRL	Injection site pain/ Pain at injection site	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1226 12261320	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N
>55/ C4591001 1226 12261329	GASTR	Diarrhoea/ diarrhea	2	12SEP2020	2/3	2	Yes		NA	R (14SEP2020)	N/N
>55/ C4591001 1226 12261333	GENRL	Injection site pain/ Pain at injection site#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N
>55/ C4591001 1226 12261334	EAR	Ear discomfort/ Feeling of stuffiness in the left ear#	3	23JAN2021	2/8	1	Yes		NA/TC	R (30JAN2021)	N/N
		Hypoacusis/ Hypoacusia#	3	23JAN2021	2/8	1	Yes		NA/TC	R (30JAN2021)	N/N
>55/ C4591001 1226 12261335	GENRL	Chills/ chills	2	10SEP2020	1/4	2	Yes		NA	R (13SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	10SEP2020	1/4	2	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ headache	2	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1226 12261342	GENRL	Chills/ Chills	2	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N
>55/ C4591001 1226 12261366	GENRL	Fatigue/ Fatigue	2	09SEP2020	1/3	2	Yes		NA/TC	R (11SEP2020)	N/N
		Injection site pain/ pain at injectin site	2	09SEP2020	1/3	2	Yes		NA/TC	R (11SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
	NERV	Headache/ headache	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
	INFEC	Helicobacter gastritis/ Helicobacter pylori gastric infection#	2	30JAN2021	144/30	2	No	O	NA/TC	R (28FEB2021)	N/N
>55/ C4591001 1226 12261367	GENRL	Injection site pain/ pain at the injection site#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/Y
>55/ C4591001 1226 12261368	NERV	Headache/ headache	1	22AUG2020	2/1	1	Yes		NA/TC	R (22AUG2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
>55/ C4591001 1226 12261370	EYE	Iritis/ left eye iritis	1	01SEP2020	12/15	1	No	O	NA/TC	R (15SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Pain at injection site#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
	NERV	Somnolence/ Somnolence#	4	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1226 12261371	GENRL	Injection site pain/ pain at injection site	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N
	MUSC	Myalgia/ generalized muscle pain	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	10SEP2020	1/2	2	Yes		NA/TC	R (11SEP2020)	N/N
	MUSC	Arthralgia/ joint pain	2	10SEP2020	1/2	2	Yes		NA/TC	R (11SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	10SEP2020	1/2	2	Yes		NA/TC	R (11SEP2020)	N/N
>55/ C4591001 1226 12261378	INFEC	Urinary tract infection/ Urinary tract infection#	2	24JAN2021	133/C	1	No	O	NA/TC	RG	N/N
	GENRL	Chills/ Chills#	3	25JAN2021	1/10	1	Yes		NA/TC	R (03FEB2021)	N/N
	GENRL	Pyrexia/ Fever (38.5 C)#	3	25JAN2021	1/10	1	Yes		NA/TC	R (03FEB2021)	N/N
>55/ C4591001 1226 12261381	GENRL	Injection site pain/ Pain at injection site	1	25AUG2020	2/4	1	Yes		NA	R (28AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1226 12261388	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1226 12261398	GENRL	Injection site pain/ Pain at injection site	1	26AUG2020	2/3	1	Yes		NA	R (28AUG2020)	N/N
>55/ C4591001 1226 12261402	GENRL	Injection site pain/ pain at the injection site#	3	23JAN2021	1/3	2	Yes		NA	R (25JAN2021)	N/N
	GENRL	Pain/ body pain#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1226 12261419	GENRL	Pyrexia/ Fever 38 C	2	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
	MUSC	Arthralgia/ Joint pain	2	17SEP2020	2/3	1	Yes		NA/TC	R (19SEP2020)	N/N
		Myalgia/ Muscle pain	2	17SEP2020	2/3	1	Yes		NA/TC	R (19SEP2020)	N/N
>55/ C4591001 1226 12261461	GENRL	Injection site pain/ pain at the injection site#	3	30JAN2021	1/3	1	Yes		NA	R (01FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	20FEB2021	1/3	2	Yes		NA	R (22FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	21FEB2021	2/2	2	Yes		NA	R (22FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1226 12261462	INV	Body temperature increased/ increased of body temperature (37.2C)#	4	21FEB2021	2/2	2	Yes		NA/TC	R (22FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	21FEB2021	2/2	2	Yes		NA	R (22FEB2021)	N/N
	NERV	Headache/ headache#	4	21FEB2021	2/2	2	Yes		NA	R (22FEB2021)	N/N
	INFEC	Dental fistula/ dental fistula	2	OCT2020	13/	2	No	O	NA	R (16NOV2020)	N/N
	RESP	Sinus disorder/ Acute sinusopathy	2	20OCT2020	32/28	2	No	O	NA/TC	R (16NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	20SEP2020	2/1	2	Yes		NA/TC	R (20SEP2020)	N/N
	NERV	Headache/ Headache	2	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
	INFEC	Appendicitis/ Appendicitis	2	12JAN2021	116/10	4	No	O	NA/TC/TCN	R (21JAN2021)	Y/N
	GENRL	Fatigue/ fatigue	2	16SEP2020	2/3	2	Yes		NA/TC	R (18SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1226 12261499	GENRL	Fatigue/ Tiredness	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N
>55/ C4591001 1226 12261510	GENRL	Injection site pain/ Pain at injection site*		01SEP2020	1/4	1	Yes		NA	R (04SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
>55/ C4591001 1226 12261513	GENRL	Injection site pain/ pain at the injection site#	3	04FEB2021	1/2	1	Yes		NA/TC	R (05FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	05FEB2021	2/1	1	Yes		NA/TC	R (05FEB2021)	N/N
>55/ C4591001 1226 12261523	GENRL	Injection site pain/ Pain at the injection site	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	INFEC	Urinary tract infection/ urinary tract infection	2	03NOV2020	42/8	1	No	O	NA/TC	R (10NOV2020)	N/N
	METAB	Hypoglycaemia/ hypoglycemia	2	03NOV2020	42/1	3	No	O	NA/TC	R (03NOV2020)	N/N
>55/ C4591001 1226 12261539	GENRL	Pyrexia/ Fever 38.6 C	2	26SEP2020	2/3	2	Yes		NA/TC	R (28SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1226 12261550	MUSC	Myalgia/ Muscle pain	2	26SEP2020	2/3	2	Yes		NA/TC	R (28SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/4	1	Yes		NA/TC	R (27SEP2020)	N/N	
		Pain/ Body pain	2	24SEP2020	1/4	1	Yes		NA/TC	R (27SEP2020)	N/N	
>55/ C4591001 1226 12261552	GENRL	Pyrexia/ fever (38.5 C)	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N	
	GENRL	Fatigue/ Tiredness	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N	
>55/ C4591001 1226 12261556	GENRL	Pyrexia/ Fever (37.5 C)	1	06SEP2020	2/1	2	Yes		NA/TC	R (06SEP2020)	N/N	
>55/ C4591001 1226 12261565	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/4	1	Yes		NA/TC	R (21FEB2021)	N/N	
>55/ C4591001 1226 12261605		Injection site pain/ Pain at the injection site#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N	
		Pyrexia/ Fever 38 C#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N	
	NERV	Headache/ Headache	1	08SEP2020	2/3	1	Yes		NA	R (10SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	1/4	2	Yes		NA	R (08FEB2021)	N/N
>55/ C4591001 1226 12261617	GENRL	Injection site pain/ Pain at injection site	1	08SEP2020	2/2	1	Yes		NA	R (09SEP2020)	N/N
>55/ C4591001 1226 12261638	NERV	Headache/ Headache	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
>55/ C4591001 1226 12261658	GENRL	Fatigue/ fatigue#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
>55/ C4591001 1226 12261662	GENRL	Injection site pain/ pain at injection site	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Injection site pain/ pain at injection site	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1226 12261671	GENRL	Injection site pain/ Pain at injection site	1	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Pain at the injection site	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
>55/ C4591001 1226 12261700	GENRL	Injection site pain/ Pain at injection site	1	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
>55/ C4591001 1226 12261708	GENRL	Injection site pain/ Pain at the injection site#	3	07FEB2021	2/2	2	Yes		NA	R (08FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	3	07FEB2021	2/2	2	Yes		NA	R (08FEB2021)	N/N
>55/ C4591001 1226 12261727	GENRL	Injection site pain/ Pain at the injection site#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
>55/ C4591001 1226 12261735	GENRL	Injection site pain/ Pain at the injection site	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
>55/ C4591001 1226 12261755	NERV	Headache/ Headache	2	23OCT2020	18/3	2	No	O	NA/TC	R (25OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	29JAN2021	1/4	2	Yes		NA/TC	R (01FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1226 12261774	GENRL	Pyrexia/ Fever (38 C)	2	07OCT2020	1/2	2	Yes		NA/TC	R (08OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	2	07OCT2020	1/2	2	Yes		NA/TC	R (08OCT2020)	N/N
>55/ C4591001 1226 12261783	GENRL	Asthenia/ weakness	2	09OCT2020	3/1	1	Yes		NA	R (09OCT2020)	N/N
>55/ C4591001 1226 12261786	GENRL	Injection site pain/ Pain at the injection site	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	08OCT2020	2/1	2	Yes		NA/TC	R (08OCT2020)	N/N
	SKIN	Papule/ Papules on abdomen	2	10OCT2020	4/4	1	Yes		NA/TC	R (13OCT2020)	N/N
>55/ C4591001 1226 12261793	GENRL	Injection site pain/ Pain at the injection site#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
>55/ C4591001 1226 12261814	MUSC	Back pain/ Left low back pain	2	05JAN2021	90/8	2	No	O	NA/TC	R (12JAN2021)	N/N
>55/ C4591001 1226 12261816	GENRL	Injection site erythema/ Erythema at injection site	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Injection site oedema/ Edema at injection site	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
		Injection site pain/ Pain at injection	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Pyrexia/ fever (38.4C)	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
	GASTR	Toothache/ Toothache	2	19OCT2020	12/7	1	No	O	NA/TC	R (25OCT2020)	N/N
>55/ C4591001 1226 12261822	GENRL	Injection site pain/ Pain at injection site	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
>55/ C4591001 1226 12261825	GENRL	Injection site pain/ pain at injection site	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
>55/ C4591001 1226 12261829	GENRL	Injection site pain/ pain at the injection site#	3	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1226 12261837	INFEC	Urinary tract infection/ Urinary tract infection	2	16OCT2020	8/4	2	No	O	NA/TC	R (19OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	06FEB2021	1/3	2	Yes		NA/TC	R (08FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	06FEB2021	1/3	2	Yes		NA/TC	R (08FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1226 12261861	NERV	Headache/ Headache#	3	06FEB2021	1/3	2	Yes		NA/TC	R (08FEB2021)	N/N
>55/ C4591001 1226 12261861	GENRL	Injection site pain/ Pain at injection site	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
>55/ C4591001 1226 12261862	VASC	Hypertension/ Systemic arterial hypertension	2	20OCT2020	13/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1226 12261862	GENRL	Injection site pain/ Pain at the injection site	2	09OCT2020	1/3	2	Yes		NA	R (11OCT2020)	N/N
>55/ C4591001 1226 12261872	GENRL	Injection site pain/ Pain at injection site#	3	30JAN2021	1/5	1	Yes		NA	R (03FEB2021)	N/Y
>55/ C4591001 1226 12261883	GENRL	Chills/ Chills	2	14OCT2020	1/1	2	Yes		NA/TC	R (14OCT2020)	N/N
>55/ C4591001 1226 12261891	MUSC	Myalgia/ Muscle pain	2	14OCT2020	1/1	2	Yes		NA/TC	R (14OCT2020)	N/N
>55/ C4591001 1226 12261891	GENRL	Injection site pain/ Pain at the injection site	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
>55/ C4591001 1226 12261913	GENRL	Injection site pain/ Pain at injection site#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ pain at the injection site#	4	17FEB2021	1/4	1	Yes		NA	R (20FEB2021)	N/N
>55/ C4591001 1226 12261915	GENRL	Injection site pain/ pain at the injection site#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
>55/ C4591001 1226 12261921	GENRL	Injection site erythema/ redness at the injection site	2	20OCT2020	2/8	1	Yes		NA	R (27OCT2020)	N/N
		Injection site pain/ pain at injection site	2	20OCT2020	2/8	1	Yes		NA	R (27OCT2020)	N/N
>55/ C4591001 1226 12261949	GENRL	Chills/ chills	2	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
>55/ C4591001 1226 12261965	GENRL	Injection site pain/ Pain at injection site#	3	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1226 12261977	GENRL	Injection site pain/ pain at the injection site#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
>55/ C4591001 1226 12261979	GENRL	Chills/ Chills	2	22OCT2020	1/2	1	Yes		NA/TC	R (23OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1226 12261984	GENRL	Injection site pain/ Pain at the injection site	2	22OCT2020	1/2	1	Yes		NA/TC	R (23OCT2020)	N/N
		Injection site pain/ Pain at the injection site#	3	24JAN2021	2/2	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Malaise/ malaise#	4	14FEB2021	2/1	1	Yes		NA/TC	R (14FEB2021)	N/N
>55/ C4591001 1226 12261986	INV	Body temperature increased/ body increased temperature#	4	14FEB2021	2/1	1	Yes		NA/TC	R (14FEB2021)	N/N
	GASTR	Nausea/ nausea	1	02OCT2020	2/2	2	Yes		NA	R (03OCT2020)	N/N
	GENRL	Chills/ chills	1	02OCT2020	2/2	2	Yes		NA	R (03OCT2020)	N/N
	NERV	Dizziness/ dizziness	1	02OCT2020	2/2	2	Yes		NA	R (03OCT2020)	N/N
	GENRL	Pain/ Body pain	2	22OCT2020	1/2	1	Yes		NA/TC	R (23OCT2020)	N/N
>55/ C4591001 1226 12261990	SKIN	Pyrexia/ Fever	2	22OCT2020	1/2	1	Yes		NA/TC	R (23OCT2020)	N/N
		Dermatitis/ Dermatitis (neck)#	3	10FEB2021	17/3	1	No	O	NA/TC	R (12FEB2021)	N/N
>55/ C4591001 1226 12261991	MUSC	Arthralgia/ Joint pain	1	07OCT2020	7/2	1	Yes		NA	R (08OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1226 12262004	MUSC	Myalgia/ Muscle pain	2	25OCT2020	3/1	1	Yes		NA/TC	R (25OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site	1	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N	
	GENRL	Pyrexia/ Fever (38 C)	1	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site	2	22OCT2020	1/3	2	Yes		NA/TC	R (24OCT2020)	N/N	
		Pyrexia/ Fever 38.5 C	2	22OCT2020	1/3	2	Yes		NA/TC	R (24OCT2020)	N/N	
	GASTR	Rectal haemorrhage/ Anorectal hemorrhage#	2	20FEB2021	122/7	4	No	O	NA/TC/TCN	R (26FEB2021)	Y/N	
	INJ&P	Rectal injury/ Anorectal laceration#	2	20FEB2021	122/1	3	No	O	NA/TC/TCN	R (20FEB2021)	N/N	
	GENRL	Injection site pain/ Pain at the injection site#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N	
	>55/ C4591001 1226 12262005	GENRL	Injection site pain/ Pain at the injection site	2	21OCT2020	1/3	2	Yes		NA/TC	R (23OCT2020)	N/N
	>55/ C4591001 1226 12262009	GENRL	Injection site pain/ Pain at the injection site	2	21OCT2020	1/3	2	Yes		NA	R (23OCT2020)	N/N
	NERV	Headache/ Headache	2	21OCT2020	1/3	2	Yes		NA/TC	R (23OCT2020)	N/N	
>55/ C4591001	GENRL	Fatigue/ Fatigue	2	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262020		Pain/ Body pain	2	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Pyrexia/ Fever 38 C	2	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
>55/ C4591001 1226 12262025	GENRL	Injection site pain/ Pain at the injection site#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	METAB	Dyslipidaemia/ dyslipidemia#	3	10FEB2021	17/C	1	No	O	NA	RG	N/N
		Glucose tolerance impaired/ pre-diabetes#	3	10FEB2021	17/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1226 12262031	GENRL	Fatigue/ Fatigue	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
		Injection site pain/ Pain at injection site	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
>55/ C4591001 1226 12262032	GENRL	Injection site pain/ Pain at the injection site#	4	16FEB2021	1/2	2	Yes		NA/TC	R (17FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	4	16FEB2021	1/2	2	Yes		NA/TC	R (17FEB2021)	N/N
>55/ C4591001	INFEC	Herpes simplex/ Herpes simplex in the buttocks	2	30OCT2020	5/9	2	No	O	NA/TC	R (07NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12262033	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N	
	NERV	Headache/ Headache#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N	
>55/ C4591001 1226 12262055	GENRL	Injection site pain/ pain at the injection site#	3	29JAN2021	2/4	1	Yes		NA	R (01FEB2021)	N/N	
	GENRL	Injection site pain/ pain at the injection site#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N	
		Pain/ body pain#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N	
>55/ C4591001 1226 12262057	GENRL	Injection site pain/ Pain at the injection site	2	26OCT2020	1/2	1	Yes		NA/TC	R (27OCT2020)	N/N	
	INV	Body temperature increased/ Body temperature increased 37.5 C	2	26OCT2020	1/1	1	Yes		NA/TC	R (26OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	26OCT2020	1/2	1	Yes		NA/TC	R (27OCT2020)	N/N	
>55/ C4591001 1226 12262066	GENRL	Fatigue/ Fatigue	2	26OCT2020	1/33	1	Yes		NA/TC	R (27NOV2020)	N/N	
		Injection site erythema/ Redness at injection site	2	26OCT2020	1/2	2	Yes		NA	R (27OCT2020)	N/N	
		Injection site pain/ Pain at injection site	2	26OCT2020	1/2	2	Yes		NA	R (27OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1226 12262074	NERV	Pyrexia/ Fever (38.2 C)	2	26OCT2020	1/2	2	Yes		NA	R (27OCT2020)	N/N	
		Headache/ Headache	2	26OCT2020	1/2	2	Yes		NA	R (27OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site	2	28OCT2020	2/3	1	Yes		NA/TC	R (30OCT2020)	N/N	
			Pain/ Body pain	2	28OCT2020	2/3	1	Yes		NA/TC	R (30OCT2020)	N/N
>55/ C4591001 1226 12262082	INJ&P	Ligament sprain/ Sprained left ankle	1	13OCT2020	9/34	1	No	O	NA	R (15NOV2020)	N/N	
>55/ C4591001 1226 12262088	GENRL	Chills/ Chills	2	27OCT2020	1/4	1	Yes		NA	R (30OCT2020)	N/N	
		Pyrexia/ Fever (38.0 C)	2	27OCT2020	1/4	1	Yes		NA	R (30OCT2020)	N/N	
	NERV	Headache/ Headache	2	28OCT2020	2/3	2	Yes		NA/TC	R (30OCT2020)	N/N	
>55/ C4591001 1226 12262088	MUSC	Myalgia/ Muscle pain#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N	
>55/ C4591001 1226 12262098	GENRL	Injection site pain/ Pain at the injection site	1	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N	
	INJ&P	Fall/ Fall from own height	2	06NOV2020	11/1	1	No	O	NA	RS (06NOV2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Pain in extremity/ Left lower limb pain	2	06NOV2020	11/7	1	No	O	NA/TC	R (12NOV2020)	N/N	
	VASC	Hypertension/ Hypertensive peak#	2	19FEB2021	116/1	2	No	O	NA/TC	R (19FEB2021)	N/N	
>55/ C4591001 1226 12262100	GENRL	Injection site pain/ pain at the injection site#	3	26JAN2021	2/3	2	Yes		NA	R (28JAN2021)	N/N	
	GENRL	Injection site pain/ pain at the injection site#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N	
>55/ C4591001 1226 12262109	MUSC	Myalgia/ Muscle pain	1	19OCT2020	12/2	1	No	O	NA	R (20OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N	
>55/ C4591001 1226 12262118	GENRL	Injection site pain/ pain at injection site	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N	
>55/ C4591001 1226 12262142	NERV	Headache/ headache#	3	14FEB2021	2/1	2	Yes		NA/TC	R (14FEB2021)	N/N	
>55/ C4591001 1226 12262147	GENRL	Injection site pain/ Pain at the injection site#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Pain at the injection site#	4	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
>55/ C4591001 1226 12262156	GENRL	Injection site pain/ pain at the injection site#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
>55/ C4591001 1226 12262158	GENRL	Injection site pain/ Pain at the injection site	1	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C4591001 1226 12262160	GASTR	Nausea/ Nauseas	2	03NOV2020	1/1	1	Yes		NA/TC	R (03NOV2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	03NOV2020	1/3	1	Yes		NA	R (05NOV2020)	N/N
	NERV	Headache/ Headache	2	03NOV2020	1/1	1	Yes		NA/TC	R (03NOV2020)	N/N
>55/ C4591001 1226 12262161	GENRL	Injection site pain/ pain at the injection site#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
>55/ C4591001 1226 12262173	GENRL	Injection site pain/ pain at the injection site#	3	18FEB2021	1/4	2	Yes		NA	R (21FEB2021)	N/N
>55/ C4591001 1226 12262175	GENRL	Malaise/ Indisposition	2	04NOV2020	2/1	2	Yes		NA/TC	R (04NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1226 12262176	INV	Body temperature increased/ Increased body temperature 37 C	2	04NOV2020	2/1	2	Yes		NA/TC	R (04NOV2020)	N/N
	INFEC	Parotitis/ (left) Parotitis	2	05NOV2020	3/6	1	No	O	NA	R (10NOV2020)	N/N
>55/ C4591001 1226 12262180	ENDO	Hypothyroidism/ hypothyroidism	2	15DEC2020	43/C	1	No	O	NA/TC	RG	N/N
	GENRL	Fatigue/ Fatigue	1	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
>55/ C4591001 1226 12262203	MUSC	Myalgia/ Muscle pain	1	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
			1	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
	NERV	Headache/ Headache	1	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
>55/ C4591001 1226 12262207	NERV	Headache/ Headache	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	04NOV2020	2/1	1	Yes		NA/TC	R (04NOV2020)	N/N
>55/ C4591001 1226 12262207	GENRL	Chills/ chills	1	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	NERV	Headache/ headache	1	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site#	3	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N	
>55/ C4591001 1226 12262210	GENRL	Asthenia/ asthenia#	3	03FEB2021	6/1	1	Yes		NA	R (03FEB2021)	N/N	
>55/ C4591001 1226 12262214	GENRL	Fatigue/ Fatigue	2	04NOV2020	1/1	1	Yes		NA	R (04NOV2020)	N/N	
>55/ C4591001 1226 12262215	GENRL	Injection site pain/ Pain at injection site#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N	
>55/ C4591001 1226 12262222	GENRL	Injection site pain/ Pain at the injection site	1	16OCT2020	1/2	2	Yes		NA/TC	R (17OCT2020)	N/N	
	MUSC	Myalgia/ Muscle pain	1	16OCT2020	1/2	2	Yes		NA/TC	R (17OCT2020)	N/N	
	EYE	Visual acuity reduced/ Decreased Visual Acuity	2	18NOV2020	14/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1226 12262235	MUSC	Arthralgia/ Joint pain	1	16OCT2020	1/2	2	Yes		NA/TC	R (17OCT2020)	N/N	
		Myalgia/ muscle pain	1	16OCT2020	1/2	2	Yes		NA/TC	R (17OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1226 12262238	NERV	Headache/ Headache	1	17OCT2020	2/1	2	Yes		NA/TC	R (17OCT2020)	N/N
	BLOOD	Lymphadenopathy/ (Left) axillary lymph node enlargement	1	16OCT2020	1/10	2	Yes		NA	R (25OCT2020)	N/N
	GENRL	Injection site erythema/ Redness at injection site	1	16OCT2020	1/10	2	Yes		NA	R (25OCT2020)	N/N
	GENRL	Injection site oedema/ Edema at injection site	1	16OCT2020	1/10	2	Yes		NA	R (25OCT2020)	N/N
>55/ C4591001 1226 12262240	GENRL	Injection site pain/ Pain at local injection	1	16OCT2020	1/10	2	Yes		NA	R (25OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	04NOV2020	1/5	1	Yes		NA	R (08NOV2020)	N/N
	INJ&P	Fall/ fall from own height	1	24OCT2020	9/1	1	No	O	NA	R (24OCT2020)	N/N
>55/ C4591001 1226 12262248	GENRL	Femur fracture/ Fracture of the right femur	1	24OCT2020	9/6	3	No	O	NA/TCN	R (29OCT2020)	Y/N
	GENRL	Injection site pain/ Pain at injection site	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
>55/ C4591001 1226 12262253	GENRL	Injection site erythema/ Redness at injection site	2	08NOV2020	3/5	1	Yes		NA/TC	R (12NOV2020)	N/N
	RENAL	Nephrolithiasis/ Nephrolithiasis	2	01JAN2021	59/3	4	No	O	NA/TCN	R (03JAN2021)	Y/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1226 12262254	MUSC	Myalgia/ myalgia#	3	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	25OCT2020	10/2	2	Yes		NA	R (26OCT2020)	N/N
	GENRL	Asthenia/ asthenia#	3	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N
		Injection site pain/ pain at the injection site#	3	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N
>55/ C4591001 1226 12262257	MUSC	Myalgia/ myalgia#	3	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain	2	07NOV2020	2/1	1	Yes		NA	R (07NOV2020)	N/N
	NERV	Somnolence/ Somnolence	2	07NOV2020	2/1	1	Yes		NA	R (07NOV2020)	N/N
>55/ C4591001 1226 12262264	GENRL	Injection site pain/ Pain at injection site#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ Muscle pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N
>55/ C4591001	GENRL	Fatigue/ fatigue#	3	28JAN2021	1/1	1	Yes		NA	R (28JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262277		Injection site pain/ pain at the injection site#	3	28JAN2021	1/1	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
>55/ C4591001 1226 12262281	BLOOD	Lymphadenopathy/ Left axillary lymphadenopathy#	4	11MAR2021	3/C	2	Yes		NA	RG	N/N
>55/ C4591001 1226 12262305	GENRL	Injection site pain/ Pain at the injection site	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Chills/ Chills	1	18OCT2020	2/1	1	Yes		NA	R (18OCT2020)	N/N
		Pyrexia/ Fever 38.4 C	1	18OCT2020	2/1	1	Yes		NA/TC	R (18OCT2020)	N/N
	NERV	Headache/ Headache	1	18OCT2020	2/1	1	Yes		NA	R (18OCT2020)	N/N
>55/ C4591001 1226 12262306	GENRL	Injection site pain/ pain at the injection site#	3	19FEB2021	2/2	2	Yes		NA/TC	R (20FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	3	19FEB2021	2/2	2	Yes		NA/TC	R (20FEB2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	17OCT2020	1/2	2	Yes		NA/TC	R (18OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262308	NERV	Hyperaesthesia/ Increased pain sensitivity in left hemicranial region	1	28OCT2020	12/14	2	No	O	NA/TC	R (10NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	07NOV2020	2/2	2	Yes		NA/TC	R (08NOV2020)	N/N
		Pyrexia/ fever (38,2 C)	2	07NOV2020	2/2	2	Yes		NA/TC	R (08NOV2020)	N/N
	MUSC	Myalgia/ muscle pain	2	07NOV2020	2/2	2	Yes		NA/TC	R (08NOV2020)	N/N
>55/ C4591001 1226 12262324	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	2/3	1	Yes		NA	R (01FEB2021)	N/N
>55/ C4591001 1226 12262325	GENRL	Injection site erythema/ Redness at injection site	1	20OCT2020	2/3	2	Yes		NA	R (22OCT2020)	N/N
		Injection site pain/ Pain at injection site	1	20OCT2020	2/3	2	Yes		NA	R (22OCT2020)	N/N
>55/ C4591001 1226 12262328	GENRL	Pyrexia/ fever#	4	19FEB2021	1/2	2	Yes		NA/TC	R (20FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	19FEB2021	1/2	2	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	4	19FEB2021	1/2	2	Yes		NA/TC	R (20FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1226 12262332	GENRL	Injection site pain/ Pain at injection site	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/Y
	NERV	Headache/ Headache	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	11NOV2020	1/32	1	Yes		NA	R (12DEC2020)	N/N
	NERV	Dizziness/ Dizziness	2	12DEC2020	32/2	2	No	CD	NA	R (13DEC2020)	N/N
>55/ C4591001 1226 12262333	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	1/3	1	Yes		NA	R (01FEB2021)	N/N
>55/ C4591001 1226 12262336	GENRL	Fatigue/ fatigue	1	20OCT2020	2/2	2	Yes		NA	R (21OCT2020)	N/N
		Injection site pain/ pain at injection site	1	20OCT2020	2/2	2	Yes		NA	R (21OCT2020)	N/N
	GENRL	Chills/ Chills	2	07NOV2020	1/3	2	Yes		NA/TC	R (09NOV2020)	N/N
		Fatigue/ Fatigue	2	07NOV2020	1/3	2	Yes		NA/TC	R (09NOV2020)	N/N
		Pyrexia/ Fever 38 C	2	07NOV2020	1/3	2	Yes		NA/TC	R (09NOV2020)	N/N
>55/ C4591001 1226 12262344	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	3/1	2	Yes		NA	R (30JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1226 12262345	GENRL	Chills/ chills	1	21OCT2020	3/1	1	Yes		NA	R (21OCT2020)	N/N
	GENRL	Pain/ body pain#	3	20FEB2021	2/2	2	Yes		NA/TC	R (21FEB2021)	N/N
>55/ C4591001 1226 12262349	GENRL	Asthenia/ asthenia	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
>55/ C4591001 1226 12262355	MUSC	Back pain/ Backache	1	26OCT2020	7/1	1	No	O	NA	R (26OCT2020)	N/N
>55/ C4591001 1229 12291005	MUSC	Myalgia/ Myalgia	2	14OCT2020	1/7	1	Yes		NA/TC	R (20OCT2020)	N/Y
>55/ C4591001 1229 12291068	INFEC	Sinusitis/ Sinusitis	2	10NOV2020	20/14	1	No	O	NA/TC	R (23NOV2020)	N/N
>55/ C4591001 1229 12291075	INFEC	Cellulitis/ Right leg Cellulitis	2	04NOV2020	14/C	2	No	O	NA/TC	N	N/N
>55/ C4591001	MUSC	Muscle spasms/ leg cramps	2	14NOV2020	23/C	1	No	O	NA/TC	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1229 12291080 >55/ C4591001	METAB	Decreased appetite/ Loss Of Appetite	2	23OCT2020	1/4	1	No	O	NA	R (26OCT2020)	N/N
1229 12291084 >55/ C4591001	INJ&P	Fall/ Slip and accidental fall	1	10OCT2020	5/1	1	No	O	NA/TC	R (10OCT2020)	N/N
1229 12291125	MUSC	Arthralgia/ Left shoulder arthralgia	1	10OCT2020	5/28	1	No	O	NA/TC	R (06NOV2020)	N/N
>55/ C4591001	MUSC	Myalgia/ Myalgia - right Lumbar area	2	23NOV2020	25/14	1	No	O	NA/TC	R (06DEC2020)	N/N
1229 12291162 >55/ C4591001	GASTR	Abdominal pain/ Abdominal cramps#	3	18FEB2021	1/18	1	No	CD	NA/TC	R (07MAR2021)	N/N
1229 12291164	NERV	Headache/ Headache#	3	20FEB2021	3/16	1	No	CD	NA/TC	R (07MAR2021)	N/N
>55/ C4591001	MUSC	Arthralgia/ Pain right hip	1	19OCT2020	8/57	1	No	O	NA/TC/TCN	R (14DEC2020)	N/N
1229 12291183 >55/ C4591001	GASTR	Gastritis/ Gastritis	2	20NOV2020	17/C	1	No	CD	NA/TC	N	N/N
1229 12291210†											

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1230 12301016	VASC	Hypertension/ Hypertension*		24SEP2020	1/C	1	No	O	NA	RG	N/N	
>55/ C4591001 1230 12301025	NEOPL	Penile neoplasm/ Penile Intra Epithelial Neoplasia	2	06NOV2020	22/C	3	No	O	NA	N	Y/N	
		Penile squamous cell carcinoma/ PENILE INVASIVE MODERATELY DIFFERENTIAL KERATINIZING SQUAMOUS CELL CARCINOMA	2	06NOV2020	22/C	3	No	O	NA	RG	N/N	
>55/ C4591001 1230 12301096	MUSC	Myalgia/ Severe Muscle Pain	1	06OCT2020	6/3	1	No	O	NA	R (08OCT2020)	N/N	
>55/ C4591001 1230 12301119	INJ&P	Arthropod bite/ Insect Bite	1	14OCT2020	12/3	1	No	O	NA/TC	R (16OCT2020)	N/N	
>55/ C4591001 1230 12301155	MUSC	Myalgia/ Muscle Pain	2	27OCT2020	1/3	3	Yes		NA	R (29OCT2020)	N/N	
>55/ C4591001 1231 12311020	GASTR	Vomiting/ vomiting#	4	11FEB2021	1/3	1	Yes		NA/TC	R (13FEB2021)	N/N	
	NERV	Headache/ headache#	4	11FEB2021	1/7	1	Yes		NA	R (17FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Sacroiliitis/ Right sacroiliitis#	4	26FEB2021	16/12	2	No	O	NA/TC/TCN	R (09MAR2021)	N/N	
>55/ C4591001 1231 12311037	GENRL	Fatigue/ Mild fatigue	1	17AUG2020	7/2	2	No	O	NA/TCN	R (18AUG2020)	N/N	
>55/ C4591001 1231 12311038	GENRL	Fatigue/ Fatigue#	4	12MAR2021	2/2	1	Yes		NA	R (13MAR2021)	N/N	
		Pyrexia/ Fever#	4	12MAR2021	2/2	1	Yes		NA/TC	R (13MAR2021)	N/N	
	GASTR	Diarrhoea/ Diarrhea#	4	13MAR2021	3/C	1	Yes		NA	N	N/N	
>55/ C4591001 1231 12311056	INFEC	Urinary tract infection/ Urinary tract infection	2	20NOV2020	80/2	2	No	O	NA/TC	R (21NOV2020)	N/N	
	REPRO	Testicular pain/ Left testicular pain	2	20NOV2020	80/2	1	No	O	NA/TC	R (21NOV2020)	N/N	
>55/ C4591001 1231 12311060	SKIN	Pruritus/ Pruritus in legs and abdomen	1	21AUG2020	11/2	1	No	O	NA/TC	R (22AUG2020)	N/N	
>55/ C4591001 1231 12311090	CARD	Palpitations/ palpitations	2	10SEP2020	9/3	1	No	O	NA	R (12SEP2020)	N/N	
	MUSC	Arthralgia/ Worsening pain in the right thumb joint	2	26JAN2021	147/C	2	No	O	NA/TC	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12311132	SKIN	Dermatitis/ Scalp dermatitis	2	03JAN2021	124/2	1	No	O	NA/TC	R (04JAN2021)	N/N	
>55/ C4591001 1231 12311133	SKIN	Urticaria/ Acute urticaria (trunk, both arms and legs)	2	12NOV2020	71/5	1	No	O	NA/TC	R (16NOV2020)	N/N	
>55/ C4591001 1231 12311146	GENRL	Asthenia/ Asthenia	1	21AUG2020	9/4	1	No	O	NA/TC	R (24AUG2020)	N/N	
>55/ C4591001 1231 12311150	RENAL	Nephrolithiasis/ left renal microlithiasis	2	14NOV2020	75/2	2	No	O	NA/TC	R (15NOV2020)	N/N	
>55/ C4591001 1231 12311155	INFEC	Tooth infection/ Upper left second molar infection	2	19SEP2020	19/16	1	No	O	NA/TC	R (04OCT2020)	N/N	
>55/ C4591001 1231 12311163	GASTR	Haemorrhoids/ Worsening of chronic hemorrhoids	2	10SEP2020	10/16	1	No	O	NA/TC	R (25SEP2020)	N/N	
>55/ C4591001 1231 12311173	NERV	Migraine/ Worsening migraine	2	02SEP2020	2/5	2	No	O	NA/TC	R (06SEP2020)	N/N	
>55/ C4591001 1231 12311182	NERV	Ischaemic stroke/ Ischemic Stroke	2	07DEC2020	95/35	3	No	O	NA/TC/TCN	RS (10JAN2021)	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1231 12311184	GENRL	Injection site swelling/ Swelling on left arm at injection site	2	09SEP2020	8/4	1	Yes		NA	R (12SEP2020)	N/N
	GASTR	Abdominal pain/ abdominal pain#	4	12MAR2021	1/C	1	No	O	NA	N	N/N
>55/ C4591001 1231 12311203	NERV	Headache/ headache	2	23SEP2020	20/1	2	No	O	NA/TC	R (23SEP2020)	N/N
	GASTR	Odynophagia/ odynophagia	2	27SEP2020	24/3	1	No	O	NA	R (29SEP2020)	N/N
	MUSC	Back pain/ low back pain	2	19FEB2021	169/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1231 12311236	GASTR	Diverticulum intestinal/ Intestinal diverticulosis	2	06NOV2020	65/1	1	No	O	NA	R (06NOV2020)	N/N
		Haemorrhoids/ internal hemorrhoids	2	06NOV2020	65/1	1	No	O	NA	R (06NOV2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	02MAR2021	2/1	1	Yes		NA	R (02MAR2021)	N/N
		Pyrexia/ Fever#	3	02MAR2021	2/1	1	Yes		NA	R (02MAR2021)	N/N
	VASC	Blood pressure fluctuation/ FLUCTUATION OF BLOOD PRESSURE#	3	02MAR2021	2/2	1	No	O	NA	R (03MAR2021)	N/N
>55/ C4591001 1231 12311240	RENAL	Chronic kidney disease/ Worsening of chronic renal insufficiency	2	01OCT2020	30/8	1	No	O	NA/TC	R (08OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12311249	INFEC	Gastroenteritis/ acute gastroenteritis	2	29SEP2020	28/1	2	No	O	NA/TCN	R (29SEP2020)	N/N	
>55/ C4591001 1231 12311254	MUSC	Myalgia/ Myalgia generalized	2	15SEP2020	13/25	1	No	CD	NA	R (09OCT2020)	N/N	
>55/ C4591001 1231 12311278	VASC	Hypertension/ episode of hypertension	2	27SEP2020	25/2	1	No	O	NA/TC	R (28SEP2020)	N/N	
>55/ C4591001 1231 12311318	GENRL	Fatigue/ Fatigue	1	21AUG2020	7/3	1	No	O	NA	R (23AUG2020)	N/N	
>55/ C4591001 1231 12311326	SKIN	Hyperhidrosis/ profus sweating	1	01SEP2020	18/1	1	No	O	NA	R (01SEP2020)	N/N	
>55/ C4591001 1231 12311329	MUSC	Back pain/ Aggravation of chronic low back pain	2	OCT2020	28/C	2	No	O	NA	N	N/N	
>55/ C4591001 1231 12311379	NEOPL	Prostate cancer/ Prostate adenocarcinoma.	2	20NOV2020	75/C	2	No	O	NA/TC/TCN	N	Y/N	
>55/ C4591001 1231 12311382	SKIN	Dermatitis/ Dermatitis on the scalp	1	31AUG2020	17/15	1	No	O	NA/TCN	R (14SEP2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache	2	30SEP2020	27/26	1	No	O	NA/TC	R (25OCT2020)	N/N
>55/ C4591001 1231 12311400	EYE	Conjunctival haemorrhage/ Conjunctival hemorrhage	1	20AUG2020	6/8	1	No	O	NA	R (27AUG2020)	N/N
>55/ C4591001 1231 12311434	SKIN	Rosacea/ Rosacea	2	14SEP2020	11/C	1	No	O	NA	RG	N/N
>55/ C4591001 1231 12311437	GENRL	Injection site pain/ Injection site pain#	4	11FEB2021	1/6	1	Yes		NA/TC	R (16FEB2021)	N/N
>55/ C4591001 1231 12311442	INFEC	Tooth abscess/ Abscess in molar	2	01OCT2020	28/8	2	No	O	NA/TC	R (08OCT2020)	N/N
>55/ C4591001 1231 12311498	GENRL	Swelling/ SWELLING IN THE RIGHT AXILLA AND IPSILATERAL CERVICAL REGION	2	05OCT2020	29/C	1	No	O	NA	N	N/N
>55/ C4591001 1231 12311510	NEOPL	Carcinoid tumour of the stomach/ Well-differentiated multifocal neuroendocrine tumor of the stomach	2	02JAN2021	118/C	3	No	O	NA/TC/TCN	N	Y/N
	HEPAT	Portosplenomesenteric venous thrombosis/ Portosplenomesenteric venous thrombosis#	2	03MAR2021	178/C	3	No	O	NA/TC	N	Y/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12311512	MUSC	Bursitis/ Left thigh bursitis	2	15JAN2021	130/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1231 12311514	CARD	Palpitations/ daily exacerbation of palpitations	2	10SEP2020	4/3	1	No	O	NA/TC	R (12SEP2020)	N/N	
>55/ C4591001 1231 12311536	PSYCH	Panic attack/ panic attack	2	14SEP2020	7/8	2	No	O	NA/TC	R (21SEP2020)	N/N	
>55/ C4591001 1231 12311563	EYE	Eyelid haematoma/ left eye eyelid hematoma	1	25AUG2020	10/5	1	No	O	NA	R (29AUG2020)	N/N	
>55/ C4591001 1231 12311564	GASTR	Irritable bowel syndrome/ irritable bowel syndrome	2	15SEP2020	9/17	1	No	O	NA/TC/TCN	R (01OCT2020)	N/N	
>55/ C4591001 1231 12311579	INJ&P	Hand fracture/ closed fracture first phalanx right little finger	2	14SEP2020	8/32	1	No	O	NA/TC/TCN	R (15OCT2020)	N/N	
	GASTR	Gastritis/ Acute gastritis	2	17OCT2020	41/18	3	No	O	NA/TC/TCN	R (03NOV2020)	Y/N	
>55/ C4591001 1231 12311589	MUSC	Myalgia/ hands myalgia	1	28AUG2020	13/2	1	No	O	NA/TC	R (29AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1231 12311603	SKIN	Rash/ Rash in lower limbs	2	24SEP2020	18/5	1	No	O	NA	R (28SEP2020)	N/N
	GASTR	Nausea/ Nausea	1	16AUG2020	1/8	1	No	O	NA/TCN	R (23AUG2020)	N/N
>55/ C4591001 1231 12311610	GASTR	Nausea/ Nausea	2	07SEP2020	1/3	1	No	O	NA/TCN	R (09SEP2020)	N/N
	SKIN	Rash/ Skin rash in upper area of the back body, both sides of the neck and both sides of the abdomen	2	20SEP2020	13/10	1	No	O	NA/TC	R (29SEP2020)	N/N
>55/ C4591001 1231 12311632	INFEC	Cystitis/ Urinary Infection (Cystitis)	2	04OCT2020	27/2	1	No	O	NA/TC	R (05OCT2020)	N/N
>55/ C4591001 1231 12311639	MUSC	Myalgia/ muscle pain (right arm)	2	09SEP2020	3/14	1	No	O	NA/TC	R (22SEP2020)	N/N
>55/ C4591001 1231 12311675	MUSC	Rotator cuff syndrome/ rotator cuff injury of the right shoulder	2	25OCT2020	49/25	2	No	O	NA/TC/TCN	RS (18NOV2020)	N/N
	MUSC	Periarthritis/ frozen shoulder#	3	09FEB2021	6/C	2	No	O	NA	RG	N/N
	RESP	Dysphonia/ dysphonia	2	29OCT2020	52/2	1	No	O	NA	R (30OCT2020)	N/N
	INJ&P	Skin laceration/ Left forefinger cutting wound	2	23NOV2020	77/2	1	No	O	NA/TC	R (24NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12311706	GASTR	Odynophagia/ odynophagia	1	03SEP2020	18/2	1	No	O	NA	R (04SEP2020)	N/N	
	NERV	Headache/ headache	1	03SEP2020	18/2	1	No	O	NA/TC	R (04SEP2020)	N/N	
	METAB	Gout/ Gout worsening	2	14JAN2021	130/41	1	No	O	NA/TC	R (23FEB2021)	N/N	
>55/ C4591001 1231 12311713	GENRL	Injection site pain/ Left deltoid muscle injection site pain	2	08SEP2020	2/3	1	Yes		NA/TCN	R (10SEP2020)	N/N	
>55/ C4591001 1231 12311716	INFEC	Vulvovaginitis/ vulvovaginitis	2	06OCT2020	29/9	1	No	O	NA/TC	R (14OCT2020)	N/N	
	INJ&P	Fibula fracture/ Left fibula fracture#	3	06MAR2021	15/C	2	No	O	NA/TC/TCN	RG	N/N	
		Ligament injury/ Peroneal calcaneo-talar ligament injury#	3	06MAR2021	15/C	2	No	O	NA/TC/TCN	RG	N/N	
>55/ C4591001 1231 12311720	MUSC	Pain in extremity/ Left arm pain	2	09SEP2020	1/2	2	No	O	NA/TC	R (10SEP2020)	N/N	
>55/ C4591001 1231 12311728	INFEC	Tooth infection/ Odontogenic infection#	3	08MAR2021	14/C	1	No	O	NA/TC/TCN	N	N/N	
>55/ C4591001	MUSC	Back pain/ Back pain	1	22AUG2020	6/7	2	No	O	NA/TC	R (28AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12311729	GASTR	Gastritis/ gastritis	2	09JAN2021	123/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1231 12311744	MUSC	Myalgia/ MYALGIAS IN UPPER LIMBS	2	25SEP2020	19/1	1	No	O	NA/TC	R (25SEP2020)	N/N	
		Temporomandibular joint syndrome/ ARTHRALGIA ON TEMPOROMANDIBULAR JOINT	2	25SEP2020	19/1	1	No	O	NA/TC	R (25SEP2020)	N/N	
>55/ C4591001 1231 12311758	SURG	Botulinum toxin injection/ botulinum toxin application	2	21SEP2020	15/1	1	No	O	NA	R (21SEP2020)	N/N	
>55/ C4591001 1231 12311775	NERV	Headache/ headache	2	08SEP2020	2/27	2	Yes		NA/TC	R (04OCT2020)	N/N	
>55/ C4591001 1231 12311800	NERV	Paraesthesia/ Left leg paresthesia located in gastrocnemius muscles	2	12SEP2020	6/173	1	No	O	NA	RS (03MAR2021)	N/N	
>55/ C4591001 1231 12311808	BLOOD	Iron deficiency anaemia/ Iron deficiency anemia	2	09OCT2020	33/99	1	No	O	NA/TC	R (15JAN2021)	N/N	
>55/ C4591001 1231 12311814	SKIN	Rash/ Skin rash in the upper right thoracic region	1	18AUG2020	2/138	1	No	O	NA/TC	R (02JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	SKIN	Urticaria/ Generalized urticaria	2	26JAN2021	141/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1231 12311815	NEOPL	Lymphoproliferative disorder/ REACTIVE LYMPHOID PROLIFERATION SUPRACLAVICULAR	1	06SEP2020	21/C	1	No	O	P	N	N/N	
	GENRL	Injection site pain/ Pain in injection site	1	18SEP2020	33/1	1	Yes		NA/TC	R (18SEP2020)	N/N	
>55/ C4591001 1231 12311864	SKIN	Urticaria/ generalized urticaria	2	03NOV2020	58/10	2	No	O	NA/TC	R (12NOV2020)	N/N	
	SURG	Dental implantation/ DENTAL IMPLANT SURGERY	2	03NOV2020	58/1	2	No	O	NA/TC	R (03NOV2020)	N/N	
	GENRL	Pyrexia/ Fever#	4	11FEB2021	2/1	3	Yes		NA/TC	R (11FEB2021)	N/N	
>55/ C4591001 1231 12311878	ENDO	Thyroid mass/ nodules in thyroid gland	2	08OCT2020	31/49	1	No	O	NA	R (25NOV2020)	N/N	
	METAB	Vitamin D deficiency/ Vitamin D deficiency	2	08OCT2020	31/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1231 12311912	GASTR	Dental caries/ Caries in the upper left second molar	2	05OCT2020	18/C	2	No	O	NA	RG	N/N	
	INFEC	Periodontitis/ periodontitis	2	14OCT2020	27/15	2	No	O	NA/TC	R (28OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12311914	INFEC	Tooth infection/ Tooth infection (lower right molar)	1	20AUG2020	3/8	1	No	O	NA/TC	R (27AUG2020)	N/N	
>55/ C4591001 1231 12311933	SURG	Tooth extraction/ Extraction of teeth	2	05OCT2020	29/1	1	No	O	NA/TC	R (05OCT2020)	N/N	
>55/ C4591001 1231 12311936	GASTR	Intestinal polyp/ benign intestinal polyp	2	18NOV2020	72/1	1	No	O	NA	R (18NOV2020)	N/N	
	METAB	Hyperuricaemia/ Hyperuricemia	2	18NOV2020	72/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1231 12311946	NERV	Headache/ headache	2	09SEP2020	2/9	1	Yes		NA/TC	R (17SEP2020)	N/N	
	NERV	Syncope/ Syncope	2	11SEP2020	4/2	3	No	O	NA/TC	R (12SEP2020)	Y/N	
>55/ C4591001 1231 12311948	INJ&P	Fall/ fall from his own height	1	29AUG2020	12/4	1	No	O	NA/TC	R (01SEP2020)	N/N	
	SKIN	Dermal cyst/ Left frontal epidermal cyst	2	10NOV2020	64/11	1	No	O	NA/TCN	R (20NOV2020)	N/N	
>55/ C4591001 1231 12311956	GENRL	Asthenia/ asthenia	2	08SEP2020	1/C	2	No	O	NA	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12311963	VASC	Hypertension/ arterial hypertension	2	29OCT2020	51/14	1	No	O	NA/TC	R (11NOV2020)	N/N	
>55/ C4591001 1231 12311970	INV	Blood glucose increased/ Elevated fasting blood glucose	2	20SEP2020	11/19	1	No	O	NA/TC	R (08OCT2020)	N/N	
>55/ C4591001 1231 12311978	NERV	Headache/ headache	1	03SEP2020	17/11	1	No	O	NA	R (13SEP2020)	N/N	
	RESP	Rhinorrhoea/ Rhinorrhea	1	03SEP2020	17/11	1	No	O	NA	R (13SEP2020)	N/N	
>55/ C4591001 1231 12311979	INJ&P	Skin laceration/ Cutting wound on left index finger	1	06SEP2020	20/16	1	No	O	NA/TC/TCN	R (21SEP2020)	N/N	
>55/ C4591001 1231 12312000	SKIN	Urticaria/ hives on the face and neck	2	16OCT2020	38/18	1	No	O	NA	R (02NOV2020)	N/N	
>55/ C4591001 1231 12312003	MUSC	Arthralgia/ Pain in left hip	2	23SEP2020	17/4	2	No	O	NA/TC	R (26SEP2020)	N/N	
		Joint swelling/ Swelling in left hip	2	23SEP2020	17/4	2	No	O	NA/TC	R (26SEP2020)	N/N	
>55/ C4591001	SURG	Dental implantation/ lower left premolar dental implant	2	24SEP2020	17/1	1	No	O	NA	R (24SEP2020)	N/N	



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12312006	INFEC	Device related infection/ Dental Implant Infection	2	27SEP2020	20/9	1	No	O	NA/TC	R (05OCT2020)	N/N	
>55/ C4591001 1231 12312016	BLOOD	Iron deficiency anaemia/ Iron deficiency anemia#	3	26FEB2021	8/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1231 12312025	GENRL	Pyrexia/ Fever#	4	12MAR2021	2/C	1	Yes		NA/TC	N	N/N	
>55/ C4591001 1231 12312025	GASTR	Abdominal distension/ ABDOMINAL DISTENSION	1	02SEP2020	16/1	1	No	O	NA/TC	R (02SEP2020)	N/N	
>55/ C4591001 1231 12312057		Abdominal pain/ GENERAL ABDOMINAL PAIN	1	02SEP2020	16/1	1	No	O	NA/TC	R (02SEP2020)	N/N	
>55/ C4591001 1231 12312073	INFEC	Periodontitis/ periodontitis	1	20AUG2020	3/8	2	No	O	NA/TC/TCN	R (27AUG2020)	N/N	
>55/ C4591001 1231 12312091	SURG	Finger amputation/ Right index finger partial distal phalanx amputation	2	05DEC2020	88/75	3	No	O	NA/TC/TCN	RS (17FEB2021)	Y/N	
>55/ C4591001 1231 12312091	INJ&P	Dental restoration failure/ Rupture of a cavity fix in a lower molar	2	17SEP2020	11/7	1	No	O	NA/TC	R (23SEP2020)	N/N	
>55/ C4591001	GASTR	Epiploic appendagitis/ Epiploic appendagitis	1	04SEP2020	18/8	1	No	O	NA/TC	R (11SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12312092 >55/ C4591001	INFEC	Gingivitis/ gingivitis	1	07SEP2020	21/1	1	No	O	NA/TC	R (07SEP2020)	N/N
1231 12312098 >55/ C4591001	METAB	Gout/ Worsening gout	1	27AUG2020	10/1	1	No	O	NA/TC	R (27AUG2020)	N/N
1231 12312156	INV	Body temperature increased/ Body temperature increased	1	29AUG2020	12/1	1	No	O	NA	R (29AUG2020)	N/N
>55/ C4591001	GASTR	Abdominal pain/ Abdominal Pain	1	19AUG2020	2/7	3	Yes		NA/TC/TCN	R (25AUG2020)	N/N
1231 12312158		Diarrhoea/ Diarrhea. Over 6 loose stools per day.	1	19AUG2020	2/7	3	Yes		NA/TC/TCN	R (25AUG2020)	N/N
	INV	Body temperature increased/ Body temperature increased	1	19AUG2020	2/7	3	Yes		NA/TC/TCN	R (25AUG2020)	N/N
>55/ C4591001	GENRL	Axillary pain/ Nonspecific left axillary pain	2	10SEP2020	4/21	1	Yes		NA	R (30SEP2020)	N/N
1231 12312162	INJ&P	Fall/ FALL FROM 50 CM HIGH	2	26SEP2020	20/1	2	No	O	NA	RS (26SEP2020)	N/N
		Humerus fracture/ Right humerus fracture	2	26SEP2020	20/111	3	No	O	NA/TC/TCN	RS (14JAN2021)	Y/N
>55/ C4591001	GASTR	Diarrhoea/ diarrhea	2	09SEP2020	2/2	3	No	O	NA	R (10SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12312163 >55/ C4591001 1231 12312206	GASTR	Odynophagia/ Odynophagia	2	10SEP2020	2/32	1	Yes		NA	R (11OCT2020)	N/N	
	GENRL	Asthenia/ Asthenia	2	10SEP2020	2/32	1	Yes		NA	R (11OCT2020)	N/N	
	NERV	Headache/ Headache	2	10SEP2020	2/32	1	Yes		NA	R (11OCT2020)	N/N	
>55/ C4591001 1231 12312208	VASC	Hypertension/ arterial hypertension associated with headache	2	15SEP2020	8/18	1	No	O	NA/TC	R (02OCT2020)	N/N	
>55/ C4591001 1231 12312220	MUSC	Pain in extremity/ pain in left arm.	1	19AUG2020	1/3	3	No	O	NA	R (21AUG2020)	N/N	
>55/ C4591001 1231 12312223	NERV	Headache/ headache	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N	
>55/ C4591001 1231 12312233	INJ&P	Tooth fracture/ Rupture of the lower right first molar	2	10OCT2020	32/150	1	No	O	NA/TC/TCN	R (08MAR2021)	N/N	
>55/ C4591001 1231 12312234	SKIN	Psoriasis/ Psoriasis exacerbation	2	11SEP2020	2/35	1	No	O	NA/TC	R (15OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12312237	GASTR	Glossitis/ Glossitis	2	15SEP2020	6/60	1	No	O	NA	R (13NOV2020)	N/N	
	NERV	Migraine with aura/ Migraine with aura	2	13SEP2020	3/17	2	No	O	NA/TC	R (29SEP2020)	N/N	
>55/ C4591001 1231 12312248	IMMUN	Seasonal allergy/ exacerbation of seasonal allergic rhinitis	2	15SEP2020	6/17	1	No	O	NA/TC	R (01OCT2020)	N/N	
>55/ C4591001 1231 12312256	MUSC	Back pain/ low back pain	2	15SEP2020	7/2	2	No	O	NA/TC	R (16SEP2020)	N/N	
>55/ C4591001 1231 12312265	NERV	Dizziness/ dizziness	2	14SEP2020	6/4	1	No	O	NA	R (17SEP2020)	N/N	
>55/ C4591001 1231 12312277	SURG	Dental implantation/ dental implant	2	25SEP2020	17/1	1	No	O	NA/TC	R (25SEP2020)	N/N	
	METAB	Vitamin D deficiency/ hypovitaminosis d	2	30OCT2020	52/1	1	No	O	NA/TC	R (30OCT2020)	N/N	
	GENRL	Asthenia/ asthenia	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N	
>55/ C4591001 1231 12312277	INV	Body temperature increased/ increased body temperature oral cavity register 37.2	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N	
	NERV	Headache/ headache	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12312318	GASTR	Toothache/ left upper molar pain	2	24SEP2020	16/5	1	No	O	NA/TC	R (28SEP2020)	N/N	
>55/ C4591001 1231 12312328	PSYCH	Insomnia/ Worsening of Insomnia	2	15NOV2020	68/17	2	No	O	NA/TC	RS (01DEC2020)	N/N	
>55/ C4591001 1231 12312332	REPRO	Genital erythema/ Nonspecific glans erythema	2	15SEP2020	8/77	1	No	O	NA/TC	R (30NOV2020)	N/N	
>55/ C4591001 1231 12312377	MUSC	Back pain/ Intermittent low back pain#	2	14FEB2021	159/5	2	No	O	NA/TC	R (18FEB2021)	N/N	
>55/ C4591001 1231 12312380	INFEC	Urinary tract infection/ Urinary tract infection	2	24SEP2020	18/19	1	No	O	NA/TC	R (12OCT2020)	N/N	
>55/ C4591001 1231 12312423	INFEC	Vulvovaginal mycotic infection/ Vaginal mycosis#	3	11MAR2021	4/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1231 12312453	GASTR	Diarrhoea/ diarrhea	1	06SEP2020	18/1	2	No	O	NA	R (06SEP2020)	N/N	
>55/ C4591001 1231 12312459	INJ&P	Ligament sprain/ Left foot sprain	2	28SEP2020	18/8	1	No	O	NA/TC	R (05OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12312463	MUSC	Arthralgia/ Left omalgia with irradiation to the left pectoral.	2	10OCT2020	19/6	1	No	O	NA	R (15OCT2020)	N/N	
>55/ C4591001 1231 12312470	GASTR	Toothache/ tooth pain	2	12SEP2020	3/29	1	No	O	NA/TC	R (10OCT2020)	N/N	
	INFEC	Tooth infection/ odontogenic infection	2	12SEP2020	3/11	1	No	O	NA/TC	R (22SEP2020)	N/N	
	NERV	Headache/ headache	2	12SEP2020	3/29	1	No	O	NA/TC	R (10OCT2020)	N/N	
>55/ C4591001 1231 12312496	MUSC	Back pain/ ACUTE LOW BACK PAIN	1	03SEP2020	15/3	1	No	O	NA/TC	R (05SEP2020)	N/N	
	MUSC	Back pain/ acute low back pain	1	28SEP2020	40/7	2	No	O	NA/TC	R (04OCT2020)	N/N	
	SKIN	Dermatitis/ Left and right forearm dermatitis	2	15OCT2020	2/35	1	No	O	NA/TC	R (18NOV2020)	N/N	
>55/ C4591001 1231 12312497	MUSC	Plantar fasciitis/ Plantar fasciitis	2	15DEC2020	97/C	1	No	O	NA/TCN	N	N/N	
>55/ C4591001 1231 12312498	NERV	Headache/ Headache	2	05OCT2020	26/2	2	No	O	NA	R (06OCT2020)	N/N	
	VASC	Hypertension/ Arterial hypertension	2	05OCT2020	26/2	1	No	O	NA	R (06OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1231 12312527	MUSC	Neck pain/ cervicalgia	2	28SEP2020	20/16	2	No	O	NA/TC/TCN	R (13OCT2020)	N/N
>55/ C4591001 1231 12312556	INJ&P	Skin laceration/ Left hand thumb and index finger cut	2	24SEP2020	14/2	1	No	O	NA/TC/TCN	R (25SEP2020)	N/N
>55/ C4591001 1231 12312565	MUSC	Bursitis/ left shoulder bursitis	2	11SEP2020	2/172	2	No	O	NA/TC/TCN	RS (01MAR2021)	N/N
>55/ C4591001 1231 12312568	GENRL	Injection site pain/ Injection site pain.	2	11SEP2020	2/14	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1231 12312614	INFEC	Urinary tract infection/ Urinary infection	1	02SEP2020	14/14	1	No	O	NA/TC	R (15SEP2020)	N/N
>55/ C4591001 1231 12312635	BLOOD	Iron deficiency anaemia/ Iron deficiency anemia	2	10NOV2020	64/94	1	No	O	NA/TC	R (11FEB2021)	N/N
	MUSC	Osteopenia/ OSTEOPENIA	2	12NOV2020	66/113	1	No	O	NA/TC	RS (04MAR2021)	N/N
	CARD	Arrhythmia/ Cardiac arrhythmia	2	02DEC2020	86/98	1	No	O	NA	RS (09MAR2021)	N/N
	GENRL	Asthenia/ Asthenia#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Chills/ Chills#	3	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1231 12312646	METAB	Hyperuricaemia/ Hyperuricemia	1	02SEP2020	14/31	1	No	O	NA/TC/TCN	R (02OCT2020)	N/N
>55/ C4591001 1231 12312689	INJ&P	Limb injury/ Trauma to middle finger of the left hand#	3	14FEB2021	14/1	2	No	O	NA	R (14FEB2021)	N/N
		Limb injury/ incised wound on middle finger of the left hand#	3	14FEB2021	14/7	2	No	O	NA/TC/TCN	RS (20FEB2021)	N/N
	INFEC	Oral herpes/ Worsening of cold sores#	3	18FEB2021	18/7	1	No	O	NA/TC/TCN	R (24FEB2021)	N/N
>55/ C4591001 1231 12312700	GASTR	Diarrhoea/ Diarrhea	2	24SEP2020	17/2	1	No	O	NA	R (25SEP2020)	N/N
>55/ C4591001 1231 12312703	SKIN	Rash/ left axilar skin rash	2	17SEP2020	8/2	1	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C4591001 1231 12312722	NERV	Headache/ headache	2	01OCT2020	24/3	1	No	O	NA	R (03OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	CARD	Acute myocardial infarction/ acute myocardial infarction with ST elevation	2	25NOV2020	79/6	4	No	O	NA/TC/TCN	R (30NOV2020)	Y/N	
>55/ C4591001 1231 12312749	INJ&P	Burns first degree/ First-degree burn	2	10OCT2020	28/14	2	No	O	NA/TC/TCN	R (23OCT2020)	N/N	
		Burns second degree/ Second-degree burn	2	10OCT2020	28/14	2	No	O	NA/TC/TCN	R (23OCT2020)	N/N	
	INJ&P	Fall/ bicycle fall#	2	20JAN2021	130/1	2	No	O	NA/TC/TCN	R (20JAN2021)	N/N	
		Humerus fracture/ Right humerus fracture#	2	20JAN2021	130/38	2	No	O	NA/TC/TCN	R (26FEB2021)	Y/N	
>55/ C4591001 1231 12312756	MUSC	Arthralgia/ Right omalgia	2	12NOV2020	64/21	1	No	O	NA/TCN	R (02DEC2020)	N/N	
>55/ C4591001 1231 12312768	GENRL	Pyrexia/ fever 37.4 c.	2	19SEP2020	9/1	1	No	O	NA/TC	R (19SEP2020)	N/N	
	NERV	Headache/ headache	2	19SEP2020	9/1	1	No	O	NA/TC	R (19SEP2020)	N/N	
>55/ C4591001 1231 12312820	MUSC	Back pain/ low back pain	2	15SEP2020	5/3	1	No	O	NA/TC	R (17SEP2020)	N/N	
	EAR	Meniere's disease/ Menieres disease exacerbation	2	20SEP2020	10/32	1	No	O	NA	R (21OCT2020)	N/N	
>55/ C4591001	INJ&P	Facial bones fracture/ Nose fracture	1	21AUG2020	1/16	2	No	O	NA/TC/TCN	R (05SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12312841	INFEC	Urinary tract infection/ Lower urinary infection#	3	06MAR2021	15/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1231 12312863	INFEC	Sinusitis/ SINUSITIS	1	21AUG2020	1/15	3	No	O	NA/TC	R (04SEP2020)	N/N
	MUSC	Temporomandibular joint syndrome/ Temporomandibular joint dysfunction	1	04SEP2020	15/134	2	No	O	NA/TC/TCN	RS (15JAN2021)	N/N
	MUSC	Exostosis/ Nasal septum spur	2	30SEP2020	6/37	2	No	O	NA/TCN	R (05NOV2020)	N/N
	RESP	Nasal turbinate hypertrophy/ hypertrophy of nasal turbinates.	2	30SEP2020	6/37	2	No	O	NA/TCN	R (05NOV2020)	N/N
	NERV	Trigeminal neuralgia/ TRIGEMINAL NEURALGIA	2	07OCT2020	13/101	2	No	O	NA/TC	RS (15JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
		Vessel puncture site haematoma/ Hematoma at blood collection site#	3	04FEB2021	1/C	1	No	O	NA	N	N/N
	NERV	Headache/ headache#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Injection site haematoma/ Injection site hematoma#	4	24FEB2021	1/12	1	Yes		NA	R (07MAR2021)	N/N
		Injection site pain/ Injection site pain#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
>55/ C4591001 1231 12312885	INJ&P	Road traffic accident/ Vehicle collision (subject was riding a bicycle)	2	02FEB2021	145/1	3	No	O	NA/TC/TCN	RS (02FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1231 12312887	GASTR	Wrist fracture/ Right wrist fracture	2	02FEB2021	145/26	2	No	O	NA/TCN	R (27FEB2021)	Y/N
		Oesophageal spasm/ esophageal spasm	2	15SEP2020	7/1	2	No	O	NA/TC	R (15SEP2020)	N/N
	SKIN	Rash pruritic/ Pruritic rash on both legs gluteal region and both arms	2	22OCT2020	44/31	1	No	O	NA/TC	R (21NOV2020)	N/N
>55/ C4591001 1231 12312893	NEOPL	Polycythaemia vera/ Polycythemia vera	2	15DEC2020	96/C	2	No	O	NA/TC	N	Y/N
>55/ C4591001 1231 12312902	GENRL	Pyrexia/ febrile syndrome	2	30SEP2020	21/1	1	No	O	NA/TC	R (30SEP2020)	N/N
>55/ C4591001 1231 12312909	INJ&P	Skin laceration/ Dirty cutting wound in right upper limb	2	04OCT2020	24/2	1	No	O	NA/TC	R (05OCT2020)	N/N
>55/ C4591001 1231 12312915	SURG	Lens extraction/ Phacoemulsification of the right eye	1	31AUG2020	11/1	1	No	O	NA/TC/TCN	R (31AUG2020)	N/N
>55/ C4591001 1231 12312945	GASTR	Gastritis/ Gastritis	1	30AUG2020	10/4	1	No	O	NA/TC	R (02SEP2020)	N/N
>55/ C4591001	METAB	Hypercholesterolaemia/ hypercholesterolemia	2	07OCT2020	27/C	1	No	O	NA/TC/TCN	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12312967 >55/ C4591001	MUSC	Back pain/ low back pain	1	07SEP2020	18/2	2	No	O	NA	R (08SEP2020)	N/N
1231 12312980		Neck pain/ cervicalgia	1	07SEP2020	18/4	2	No	O	NA	R (10SEP2020)	N/N
	NERV	Paraesthesia/ Intermittent paresthesia in hands	1	07SEP2020	18/2	1	No	O	NA	R (08SEP2020)	N/N
>55/ C4591001	ENDO	Thyroid mass/ thyroid nodules	2	07OCT2020	27/C	1	No	O	NA	N	N/N
1231 12312993		Diabetes mellitus inadequate control/ Dysregulation of your insulin-dependent Diabetes Mellitus with poor management of blood glucose lev.	2	21SEP2020	12/C	1	No	O	NA/TC	RG	N/N
1231 12312997											
>55/ C4591001	MUSC	Arthralgia/ interphalangeal joint arthralgias of both hands	2	16SEP2020	6/7	2	No	O	NA/TC	R (22SEP2020)	N/N
1231 12313073											
>55/ C4591001	INJ&P	Fall/ Fall from own height	2	16OCT2020	37/1	2	No	O	NA/TC/TCN	R (16OCT2020)	N/N
1231 12313089											
		Joint injury/ RIGHT KNEE TRAUMA	2	16OCT2020	37/1	2	No	O	NA/TC/TCN	R (16OCT2020)	N/N
		Tibia fracture/ right tibia anterior tuberosity fracture	2	16OCT2020	37/19	2	No	O	NA/TC/TCN	R (03NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12313114	SURG	Tooth extraction/ tooth extraction	1	03SEP2020	13/1	1	No	O	NA/TC	R (03SEP2020)	N/N	
>55/ C4591001 1231 12313118	MUSC	Myalgia/ myalgia	2	12OCT2020	33/5	1	No	O	NA/TC	R (16OCT2020)	N/N	
>55/ C4591001 1231 12313150	MUSC	Myalgia/ myalgia in left lower limb	2	22SEP2020	10/20	1	Yes		NA	R (11OCT2020)	N/N	
>55/ C4591001 1231 12313185	GASTR	Abdominal pain/ Abdominal pain#	3	19JAN2021	2/3	1	No	O	NA/TC/TCN	R (21JAN2021)	N/N	
>55/ C4591001 1231 12313208	RENAL	Dysuria/ Dysuria	2	17SEP2020	8/8	1	No	O	NA/TC	R (24SEP2020)	N/N	
>55/ C4591001 1231 12313230	SKIN	Rash/ rash on face and neck. etiology unknown	2	18SEP2020	9/3	1	No	O	NA/TC	R (20SEP2020)	N/N	
>55/ C4591001 1231 12313252	INFEC	Tooth infection/ dental infection#	3	06FEB2021	10/4	1	No	O	NA/TC	RS (09FEB2021)	N/N	
	INFEC	Tooth infection/ Infection of the lower right first and second molar dental pulp#	4	24FEB2021	3/C	1	No	O	NA/TC/TCN	N	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12313261	EYE	Keratitis/ Keratitis in the right eye#	3	11FEB2021	7/8	1	No	O	NA/TC	R (18FEB2021)	N/N	
>55/ C4591001 1231 12313267	SKIN	Rash maculo-papular/ Itchy, erythematous maculopapular skin rash involving posterior neck, left arm, and trunk	1	25AUG2020	4/1	1	Yes		NA/TC	R (25AUG2020)	N/N	
>55/ C4591001 1231 12313323	MUSC	Neck pain/ NECK PAIN	2	20SEP2020	8/33	1	No	O	NA	R (22OCT2020)	N/N	
>55/ C4591001 1231 12313331	INJ&P	Muscle rupture/ right calf muscle tear#	4	25FEB2021	16/C	1	No	O	NA/TCN	RG	N/N	
>55/ C4591001 1231 12313344	GASTR	Diarrhoea/ Diarrhea	2	22SEP2020	10/3	1	No	O	NA	R (24SEP2020)	N/N	
>55/ C4591001 1231 12313354	BLOOD	Anaemia/ exacerbation of chronic anemia	2	23SEP2020	11/99	2	No	O	NA/TC	R (30DEC2020)	N/N	
>55/ C4591001 1231 12313359	MUSC	Intervertebral disc protrusion/ Worsening of herniated discs	1	23SEP2020	32/97	2	No	O	NA/TC	R (28DEC2020)	N/N	
	GENRL	Injection site pain/ Injection site pain left arm.	2	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pyrexia/ Fever	2	21NOV2020	2/1	1	Yes		NA/TC	R (21NOV2020)	N/N
	MUSC	Arthralgia/ Generalized arthralgias	2	21NOV2020	2/4	1	Yes		NA	R (24NOV2020)	N/N
		Myalgia/ Generalized myalgia	2	21NOV2020	2/2	1	Yes		NA	R (22NOV2020)	N/N
>55/ C4591001 1231 12313371	REPRO	Benign prostatic hyperplasia/ benign prostatic hyperplasia	2	08OCT2020	26/32	2	No	O	NA/TC	R (08NOV2020)	N/N
	MUSC	Arthralgia/ arthralgias#	4	12MAR2021	1/C	1	Yes		NA/TC	N	N/N
		Myalgia/ Generalized myalgia#	4	12MAR2021	1/C	1	Yes		NA/TC	N	N/N
>55/ C4591001 1231 12313391	MUSC	Back pain/ LOW BACK PAIN	1	07SEP2020	16/2	1	No	O	NA/TC/TCN	R (08SEP2020)	N/N
>55/ C4591001 1231 12313397	INJ&P	Limb injury/ puncture injury to left index finger	2	15SEP2020	5/10	2	No	O	NA/TC	R (24SEP2020)	N/N
	PSYCH	Sleep disorder/ Worsening of sleep disorder	2	22SEP2020	12/42	2	No	O	NA/TC	R (02NOV2020)	N/N
>55/ C4591001 1231 12313401	INJ&P	Road traffic accident/ Mild car accident	2	13OCT2020	29/1	1	No	O	NA	R (13OCT2020)	N/N
>55/ C4591001	SKIN	Rash pruritic/ Itchy rash on forehead and right buttock	2	01OCT2020	18/4	1	No	O	NA	R (04OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12313410 >55/ C4591001	GASTR	Anal pruritus/ Anal itching	2	05OCT2020	23/12	1	No	O	NA	R (16OCT2020)	N/N	
1231 12313411 >55/ C4591001	SKIN	Dermatitis allergic/ skin allergy	2	29SEP2020	16/3	1	No	O	NA/TC	R (01OCT2020)	N/N	
1231 12313418 >55/ C4591001	NERV	Dizziness/ dizziness#	3	19FEB2021	15/2	1	No	O	NA	R (20FEB2021)	N/N	
1231 12313464 >55/ C4591001	GENRL	Injection site pain/ injection site pain	1	23AUG2020	1/2	1	Yes		NA/TC	R (24AUG2020)	N/Y	
1231 12313478 >55/ C4591001	MUSC	Back pain/ Low back pain#	1	30SEP2020	39/4	1	Yes		NA/TC	R (03OCT2020)	N/N	
1231 12313480 >55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	23AUG2020	1/3	1	Yes		NA	R (25AUG2020)	N/N	
1231 12313485 >55/ C4591001	BLOOD	Lymphadenopathy/ LEFT INFRACLAVICULAR ADENOPATHY, 5 mm IN DIAMETER.#	2	17SEP2020	3/8	1	No	O	NA	R (24SEP2020)	N/N	
1231 12313496												



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	VASC	Hypertension/ Arterial hypertension#	2	24OCT2020	40/2	1	No	O	NA	R (25OCT2020)	N/N
>55/ C4591001 1231 12313523	GENRL	Pyrexia/ FEVER#	3	20FEB2021	2/1	1	Yes		NA/TC	R (20FEB2021)	N/N
>55/ C4591001 1231 12313552	GASTR	Parotid duct obstruction/ PAROTID BLOCKAGE	2	19SEP2020	7/4	2	No	O	NA/TC	R (22SEP2020)	N/N
	INFEC	Parotitis/ ACUTE PAROTITIS	2	19SEP2020	7/4	2	No	O	NA/TC	R (22SEP2020)	N/N
	NERV	Headache/ headache#	4	05MAR2021	8/4	1	No	O	NA/TC	R (08MAR2021)	N/N
>55/ C4591001 1231 12313568	METAB	Hyperglycaemia/ Hyperglycemia	2	01NOV2020	50/116	1	No	O	NA/TCN	R (24FEB2021)	N/N
>55/ C4591001 1231 12313573	NERV	Headache/ HEADACHE	2	09OCT2020	26/2	2	No	O	NA/TCN	R (10OCT2020)	N/N
	MUSC	Neck pain/ positional cervicalgia	2	12OCT2020	29/5	1	No	O	NA	R (16OCT2020)	N/N
>55/ C4591001 1231 12313582	RENAL	Bladder spasm/ Bladder spasms	2	01OCT2020	18/4	1	No	O	NA/TC	R (04OCT2020)	N/N
	MUSC	Back pain/ low back pain	2	23DEC2020	101/15	2	No	O	NA/TC	R (06JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12313600	EAR	Vertigo/ Worsening of vertiginous syndrome	2	07OCT2020	25/10	2	No	O	NA	R (16OCT2020)	N/N	
>55/ C4591001 1231 12313604	INFEC	Tooth infection/ dental infection	1	12SEP2020	21/13	1	No	O	NA/TC	R (24SEP2020)	N/N	
>55/ C4591001 1231 12313608	INJ&P	Meniscus injury/ exacerbation of previous pathology, knee meniscus injury.	2	15SEP2020	5/6	2	No	O	NA/TC	R (20SEP2020)	N/N	
	NERV	Carpal tunnel syndrome/ predominantly right bilateral carpal tunnel syndrome	2	16SEP2020	6/C	1	No	O	NA/TCN	N	N/N	
>55/ C4591001 1231 12313610	CARD	Atrial flutter/ Atrial Flutter#	2	19FEB2021	162/C	2	No	O	NA/TC	N	Y/N	
>55/ C4591001 1231 12313621	RESP	Pulmonary mass/ Right pulmonary nodule	2	24SEP2020	10/C	3	No	O	NA/TCN	UNK	Y/N	
>55/ C4591001 1231 12313625	INJ&P	Fall/ Fall from your own height	1	05SEP2020	13/1	1	No	O	NA	R (05SEP2020)	N/N	
	MUSC	Arthralgia/ Hip joint pain	1	05SEP2020	13/44	1	No	O	NA	R (18OCT2020)	N/N	
>55/ C4591001	GASTR	Odynophagia/ Odynophagia	1	01SEP2020	9/10	2	No	O	NA/TC	R (10SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12313628	NERV	Headache/ headache	1	01SEP2020	9/2	1	No	O	NA/TC	R (02SEP2020)	N/N
	RESP	Rhinorrhoea/ Rhinorrhea	1	01SEP2020	9/35	1	No	O	NA/TC	R (05OCT2020)	N/N
>55/ C4591001 1231 12313651	VASC	Hypertension/ Arterial Hypertension	1	16OCT2020	54/5	1	No	O	NA/TC/TCN	R (20OCT2020)	N/N
>55/ C4591001 1231 12313652	NERV	Headache/ Headache	1	25AUG2020	2/2	1	Yes		NA/TC	R (26AUG2020)	N/N
	SKIN	Rash pruritic/ Pruritic rash on periocular region	1	25AUG2020	2/2	1	Yes		NA/TC	R (26AUG2020)	N/N
	EYE	Keratitis/ Keratitis	2	22SEP2020	10/112	1	No	O	NA/TC	R (11JAN2021)	N/N
	SKIN	Eczema/ Scalp eczema	2	08OCT2020	26/59	1	No	O	NA/TC	R (05DEC2020)	N/N
>55/ C4591001 1231 12313674	RESP	Pneumonitis/ Non-specific Pneumonitis	2	29SEP2020	17/12	2	No	O	NA	R (10OCT2020)	Y/N
	BLOOD	Lymphadenopathy mediastinal/ ENLARGEMENT OF MEDIASTINAL LYMPH NODES	2	09OCT2020	27/64	1	No	O	NA/TC	R (11DEC2020)	N/N
		Lymphadenopathy/ Bilateral axillary adenopathy	2	09OCT2020	27/C	1	No	O	NA	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	RESP	Emphysema/ Panlobar emphysema	2	09OCT2020	27/C	1	No	O	NA	N	N/N	
	INFEC	Sialoadenitis/ Left submaxillary sialadenitis	2	03NOV2020	52/7	2	No	O	NA/TC	R (09NOV2020)	N/N	
>55/ C4591001 1231 12313688	Produ	Device breakage/ detachment of lower left premolar crown	2	09OCT2020	27/8	1	No	O	NA/TCN	R (16OCT2020)	N/N	
>55/ C4591001 1231 12313730	INFEC	Extradural abscess/ Epidural abscess	2	01DEC2020	77/51	2	No	O	NA/TC/TCN	R (20JAN2021)	Y/N	
		Staphylococcal sepsis/ Oxacillin sensitive Staphylococcus aureus sepsis	2	01DEC2020	77/51	3	No	O	NA/TC/TCN	R (20JAN2021)	Y/N	
	MUSC	Intervertebral disc protrusion/ Herniated disc L3 -L4	2	05DEC2020	81/47	2	No	O	NA	R (20JAN2021)	N/N	
		Spinal osteoarthritis/ L2 to L4 spinal osteoarthritis	2	05DEC2020	81/47	2	No	O	NA	R (20JAN2021)	N/N	
>55/ C4591001 1231 12313741	SKIN	Rash/ Rash on cheeks and forehead	2	21SEP2020	8/3	1	No	O	NA/TC	R (23SEP2020)	N/N	
	SKIN	Rash/ rash on cheeks and forehead	2	11OCT2020	28/5	1	No	O	NA	R (15OCT2020)	N/N	
>55/ C4591001 1231 12313744	GENRL	Injection site pain/ Local pain at injection site	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/N	
	NERV	Headache/ headache	1	24AUG2020	1/3	1	No	O	NA	R (26AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12313748	METAB	Dyslipidaemia/ Dyslipidemia	2	15OCT2020	32/89	1	No	O	NA/TC/TCN	R (11JAN2021)	N/N	
>55/ C4591001 1231 12313753	CARD	Atrial fibrillation/ Atrial fibrillation#	3	25FEB2021	7/C	2	No	O	NA/TC	RG	Y/N	
>55/ C4591001 1231 12313754	GENRL	Injection site pain/ pain at the injection site	1	01SEP2020	9/45	1	Yes		NA	R (15OCT2020)	N/N	
>55/ C4591001 1231 12313755	NERV	Facial paresis/ right peripheral facial hemiparesis	2	16OCT2020	32/15	2	No	O	NA	R (30OCT2020)	N/N	
>55/ C4591001 1231 12313775	INFEC	Tooth infection/ Odontogenic infection of the upper left second molar.	2	13OCT2020	31/7	1	No	O	NA/TC	R (19OCT2020)	N/N	
>55/ C4591001 1231 12313783	MUSC	Intervertebral disc protrusion/ Worsening lumbar disc herniation	1	10SEP2020	18/64	3	No	O	NA/TC/TCN	R (12NOV2020)	Y/N	
>55/ C4591001 1231 12313796	GASTR	Gastritis/ Acute gastritis#	4	19FEB2021	10/6	2	No	O	NA/TC	R (24FEB2021)	N/N	
>55/ C4591001 1231 12313807	GENRL	Injection site pain/ LOCAL PAIN AT THE INJECTION SITE	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12313817	GENRL	Pyrexia/ FEVER	1	27AUG2020	3/2	1	Yes		NA/TC	R (28AUG2020)	N/N	
	MUSC	Myalgia/ Generalized myalgia	1	27AUG2020	3/2	1	Yes		NA/TC	R (28AUG2020)	N/N	
	MUSC	Back pain/ Low back pain	2	01OCT2020	16/C	1	No	O	NA	RG	N/N	
	CARD	Arrhythmia/ ARRHYTHMIA	2	19OCT2020	37/1	2	No	O	NA/TC	R (19OCT2020)	N/N	
	GENRL	Injection site pain/ injection site pain	2	13SEP2020	1/2	3	Yes		NA/TC	R (14SEP2020)	N/N	
	VASC	Hypertension/ Arterial hypertension	1	17SEP2020	24/C	1	No	O	NA	N	N/N	
	CONG	Congenital bladder neck obstruction/ primary bladder neck obstruction	2	15OCT2020	31/148	2	No	O	NA/TC/TCN	R (11MAR2021)	Y/N	
	INJ&P	Muscle rupture/ Right hamstring muscle tear	2	16OCT2020	32/22	1	No	O	NA	R (06NOV2020)	N/N	
	RENAL	Bladder neck obstruction/ bladder neck obstruction#	3	09FEB2021	21/C	2	No	O	NA	N	N/N	
	MUSC	Myalgia/ myalgia#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1231 12313897	NERV	Headache/ headache#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
	SKIN	Pruritus/ generalized itching	1	08SEP2020	15/55	1	No	O	NA/TC	R (01NOV2020)	N/N
	MUSC	Myalgia/ Myalgia#	4	12FEB2021	1/2	2	Yes		NA/TC	R (13FEB2021)	N/N
>55/ C4591001 1231 12313920	NERV	Headache/ Headache#	4	12FEB2021	1/2	1	Yes		NA/TC	R (13FEB2021)	N/N
	MUSC	Back pain/ Low back pain	2	26SEP2020	12/4	2	No	O	NA/TCN	R (29SEP2020)	N/N
>55/ C4591001 1231 12313928	PSYCH	Insomnia/ Insomnia	2	01NOV2020	50/21	1	No	O	NA/TC	R (21NOV2020)	N/N
>55/ C4591001 1231 12313938	GENRL	Injection site pain/ Pain at the injection site	1	08SEP2020	15/8	1	Yes		NA/TC	R (15SEP2020)	N/N
>55/ C4591001 1231 12313940	SKIN	Dermatitis contact/ Contact dermatitis#	3	03MAR2021	13/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1231 12313947	SKIN	Eczema/ Scalp eczema	2	16SEP2020	4/41	1	No	O	NA/TC	R (26OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1231 12313952	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE	1	25AUG2020	1/8	1	Yes		NA	R (01SEP2020)	N/N
>55/ C4591001 1231 12313961	METAB	Hypercholesterolaemia/ Worsening of Hypercholesterolemia	2	15OCT2020	33/4	2	No	O	NA/TC/TCN	R (18OCT2020)	N/N
>55/ C4591001 1231 12313972	NERV	Haemorrhagic stroke/ Hemorrhagic stroke	2	27SEP2020	15/2	4	No	O	NA/TC/W	F (28SEP2020)	Y/N
>55/ C4591001 1231 12313997	CARD	Palpitations/ palpitations	2	01OCT2020	17/12	1	No	O	NA/TC	R (12OCT2020)	N/N
>55/ C4591001 1231 12314001	CARD	Angina unstable/ Unstable angina	2	08NOV2020	55/5	3	No	O	NA/TC/TCN	R (12NOV2020)	Y/N
>55/ C4591001 1231 12314014	NERV	Tremor/ left hand tremor	1	31AUG2020	7/121	1	No	O	NA	R (29DEC2020)	N/N
>55/ C4591001 1231 12314019	GASTR	Dyspepsia/ Worsening of heartburn	1	27AUG2020	3/8	1	No	O	NA/TC	R (03SEP2020)	N/N
	MUSC	Back pain/ Back pain	1	27AUG2020	3/22	1	No	O	NA	R (17SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12314025	NERV	Headache/ Headache	2	01OCT2020	16/1	1	No	O	NA	R (01OCT2020)	N/N	
	VASC	Hypertension/ Exacerbation of arterial hypertension	2	01OCT2020	16/1	1	No	O	NA/TC	R (01OCT2020)	N/N	
	MUSC	Back pain/ LOWER BACK PAIN	2	20OCT2020	35/5	1	No	O	NA	R (24OCT2020)	N/N	
>55/ C4591001 1231 12314035	CARD	Angina pectoris/ Angina Pectoris	2	20SEP2020	7/5	3	No	O	NA/TC/TCN	R (24SEP2020)	Y/N	
	PSYCH	Anxiety/ Anxiety Crisis	2	29SEP2020	16/1	2	No	O	NA	R (29SEP2020)	N/N	
>55/ C4591001 1231 12314041	EYE	Retinal tear/ Right eye retinal tear#	2	03MAR2021	172/C	2	No	O	NA/TC/TCN	RG	Y/N	
>55/ C4591001 1231 12314044	INJ&P	Tooth fracture/ Molar fracture	2	10OCT2020	28/5	1	No	O	NA/TC	R (14OCT2020)	N/N	
>55/ C4591001 1231 12314054	SKIN	Pruritus/ pruritus on torax and abdomen zone	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N	
	GENRL	Pyrexia/ fever	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N	
	NERV	Headache/ headache	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12314060	PSYCH	Anxiety/ Anxiety crisis	1	25SEP2020	32/4	1	No	O	NA	R (28SEP2020)	N/N	
>55/ C4591001 1231 12314063	NERV	Tension headache/ Morning Tension Headache	2	15OCT2020	31/6	1	No	O	NA	R (20OCT2020)	N/N	
>55/ C4591001 1231 12314089	MUSC	Back pain/ worsening low back pain	1	10SEP2020	16/6	1	No	O	NA/TC	R (15SEP2020)	N/N	
>55/ C4591001 1231 12314091	INFEC	Appendicitis/ Accute appendictis	2	06JAN2021	115/18	3	No	O	NA/TC/TCN	R (23JAN2021)	Y/N	
	METAB	Type 2 diabetes mellitus/ TYPE 2 DIABETES	2	13JAN2021	122/C	1	No	O	NA/TC/TCN	RG	N/N	
>55/ C4591001 1231 12314101	EYE	Glaucoma/ Glaucoma	2	15JAN2021	124/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1231 12314103	MUSC	Muscle contracture/ left arm and shoulder muscle contracture	1	05SEP2020	11/6	2	No	O	NA/TC/TCN	R (10SEP2020)	N/N	
>55/ C4591001 1231 12314139	INFEC	Tooth infection/ dental infection	2	12OCT2020	29/3	1	No	O	NA/TC	R (14OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12314149	MUSC	Osteoarthritis/ Arthrosis	1	30AUG2020	5/138	1	No	O	NA/TC	RS (14JAN2021)	N/N	
	INFEC	Primary syphilis/ Primary Syphilis	2	17NOV2020	65/8	1	No	O	NA	R (24NOV2020)	N/N	
>55/ C4591001 1231 12314164	INJ&P	Thermal burn/ right forearm and hand burn	1	11SEP2020	17/38	1	No	O	NA/TC	RS (18OCT2020)	N/N	
>55/ C4591001 1231 12314187	GENRL	Chills/ isolated chills	1	09SEP2020	15/2	1	No	O	NA	R (10SEP2020)	N/N	
>55/ C4591001 1231 12314197	MUSC	Osteoarthritis/ hip osteoarthritis	2	11NOV2020	59/16	1	No	O	NA/TC	R (26NOV2020)	N/N	
	MUSC	Osteoarthritis/ Worsening of left hip osteoarthritis	2	23JAN2021	132/C	3	No	O	NA/TC/TCN	N	Y/N	
>55/ C4591001 1231 12314214	GASTR	Abdominal pain/ Nonspecific abdominal pain	2	15OCT2020	32/1	1	No	O	NA	R (15OCT2020)	N/N	
	GASTR	Abdominal pain/ Abdominal pain	2	28OCT2020	45/20	1	No	O	NA	R (16NOV2020)	N/N	
>55/ C4591001 1231 12314216	INFEC	Appendicitis/ Acute Appendicitis	1	05SEP2020	11/5	3	No	O	NA/TC/TCN	R (09SEP2020)	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	EAR	Vertigo/ Vertigo	1	07OCT2020	43/51	2	No	O	NA	R (26NOV2020)	N/N	
	VASC	Orthostatic hypotension/ orthostatic hypotension	1	11OCT2020	47/2	1	No	O	NA	R (12OCT2020)	N/N	
>55/ C4591001 1231 12314231	INFEC	Laryngitis/ Worsening of chronic laryngitis.	2	09OCT2020	26/6	1	No	O	NA/TC	R (14OCT2020)	N/N	
>55/ C4591001 1231 12314233	NEOPL	Non-Hodgkin's lymphoma recurrent/ Recurrence of Non-Hodgkin Lymphoma	2	20NOV2020	68/C	2	No	O	NA	N	Y/N	
>55/ C4591001 1231 12314234	GENRL	Injection site pain/ Local pain at injection site	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N	
>55/ C4591001 1231 12314255	BLOOD	Lymphadenopathy/ Painful left axillary adenopathy	2	19SEP2020	4/4	1	No	O	NA/TC	R (22SEP2020)	N/N	
>55/ C4591001 1231 12314258	GENRL	Asthenia/ Asthenia	1	27AUG2020	2/1	2	Yes		NA/TC	R (27AUG2020)	N/N	
>55/ C4591001 1231 12314281	NERV	Dizziness/ LIPOTHYMIA(DIZZINESS)	2	15SEP2020	2/1	2	No	O	NA/TC/TCN	R (15SEP2020)	N/N	
>55/ C4591001	NERV	Headache/ headache	2	23SEP2020	10/5	1	Yes		NA	R (27SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12314289	INFEC	Urinary tract infection/ urinary infection#	2	14FEB2021	154/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1231 12314299	GASTR	Dyspepsia/ Postprandial dyspepsia	2	09OCT2020	25/34	1	No	O	NA/TC	R (11NOV2020)	N/N
>55/ C4591001 1231 12314313	GENRL	Asthenia/ ASTHENIA	1	02SEP2020	8/4	1	No	O	NA	R (05SEP2020)	N/N
>55/ C4591001 1231 12314332	INFEC	Urinary tract infection/ urinary infection	2	20SEP2020	6/5	1	No	O	NA/TC	R (24SEP2020)	N/N
>55/ C4591001 1231 12314335	INFEC	Urinary tract infection/ urinary infection	2	20OCT2020	36/10	1	No	O	NA/TC	R (29OCT2020)	N/N
>55/ C4591001 1231 12314367	EAR	Deafness neurosensory/ Bilateral moderate sensorineural hearing loss	2	20SEP2020	7/156	2	No	O	NA	RS (22FEB2021)	N/N
>55/ C4591001 1231 12314378	INFEC	Postoperative wound infection/ left mastopexy surgical site infection#	4	10MAR2021	28/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1231 12314378	SKIN	Dermatitis allergic/ skin allergy that was located in the neck and between the eyebrows	2	02OCT2020	16/5	1	No	O	NA/TC	R (06OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12314384	REPRO	Ejaculation disorder/ brownish ejaculation	2	13NOV2020	58/3	1	No	O	NA	R (15NOV2020)	N/N	
>55/ C4591001 1231 12314399	METAB	Dyslipidaemia/ Dyslipidemia#	3	08FEB2021	5/C	1	No	O	NA/TC/TCN	RG	N/N	
>55/ C4591001 1231 12314401	SKIN	Psoriasis/ exacerbation of his psoriasis manifests itself in both legs, both elbows, gluteal region and back	2	23SEP2020	8/22	2	No	O	NA/TC	R (14OCT2020)	N/N	
>55/ C4591001 1231 12314411	CARD	Coronary artery disease/ Coronary Cardiopathy	2	04DEC2020	81/57	2	No	O	NA/TC/TCN	R (29JAN2021)	Y/N	
>55/ C4591001 1231 12314412	NERV	Presyncope/ Vasovagal hypotension	2	21OCT2020	35/1	1	No	O	NA	R (21OCT2020)	N/N	
>55/ C4591001 1231 12314413	INFEC	Tooth infection/ Dental infection	2	06NOV2020	41/5	1	No	O	NA/TC	R (10NOV2020)	N/N	
>55/ C4591001 1231 12314414	INFEC	Pneumonia/ Community-acquired pneumonia	2	12NOV2020	57/6	3	No	O	NA/TC	R (17NOV2020)	Y/N	
>55/ C4591001 1231 12314428	NERV	Headache/ headache.	2	09OCT2020	25/1	1	No	O	NA	R (09OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1231 12314432	GENRL	Chills/ chills	1	27AUG2020	1/1	3	Yes		NA	R (27AUG2020)	N/N
	NERV	Headache/ Headache	1	27AUG2020	1/1	3	Yes		NA	R (27AUG2020)	N/N
	RESP	Rhinorrhoea/ Rhinorrhea	1	27AUG2020	1/1	3	Yes		NA	R (27AUG2020)	N/N
>55/ C4591001 1231 12314446	MUSC	Back pain/ low back pain	2	10OCT2020	25/4	1	No	O	NA/TC	R (13OCT2020)	N/N
>55/ C4591001 1231 12314453	SURG	Lacrimal duct procedure/ Tear duct closure for dry eye.	2	17OCT2020	32/1	1	No	O	NA/TCN	R (17OCT2020)	N/N
>55/ C4591001 1231 12314458	VASC	Hypertension/ Exacerbation of arterial hypertension	1	14SEP2020	19/4	1	No	O	NA/TC	R (17SEP2020)	N/N
>55/ C4591001 1231 12314465	INFEC	Penile infection/ Penile infection	2	22JAN2021	130/C	3	No	O	NA/TC/TCN	RG	Y/N
>55/ C4591001 1231 12314469	MUSC	Back pain/ low back pain	1	29AUG2020	3/3	1	No	O	NA/TC	R (31AUG2020)	N/N
>55/ C4591001	INFEC	Onychomycosis/ worsening of onychomycosis	1	31AUG2020	5/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12314495 >55/ C4591001	VASC	Hypertension/ ARTERIAL HYPERTENSION	2	13NOV2020	60/5	2	No	O	NA/TC/TCN	R (17NOV2020)	N/N	
1231 12314504 >55/ C4591001	GASTR	Odynophagia/ ODYNOPHAGIA	1	11SEP2020	16/2	1	No	O	NA	R (12SEP2020)	N/N	
1231 12314518 >55/ C4591001	INJ&P	Joint dislocation/ Left hand ring finger dislocation	2	07JAN2021	115/C	2	No	O	NA/TC/TCN	N	N/N	
1231 12314527 >55/ C4591001	MUSC	Back pain/ low back pain	1	29AUG2020	3/3	1	No	O	NA/TC/TCN	R (31AUG2020)	N/N	
1231 12314561	MUSC	Muscle spasms/ Cramps in left lower limb	2	17SEP2020	3/4	2	No	O	NA/TC	R (20SEP2020)	N/N	
		Myalgia/ Moderate general myalgia	2	17SEP2020	3/4	2	Yes		NA/TC	R (20SEP2020)	N/N	
>55/ C4591001 1231 12314567	GENRL	Injection site pain/ local pain in the left arm at injection site	2	16SEP2020	2/4	3	Yes		NA/TC	R (19SEP2020)	N/N	
>55/ C4591001 1231 12314579	INJ&P	Skin abrasion/ excoriation on the thumb of the right hand	2	03NOV2020	50/1	1	No	O	NA/TC	R (03NOV2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1231 12314588	MUSC	Rheumatoid arthritis/ Rheumatoid Arthritis#	3	10FEB2021	13/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1231 12314657	GASTR	Dry mouth/ dry mouth	1	11SEP2020	16/65	1	No	O	NA	R (14NOV2020)	N/N
	SKIN	Rash/ skin rash on the face	1	12SEP2020	17/3	1	No	O	NA	R (14SEP2020)	N/N
	GENRL	Face oedema/ edema on face	2	21SEP2020	7/6	1	No	O	NA/TC/TCN	R (26SEP2020)	N/N
	REPRO	Pruritus genital/ ITCHING OF GENITALS	2	21SEP2020	7/6	1	No	O	NA/TC	R (26SEP2020)	N/N
	SKIN	Pruritus/ ITCHING OF THE SCALP	2	21SEP2020	7/6	1	No	O	NA/TC	R (26SEP2020)	N/N
>55/ C4591001 1231 12314664	INFEC	Urinary tract infection/ Urinary tract infection#	4	27FEB2021	2/7	1	No	O	NA/TC	R (05MAR2021)	N/N
>55/ C4591001 1231 12314668	INFEC	Tooth infection/ Odontogenic infection	2	28SEP2020	13/6	1	No	O	NA/TC/TCN	R (03OCT2020)	N/N
>55/ C4591001 1231 12314669	VASC	Blood pressure inadequately controlled/ Poorly controlled high blood pressure	2	15JAN2021	120/C	1	No	O	NA/TC	N	N/N
>55/ C4591001	NERV	Hypoaesthesia/ increase of frequency of hypoesthesia at the level of the left upper limb	1	30AUG2020	3/24	1	No	O	NA	R (22SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12314675 >55/ C4591001	NERV	Myoclonus/ chin myoclonus	1	05SEP2020	9/66	1	No	O	NA	R (09NOV2020)	N/N
1231 12314681 >55/ C4591001	GASTR	Gastroesophageal reflux disease/ exacerbation of gastroesophageal reflux	2	01OCT2020	16/29	1	No	O	NA/TC	R (29OCT2020)	N/N
1231 12314690	NEOPL	Gastric cancer/ Signetringcellgastriccarcinoma(SRCGC)	2	29JAN2021	136/C	3	No	O	NA	N	Y/N
>55/ C4591001	METAB	Hyperglycaemia/ Hyperglycemia	2	05OCT2020	20/6	1	No	O	NA/TC/TCN	R (10OCT2020)	N/N
1231 12314707 >55/ C4591001	RESP	Rhinitis allergic/ Exacerbation of allergic rhinitis#	3	09FEB2021	8/6	1	No	O	NA/TC	R (14FEB2021)	N/N
1231 12314747 >55/ C4591001	NERV	Amyotrophic lateral sclerosis/ potential amyotrophic lateral sclerosis	2	10OCT2020	25/C	2	No	O	NA/TC/TCN	N	Y/N
1231 12314759	RESP	Pulmonary mass/ Pulmonary micronodules	2	04NOV2020	50/26	1	No	O	NA	R (29NOV2020)	N/N
>55/ C4591001	GENRL	Chills/ Chills#	4	25FEB2021	2/1	2	Yes		NA	R (25FEB2021)	N/N
1231 12314770											

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Pyrexia/ Fever#	4	25FEB2021	2/1	2	Yes		NA/TC	R (25FEB2021)	N/N	
	MUSC	Myalgia/ Generalized myalgia#	4	25FEB2021	2/1	2	Yes		NA/TC	R (25FEB2021)	N/N	
	NERV	Headache/ Headache#	4	25FEB2021	2/1	1	Yes		NA/TC	R (25FEB2021)	N/N	
>55/ C4591001 1231 12314805	INJ&P	Ligament sprain/ Right ankle external lateral sprain#	3	02MAR2021	12/12	2	No	O	NA/TC/TCN	R (13MAR2021)	N/N	
>55/ C4591001 1231 12314807	VASC	Hypertensive crisis/ hypertensive crisis	1	08SEP2020	12/2	3	No	O	NA/TC/TCN	R (09SEP2020)	N/N	
	PSYCH	Panic attack/ panic attack	1	14SEP2020	18/1	1	No	O	NA	R (14SEP2020)	N/N	
>55/ C4591001 1231 12314830	INJ&P	Wound/ scalp wound#	3	27FEB2021	8/1	1	No	O	NA/TCN	R (27FEB2021)	N/N	
>55/ C4591001 1231 12314879	SKIN	Rash/ localised back exanthema	2	15OCT2020	30/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 1231 12314891	PSYCH	Depression/ Acute Depressive Syndrome	2	05NOV2020	51/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001	INFEC	Pneumonia/ community acquired pneumonia	2	03OCT2020	18/13	4	No	O	NA/TC/TCN	R (15OCT2020)	Y/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12314898 >55/ C4591001 1231 12314911	NERV	Headache/ Headache	1	29AUG2020	2/18	1	Yes		NA/TC	R (15SEP2020)	N/N
	GASTR	Abdominal distension/ Abdominal distension	2	15JAN2021	122/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1231 12314916	METAB	Hypertriglyceridaemia/ Hypertriglyceridemia	1	12SEP2020	16/29	1	No	O	NA/TC	R (10OCT2020)	N/N
>55/ C4591001 1231 12314953	INFEC	Tooth infection/ dental infection	2	18OCT2020	31/10	1	No	O	NA/TC	R (27OCT2020)	N/N
	SKIN	Rash pruritic/ Pruritic rash in lower back, abdomen and neck.	2	30OCT2020	43/7	1	No	O	NA	R (05NOV2020)	N/N
>55/ C4591001 1231 12314960	GENRL	Axillary pain/ left armpit pain	2	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N
	GENRL	Application site pruritus/ itching at the product application site	2	20SEP2020	3/6	1	Yes		NA	R (25SEP2020)	N/N
	VASC	Hypertension/ Worsening arterial hypertension	2	18NOV2020	62/C	1	No	O	NA	N	N/N
>55/ C4591001 1231 12314961	GENRL	Injection site erythema/ erythema at injection site	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1231 12314966	VASC	Injection site induration/ induration at injection site	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
		Injection site pain/ injection site pain	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
		Hypertension/ arterial hypertension	2	20SEP2020	5/28	1	No	O	NA/TC	R (17OCT2020)	N/N
>55/ C4591001 1231 12314972	RESP	Bronchospasm/ Worsening bronchospasm	1	29AUG2020	2/18	2	No	O	NA/TC	R (15SEP2020)	N/N
>55/ C4591001 1231 12314973	NERV	Headache/ Mild and intermittent headache. Retro ocular location.	1	29AUG2020	2/6	1	Yes		NA/TC	R (03SEP2020)	N/N
>55/ C4591001 1231 12314988	MUSC	Muscle spasms/ Rigth masseter muscle spasm	2	17SEP2020	2/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1231 12314993	INFEC	Herpes zoster/ herpez zooster in left orbital region	2	19SEP2020	2/12	1	No	O	NA/TC	R (30SEP2020)	N/N
>55/ C4591001 1231 12314997	MUSC	Osteoporosis/ Osteoporosis	2	01OCT2020	16/C	1	No	O	NA/TC/TCN	RG	N/N
>55/ C4591001	EAR	Vertigo positional/ benign paroxysmal positional vertigo	2	21SEP2020	4/3	2	No	O	NA/TC/TCN	R (23SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12315004 >55/ C4591001	VASC	Hypertension/ HYPERTENSION	1	31AUG2020	4/3	2	No	O	NA/TC	R (02SEP2020)	N/N
1231 12315010 >55/ C4591001	GASTR	Toothache/ Toothache	1	05SEP2020	9/8	1	No	O	NA/TC	R (12SEP2020)	N/N
1231 12315017 >55/ C4591001	MUSC	Back pain/ Low back pain	1	16SEP2020	20/1	2	No	O	NA/TC	R (16SEP2020)	N/N
1231 12315018 >55/ C4591001	VASC	Hypertension/ arterial hypertension	2	27DEC2020	103/C	1	No	O	NA/TC/TCN	N	N/N
1231 12315019 >55/ C4591001	BLOOD	Lymphadenopathy/ Left cervical adenopathy	2	21SEP2020	6/4	1	No	O	NA	R (24SEP2020)	N/N
1231 12315023 >55/ C4591001	GASTR	Irritable bowel syndrome/ Irritable bowel syndrome exacerbation	2	06OCT2020	21/4	2	No	O	NA/TC/TCN	R (09OCT2020)	N/N
1231 12315025 >55/ C4591001	MUSC	Groin pain/ groin pain	1	01SEP2020	5/35	2	No	O	NA	R (05OCT2020)	N/N
1231 12315030											

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1231 12315032	SKIN	Pruritus/ Itching with small vesicles, macules and scabs on the hands and feet.	2	18SEP2020	3/C	1	No	O	NA/TC/TCN	N	N/N
>55/ C4591001 1231 12315041	GENRL	Injection site pain/ Pain at the injection site#	4	11MAR2021	1/3	1	Yes		NA/TC	R (13MAR2021)	N/N
	GENRL	Pyrexia/ Fever#	4	12MAR2021	2/2	1	Yes		NA/TC	R (13MAR2021)	N/N
	MUSC	Myalgia/ Generalized myalgia#	4	12MAR2021	2/2	1	Yes		NA/TC	R (13MAR2021)	N/N
>55/ C4591001 1231 12315044	INFEC	Gastroenteritis/ gastroenteritis	1	06SEP2020	10/5	1	No	O	NA	R (10SEP2020)	N/N
>55/ C4591001 1231 12315049	GENRL	Chills/ Chills	2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N
		Pyrexia/ Fever	2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C4591001 1231 12315051	SURG	Tooth extraction/ tooth extraction	2	05OCT2020	20/1	2	No	O	NA/TC/TCN	R (05OCT2020)	N/N
>55/ C4591001 1231 12315058	GENRL	Injection site pain/ Pain at injection site	1	30AUG2020	2/2	1	Yes		NA	R (31AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12315081	GASTR	Dental caries/ Cavities in left inferior third molar	2	28NOV2020	73/6	2	No	O	NA/TC/TCN	R (03DEC2020)	N/N	
	INFEC	Pyelonephritis/ left pyelonephritis	2	04DEC2020	79/19	2	No	O	NA/TC	R (22DEC2020)	Y/N	
>55/ C4591001 1231 12315106	VASC	Hypertension/ arterial hypertension	2	20SEP2020	4/2	2	No	O	NA/TC	R (21SEP2020)	N/N	
>55/ C4591001 1231 12315126	NEOPL	Squamous cell carcinoma/ In situ squamous cell carcinoma	2	15JAN2021	121/C	2	No	O	NA	N	Y/N	
>55/ C4591001 1231 12315148	NERV	Paraesthesia/ paresthesias of the right forearm	2	12OCT2020	26/59	1	No	O	NA	R (09DEC2020)	N/N	
	GENRL	Pyrexia/ fever#	3	24FEB2021	2/3	1	Yes		NA	R (26FEB2021)	N/N	
>55/ C4591001 1231 12315159	SKIN	Dermatitis exfoliative/ desquamative dermatitis	1	01SEP2020	4/58	1	No	O	NA	R (28OCT2020)	N/N	
>55/ C4591001 1231 12315193	CARD	Arteriosclerosis coronary artery/ Worsening of Coronary atherosclerosis	2	02DEC2020	77/43	2	No	O	NA/TCN	R (13JAN2021)	Y/N	
>55/ C4591001	NERV	Headache/ headache#	3	01FEB2021	1/21	1	Yes		NA/TC	R (21FEB2021)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12315207 >55/ C4591001	INFEC	Gastroenteritis/ GASTROENTERITIS	1	05SEP2020	8/8	2	No	O	NA/TC	R (12SEP2020)	N/N
1231 12315237 >55/ C4591001	GENRL	Asthenia/ asthenia	2	20SEP2020	2/2	2	Yes		NA	R (21SEP2020)	N/N
1231 12315250 >55/ C4591001	HEPAT	Biliary colic/ Biliary colic	2	22SEP2020	6/3	3	No	O	NA/TC	R (24SEP2020)	N/N
1231 12315273 >55/ C4591001	NERV	Burning sensation/ Lower limbs burning sensation.	2	13OCT2020	27/25	1	No	O	NA	R (06NOV2020)	N/N
1231 12315290 >55/ C4591001	GENRL	Peripheral swelling/ Pain and swelling in the first phalanx of your right index finger	2	28OCT2020	42/30	1	No	O	NA	R (26NOV2020)	N/N
1231 12315293 >55/ C4591001	METAB	Hyperglycaemia/ Hyperglycemia	2	27NOV2020	72/9	2	No	O	NA/TC/TCN	R (05DEC2020)	Y/N
1231 12315301	GASTR	Anal fistula/ perianal fistula#	3	02FEB2021	6/2	1	No	O	NA/TCN	R (03FEB2021)	N/N
>55/ C4591001	GENRL	Injection site erythema/ Injection site redness	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12315305		Injection site pain/ Injection site pain	2	17SEP2020	1/8	2	Yes		NA/TC	R (24SEP2020)	N/N	
		Injection site swelling/ Injection site swelling	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N	
	MUSC	Arthralgia/ Generalized arthralgia	2	17SEP2020	1/2	2	Yes		NA/TC	R (18SEP2020)	N/N	
		Myalgia/ Myalgia	2	17SEP2020	1/2	2	Yes		NA/TC	R (18SEP2020)	N/N	
>55/ C4591001 1231 12315315	MUSC	Back pain/ Low back pain	2	24SEP2020	8/4	1	No	O	NA/TC	R (27SEP2020)	N/N	
	GASTR	Dyspepsia/ dyspepsia#	3	21FEB2021	21/1	1	No	O	NA/TC	R (21FEB2021)	N/N	
>55/ C4591001 1231 12315324	INFEC	COVID-19/ Severe Covid-19 illness	2	25DEC2020	99/38	4	No	O	NA/TC/TCN	F (31JAN2021)	Y/N	
		Septic shock/ Septic shock	2	25DEC2020	99/38	4	No	O	NA/TC/TCN/W	F (31JAN2021)	Y/N	
>55/ C4591001 1231 12315328	MUSC	Osteoporosis/ Osteoporosis	2	16OCT2020	28/C	1	No	O	NA/TC/TCN	RG	N/N	
>55/ C4591001 1231 12315336	SKIN	Pruritus/ mild itching	1	29AUG2020	1/23	1	No	O	NA	R (20SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12315341	IMMUN	Allergy to arthropod bite/ Allergic reaction secondary to insect bite	2	08NOV2020	53/10	1	No	O	NA/TC	R (17NOV2020)	N/N	
>55/ C4591001 1231 12315345	EAR	Tinnitus/ TINNITUS IN LEFT EAR	1	09SEP2020	12/111	1	No	O	NA	R (28DEC2020)	N/N	
>55/ C4591001 1231 12315366	REPRO	Breast calcifications/ Microcalcifications in the right breast	2	10OCT2020	24/C	1	No	O	NA	N	N/N	
>55/ C4591001 1231 12315382	SURG	Tooth extraction/ tooth extraction	1	15SEP2020	17/16	1	No	O	NA/TC	R (30SEP2020)	N/N	
>55/ C4591001 1231 12315384	GASTR	Haemorrhoidal haemorrhage/ Hemorrhoidal bleeding	2	20SEP2020	2/32	1	No	O	NA/TC/TCN	R (21OCT2020)	N/N	
>55/ C4591001 1231 12315389	INJ&P	Fall/ fall from own height#	3	22FEB2021	4/1	1	No	O	NA	R (22FEB2021)	N/N	
	MUSC	Arthralgia/ Right gonalgia#	3	22FEB2021	4/2	1	No	O	NA	R (23FEB2021)	N/N	
>55/ C4591001 1231 12315392	GASTR	Abdominal pain/ Abdominal pain#	3	18FEB2021	14/6	1	No	O	NA/TC/TCN	RS (23FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1231 12315403	NERV	Sciatica/ WORSENING OF LUMBOSCIATALGIA#	2	17FEB2021	152/1	1	No	O	NA/TC	R (17FEB2021)	N/N	
>55/ C4591001 1231 12315404	INFEC	Urinary tract infection/ Uncomplicated urinary infection	1	31AUG2020	2/33	1	No	O	NA/TC	R (02OCT2020)	N/N	
	RENAL	Haematuria/ Exacerbation of gross hematuria	2	11OCT2020	4/80	1	No	O	NA	R (29DEC2020)	N/N	
	NEOPL	Transitional cell carcinoma/ High grade infiltrating urothelial carcinoma	2	29DEC2020	83/C	3	No	O	NA/TC	N	Y/N	
>55/ C4591001 1231 12315410	EYE	Cataract/ bilateral cataract	2	23SEP2020	6/C	1	No	O	NA	N	N/N	
>55/ C4591001 1231 12315423	METAB	Dyslipidaemia/ Dyslipidemia	2	11JAN2021	115/41	1	No	O	NA/TC	R (20FEB2021)	N/N	
>55/ C4591001 1231 12315455	MUSC	Back pain/ low back pain	1	14SEP2020	16/1	2	No	O	NA/TC	R (14SEP2020)	N/N	
>55/ C4591001 1231 12315507	INFEC	Bone abscess/ abscessed lesion in left iliac fossa	2	29SEP2020	12/15	1	No	O	NA/TC/TCN	R (13OCT2020)	N/N	
>55/ C4591001	ENDO	Hypothyroidism/ hypothyroidism	2	13OCT2020	25/31	1	No	O	NA/TC	R (12NOV2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12315509	METAB	Insulin resistance/ Resistance to the insulin	2	13OCT2020	25/31	1	No	O	NA/TC/TCN	R (12NOV2020)	N/N
>55/ C4591001 1231 12315510	GASTR	Abdominal pain upper/ epigastralgia	1	07SEP2020	9/12	1	No	O	NA/TC	R (18SEP2020)	N/N
>55/ C4591001 1231 12315520	METAB	Type 2 diabetes mellitus/ Diabetes type 2	1	11SEP2020	13/1	1	No	O	NA/TC/TCN	R (11SEP2020)	N/N
	INV	Body temperature increased/ Body temperature increased	1	06SEP2020	8/4	1	No	O	NA/TC	R (09SEP2020)	N/N
	EYE	Macular oedema/ macular edema of the right eye	2	05NOV2020	48/C	3	No	O	NA/TC	RG	N/N
		Ophthalmic vein thrombosis/ Venous thrombosis of the right eye	2	05NOV2020	48/C	3	No	O	NA/TC	RG	Y/N
	VASC	Hypertension/ Arterial hypertension	2	18NOV2020	61/19	1	No	O	NA/TC/TCN	R (06DEC2020)	N/N
>55/ C4591001 1231 12315531	GASTR	Diarrhoea/ diarrhea#	4	13MAR2021	2/C	1	Yes		NA	N	N/N
	MUSC	Myalgia/ Generalized myalgia#	4	13MAR2021	2/1	1	Yes		NA	R (13MAR2021)	N/N
	NERV	Headache/ headache#	4	13MAR2021	2/1	1	Yes		NA	R (13MAR2021)	N/N
>55/ C4591001	GASTR	Abdominal pain/ Abdominal pain#	4	13MAR2021	3/C	2	Yes		NA	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12315557		Diarrhoea/ Diarrhea#	4	13MAR2021	3/C	2	Yes		NA	N	N/N
>55/ C4591001 1231 12315571	MUSC	Muscle contracture/ pectoral muscle contracture	1	07SEP2020	8/4	2	No	O	NA/TC/TCN	R (10SEP2020)	N/N
>55/ C4591001 1231 12315579	INJ&P	Fall/ fall from his own height	2	30JAN2021	134/1	2	No	O	NA/TCN	RS (30JAN2021)	N/N
>55/ C4591001 1231 12315582	GENRL	Patella fracture/ Left Patella fracture Injection site pain/ Pain at injection site	2	30JAN2021	134/C	3	No	O	NA/TC/TCN	N	Y/N
>55/ C4591001 1231 12315598	NERV	Dysgeusia/ dysgeusia	1	06SEP2020	7/2	1	No	O	NA	R (07SEP2020)	N/N
>55/ C4591001 1231 12315607	MUSC	Back pain/ Moderate low back pain	2	24SEP2020	6/5	2	No	O	NA	R (28SEP2020)	N/N
>55/ C4591001 1231 12315614	REPRO	Benign prostatic hyperplasia/ Benign prostatic hyperplasia#	3	25FEB2021	6/1	1	No	O	NA/TC	RS (25FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1231 12315617	RESP	Epistaxis/ Acute epistaxis of the right nostril	2	09OCT2020	21/1	2	No	O	NA/TCN	R (09OCT2020)	N/N
>55/ C4591001 1231 12315625	INJ&P	Animal bite/ dog bite injury in left outer thigh	1	18SEP2020	19/8	2	No	O	NA/TC	R (25SEP2020)	N/N
>55/ C4591001 1231 12315632	CARD	Pericarditis/ Pericarditis	2	17OCT2020	29/C	2	No	O	NA/TC/TCN	N	Y/N
	GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux disease	2	30OCT2020	42/43	2	No	O	NA/TC	R (11DEC2020)	N/N
>55/ C4591001 1231 12315653	NERV	Ischaemic stroke/ Ischemic stroke	2	12OCT2020	24/5	2	No	O	NA/TC	R (16OCT2020)	Y/N
>55/ C4591001 1231 12315657	GASTR	Haemorrhoids/ Hemorrhoidal crisis	2	22SEP2020	4/24	2	No	O	NA/TC/TCN	R (15OCT2020)	N/N
>55/ C4591001 1231 12315665	NERV	Headache/ Mild Headache	1	31AUG2020	1/2	1	No	O	NA	R (01SEP2020)	N/N
	SKIN	Pruritus/ Generalized Pruritus	1	31AUG2020	1/2	1	No	O	NA	R (01SEP2020)	N/N
		Rash erythematous/ Generalized pruritic erythematous rash	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Rash/ Facial Rash	1	31AUG2020	1/2	1	No	O	NA	R (01SEP2020)	N/N	
>55/ C4591001 1231 12315671	NEOPL	Transitional cell carcinoma/ High-grade urothelial carcinoma	2	11NOV2020	54/C	3	No	O	NA/TC/TCN	N	Y/N	
	GASTR	Diverticulum intestinal/ Diverticulosis in the sigmoid colon	2	27JAN2021	131/1	1	No	O	NA	RS (27JAN2021)	N/N	
	RENAL	Renal cyst/ Cortical cyst in right kidney	2	27JAN2021	131/1	1	No	O	NA	RS (27JAN2021)	N/N	
>55/ C4591001 1231 12315683	INFEC	Periodontitis/ periodontitis	2	15OCT2020	27/3	1	No	O	NA/TC/TCN	R (17OCT2020)	N/N	
>55/ C4591001 1232 12321047	GENRL	Injection site mass/ knot on arm (injection site)#	2	12JAN2021	126/8	1			NA	R (19JAN2021)	N/N	
>55/ C4591001 1232 12321203	MUSC	Back pain/ Backache	1	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N	
	MUSC	Back pain/ Backache	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N	
>55/ C4591001 1235 12351001	GENRL	Fatigue/ fatigue#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N	
	NERV	Headache/ headache#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1235 12351031	MUSC	Myalgia/ myalgia	1	11SEP2020	5/15	2	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1235 12351039	GENRL	Fatigue/ Fatigue#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
		Pyrexia/ Pyrexia#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
	NERV	Headache/ Cephalgia#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
>55/ C4591001 1235 12351047	GENRL	Fatigue/ Fatigue#	3	18DEC2020	2/2	1	Yes		NA	R (19DEC2020)	N/N
		Pyrexia/ Fever#	3	18DEC2020	2/2	1	Yes		NA	R (19DEC2020)	N/N
	MUSC	Myalgia/ Myalgia#	3	18DEC2020	2/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
		Pyrexia/ Fever#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Myalgia/ Myalgia, generalized#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ Headache#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
>55/ C4591001	MUSC	Myalgia/ Right arm myalgia#	4	24FEB2021	1/3	1	Yes		NA/TC	R (26FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1235 12351076	GENRL	Pyrexia/ Pyrexia#	4	25FEB2021	2/2	2	Yes		NA/TC	R (26FEB2021)	N/N
	MUSC	Myalgia/ Myalgia, generalized#	4	25FEB2021	2/2	2	Yes		NA/TC	R (26FEB2021)	N/N
>55/ C4591001 1235 12351086	GENRL	Fatigue/ fatigue	2	06OCT2020	1/11	2	Yes		NA	R (16OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N
>55/ C4591001 1235 12351096	MUSC	Myalgia/ Myalgia generalized#	4	13JAN2021	2/1	1	Yes		NA/TC	R (13JAN2021)	N/N
>55/ C4591001 1235 12351120	MUSC	Myalgia/ localized myalgia	2	10OCT2020	2/3	2	Yes		NA	R (12OCT2020)	N/N
>55/ C4591001 1235 12351123	GASTR	Vomiting/ vomiting	2	12OCT2020	1/12	1	Yes		NA/TC	R (23OCT2020)	N/N
	GENRL	Chills/ chills	2	12OCT2020	1/12	2	Yes		NA/TC	R (23OCT2020)	N/N
		Pyrexia/ fever	2	12OCT2020	1/12	2	Yes		NA/TC	R (23OCT2020)	N/N
	MUSC	Arthralgia/ joint aches	2	12OCT2020	1/12	1	Yes		NA/TC	R (23OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	RESP	Dyspnoea/ shortness of breath	2	12OCT2020	1/12	2	No	O	NA/TC	R (23OCT2020)	N/N
		Oropharyngeal pain/ sore throat	2	12OCT2020	1/12	1	No	O	NA/TC	R (23OCT2020)	N/N
>55/ C4591001 1235 12351136	MUSC	Pain in extremity/ Left arm soreness#	4	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
>55/ C4591001 1235 12351139	GENRL	Pyrexia/ Pyrexia	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
>55/ C4591001 1235 12351148	GENRL	Fatigue/ Fatigue	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C4591001 1235 12351150	INFEC	Urinary tract infection/ urinary tract infection	1	10OCT2020	17/11	2	No	O	NA/TC	R (20OCT2020)	N/N
>55/ C4591001 1235 12351177	MUSC	Musculoskeletal pain/ Myalgia and arthralgia	1	27OCT2020	14/2	1	No	O	NA	R (28OCT2020)	N/N
>55/ C4591001 1235 12351179	GENRL	Fatigue/ Fatigue	1	15OCT2020	1/3	2	Yes		NA	R (17OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1235 12351182	MUSC	Pain in extremity/ Arm soreness	1	15OCT2020	1/3	2	Yes		NA	R (17OCT2020)	N/N
	NERV	Headache/ Cephalgia	1	21OCT2020	2/3	1	Yes		NA/TC	R (23OCT2020)	N/N
	GENRL	Chills/ Chills	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
>55/ C4591001 1235 12351183	NERV	Headache/ Cephalgia	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
	GENRL	Fatigue/ fatigue#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
>55/ C4591001 1235 12351185	MUSC	Myalgia/ myalgia-generalized#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
>55/ C4591001 1235 12351201	GENRL	Chills/ Chills	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
>55/ C4591001 1235 12351202	INV	Body temperature increased/ Elevated temperature	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ Myalgia of bilateral shoulders and left arm	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
	INV	Body temperature increased/ Elevated temperature	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Cephalgia	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
>55/ C4591001 1235 12351204	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
>55/ C4591001 1235 12351205	NEOPL	Oropharyngeal squamous cell carcinoma/ squamous cell carcinoma of oropharynx	1	23OCT2020	4/C	3	No	O	NA/TC/TCN	N	Y/N
	BLOOD	Lymphadenopathy/ Cervical lymphadenopathy, left side	1	01NOV2020	13/C	2	No	O	NA/TC	N	N/N
	GENRL	Chills/ chills	2	12NOV2020	2/4	1	Yes		NA/TC	R (15NOV2020)	N/N
		Injection site pain/ injection site pain	2	12NOV2020	2/4	1	Yes		NA/TC	R (15NOV2020)	N/N
		Pyrexia/ pyrexia	2	12NOV2020	2/4	1	Yes		NA/TC	R (15NOV2020)	N/N
	MUSC	Myalgia/ body aches, myalgia	2	12NOV2020	2/4	1	Yes		NA/TC	R (15NOV2020)	N/N
>55/ C4591001 1235 12351206	GASTR	Toothache/ Dental Pain	2	09DEC2020	29/1	1	No	O	NA	R (09DEC2020)	N/N
>55/ C4591001 1235 12351213	GENRL	Fatigue/ Fatigue	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Chills/ Chills	2	11NOV2020	2/1	1	Yes		NA	R (11NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1235 12351220	GENRL	Pyrexia/ Pyrexia	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	13NOV2020	1/2	2	Yes		NA	R (14NOV2020)	N/N
	VASC	Hypotension/ hypotension	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
>55/ C4591001 1235 12351221	MUSC	Back pain/ BACK SORENESS	2	20NOV2020	3/1	1	Yes		NA/TC	R (20NOV2020)	N/N
	GENRL	Chills/ chills#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
	MUSC	Pain in extremity/ arm pain#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
	NERV	Headache/ headache#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
>55/ C4591001 1241 12411008	GENRL	Injection site pain/ Injection site pain	1	07AUG2020	1/1	1	Yes		NA	R (07AUG2020)	N/Y
	NERV	Headache/ Headache	1	07AUG2020	1/4	1	Yes		NA	R (10AUG2020)	N/N
>55/ C4591001 1241 12411015	GENRL	Injection site pain/ Injection site burning	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y
	INJ&P	Ankle fracture/ Fractured left ankle#	2	15FEB2021	169/1	2	No	O	NA/TC/TCN	R (15FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1241 12411035	GENRL	Fall/ Fall from stair#	2	15FEB2021	169/1	2	No	O	NA	R (15FEB2021)	N/N
		Injection site pain/ injection site pain	1	11AUG2020	1/1	1	Yes		NA	R (11AUG2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/1	2	Yes		NA/TC	R (25JAN2021)	N/N
	NERV	Headache/ Headache#	3	25JAN2021	1/1	2	Yes		NA/TC	R (25JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
>55/ C4591001 1241 12411067	GASTR	Colitis/ Inflammatory colitis	2	16DEC2020	106/C	2	No	O	NA/TC	RG	N/N
		Diverticulum intestinal/ Diverticular disease of the colon	2	16DEC2020	106/C	4	No	O	NA/TC/TCN	RG	Y/N
	INFEC	Urinary tract infection/ Urinary tract infection	2	16DEC2020	106/7	2	No	O	NA/TC	R (22DEC2020)	N/N
	IMMUN	Drug hypersensitivity/ Dipyron allergy#	2	30JAN2021	151/1	1	No	O	NA	R (30JAN2021)	N/N
	GASTR	Intestinal mass/ Mass in sigmoid#	2	08FEB2021	160/2	4	No	O	NA/TCN	RS (09FEB2021)	Y/N
	GASTR	Chronic gastritis/ Chronic pangastritis#	3	02MAR2021	7/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1241 12411092	INFEC	Conjunctivitis/ Conjunctivitis	1	18AUG2020	6/28	1	No	O	NA/TC	R (14SEP2020)	N/N
>55/ C4591001 1241 12411105	GENRL	Injection site swelling/ Injection site swelling	1	13AUG2020	1/1	1	Yes		NA	R (13AUG2020)	N/Y
	MUSC	Myalgia/ Myalgia#	3	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	2/3	1	Yes		NA/TC	R (25FEB2021)	N/N
>55/ C4591001 1241 12411117	GENRL	Injection site pain/ Injection site pain#	3	30JAN2021	2/4	1	Yes		NA	R (02FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	30JAN2021	2/4	1	Yes		NA/TC	R (02FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Left axillary lymph node enlargement#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	20FEB2021	2/3	1	Yes		NA/TC	R (22FEB2021)	N/N
	GENRL	Fatigue/ Prostration#	4	20FEB2021	2/3	1	Yes		NA/TC	R (22FEB2021)	N/N
>55/ C4591001 1241 12411160	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001	GENRL	Chills/ Chills#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411173		Fatigue/ Fatigue#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1241 12411182	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/Y
	GENRL	Fatigue/ Fatigue#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
>55/ C4591001 1241 12411187	MUSC	Back pain/ Backache	1	04SEP2020	19/1	1	No	O	NA/TC	R (04SEP2020)	N/N
>55/ C4591001 1241 12411191	GENRL	Chills/ Chills#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1241 12411193	GENRL	Fatigue/ Fatigue#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1241 12411196	NERV	Injection site pain/ Injection site pain#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		Dysgeusia/ Bitter taste	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1241 12411201	GENRL	Fatigue/ Prostration#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
	MUSC	Back pain/ Backache	1	30AUG2020	14/1	1	No	O	NA/TC	R (30AUG2020)	N/N
>55/ C4591001 1241 12411218	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N
	MUSC	Pyrexia/ Fever#	3	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N
GENRL		Myalgia/ Myalgia#	3	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N
>55/ C4591001	GENRL	Chills/ Chills#	4	22FEB2021	1/2	2	Yes		NA/TC	R (23FEB2021)	N/N
		Fatigue/ Prostration#	4	22FEB2021	1/2	2	Yes		NA/TC	R (23FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	22FEB2021	1/5	1	Yes		NA	R (26FEB2021)	N/N
		Pyrexia/ Fever#	4	22FEB2021	1/2	2	Yes		NA/TC	R (23FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	22JAN2021	2/1	1	Yes		NA	R (22JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411244 >55/ C4591001 1241 12411247	GENRL	Injection site pain/ Injection site pain#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
>55/ C4591001 1241 12411252	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
		Pyrexia/ Fever#	3	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/3	1	Yes		NA/TC	R (24FEB2021)	N/N
		Pyrexia/ Fever#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
>55/ C4591001 1241 12411306	GASTR	Diarrhoea/ Diarrhea	2	11SEP2020	2/4	2	Yes		NA	R (14SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N
		Pyrexia/ Fever#	3	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
		Pyrexia/ Fever#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Myalgia/ Myalgia#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N	
>55/ C4591001 1241 12411320	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N	
>55/ C4591001 1241 12411325	GENRL	Injection site pain/ Injection site pain#	4	18FEB2021	2/6	2	Yes		NA/TC	R (23FEB2021)	N/N	
>55/ C4591001 1241 12411340	NERV	Headache/ Headache	1	21AUG2020	2/2	1	No	O	NA/TC	R (22AUG2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N	
>55/ C4591001 1241 12411352	NERV	Headache/ Headache	2	02OCT2020	22/1	1	No	O	NA/TC	R (02OCT2020)	N/N	
>55/ C4591001 1241 12411371	MUSC	Myalgia/ myalgia#	4	09FEB2021	1/4	1	Yes		NA/TC	R (12FEB2021)	N/N	
	NERV	Headache/ Headache#	4	09FEB2021	1/4	1	Yes		NA/TC	R (12FEB2021)	N/N	
>55/ C4591001 1241 12411391	INFEC	Onychomycosis/ Second right finger onychomycosis	1	07SEP2020	19/	1	No	O	NA	R	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1241 12411392	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
>55/ C4591001 1241 12411394	GENRL	Injection site pain/ Injection site pain	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	4	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
>55/ C4591001 1241 12411404	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1241 12411406	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/4	1	Yes		NA	R (19FEB2021)	N/N
>55/ C4591001 1241 12411428	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001	INFEC	Otitis media acute/ Acute otitis media	2	10OCT2020	26/11	1	No	O	NA	R (20OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411479	GENRL	Pyrexia/ Fever	2	16SEP2020	2/1	2	Yes		NA	R (16SEP2020)	N/N	
>55/ C4591001 1241 12411485	GENRL	Fatigue/ Prostration#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N	
>55/ C4591001 1241 12411496	GENRL	Pyrexia/ Fever	2	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N	
>55/ C4591001 1241 12411498	GENRL	Fatigue/ Fatigue	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N	
1241 12411523	GENRL	Fatigue/ Fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N	
>55/ C4591001 1241 12411529	GENRL	Injection site pain/ Injection site pain#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	19FEB2021	2/1	2	Yes		NA/TCN	R (19FEB2021)	N/N	
>55/ C4591001	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/4	1	Yes		NA/TC	R (19FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411534 >55/ C4591001 1241 12411545	GENRL	Fatigue/ Fatigue	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N
		Injection site pain/ Injection site pain	1	03SEP2020	2/1	2	Yes		NA	R (03SEP2020)	N/N
	NERV	Headache/ Headache	1	03SEP2020	2/1	2	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	1/3	2	Yes		NA/TC	R (24SEP2020)	N/N
	INJ&P	Fall/ Fall from own height	2	23SEP2020	2/1	3	No	O	NA	R (23SEP2020)	N/N
	NERV	Dizziness/ Dizziness	2	23SEP2020	2/1	2	Yes		NA/TC	R (23SEP2020)	N/N
		Dizziness/ Lipothymia (Dizziness)	2	23SEP2020	2/1	3	No	O	NA	R (23SEP2020)	N/N
>55/ C4591001 1241 12411550	GENRL	Fatigue/ Fatigue	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N
		Injection site pain/ Injection site pain	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1241 12411554	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Prostration	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C4591001 1241 12411571	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1241 12411585	GENRL	Pyrexia/ Fever	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C4591001 1241 12411612	GENRL	Injection site pain/ Injection site pain#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
		Pyrexia/ Fever#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
>55/ C4591001 1241 12411614	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
	NERV	Headache/ Headache#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1241 12411615	GENRL	Injection site pain/ Injection site pain	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
>55/ C4591001 1241 12411623	GENRL	Fatigue/ Tiredness	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
		Injection site pain/ Injection site pain	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1241 12411628	GENRL	Fatigue/ Fatigue	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
>55/ C4591001 1241 12411642	NERV	Headache/ Headache#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
>55/ C4591001 1241 12411643	HEPAT	Cholecystitis acute/ Acute cholecystitis	2	24OCT2020	31/5	3	No	O	NA/TC	R (28OCT2020)	Y/N
		Cholelithiasis/ Cholelithiasis	2	24OCT2020	31/5	3	No	O	NA/TC	R (28OCT2020)	Y/N
>55/ C4591001 1241 12411644	GENRL	Chills/ Chills	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		Fatigue/ Fatigue	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Myalgia	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ Headache	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
>55/ C4591001 1241 12411669	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA/TCN	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
>55/ C4591001 1241 12411670	GENRL	Injection site pain/ Injection site pain	2	30SEP2020	2/3	2	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1241 12411671	INFEC	Vulvovaginal candidiasis/ Vaginal candidiasis	1	20SEP2020	11/4	1	No	O	NA/TC	R (23SEP2020)	N/N
	INFEC	Urinary tract infection/ Urinary tract infection	2	20OCT2020	22/7	1	No	O	NA/TC	R (26OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA/TCN	R (26JAN2021)	N/N
>55/ C4591001 1241 12411675	GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
>55/ C4591001 1241 12411676	GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1241 12411682	GENRL	Pyrexia/ Fever	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
		Injection site pain/ Injection site pain#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001 1241 12411704	GENRL	Fatigue/ Prostration#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
		Injection site pain/ Injection site pain	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1241 12411711	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ Fever	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
>55/ C4591001 1241 12411721	NERV	Headache/ Headache#	3	03FEB2021	1/1	1	Yes		NA/TC	R (03FEB2021)	N/N
>55/ C4591001 1241 12411728	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001 1241 12411732	GENRL	Injection site swelling/ Injection site swelling	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1241 12411746	MUSC	Arthralgia/ Arthralgia in the left knee	1	22SEP2020	7/6	2	Yes		NA/TC	R (27SEP2020)	N/N
		Myalgia/ Muscle pains in left shoulder	1	22SEP2020	7/6	2	Yes		NA/TC	R (27SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	02FEB2021	2/3	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	02FEB2021	2/3	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1241 12411748	GENRL	Fatigue/ Fatigue	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
>55/ C4591001 1241 12411751	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/21	1	Yes		NA	R (23FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	24FEB2021	2/3	1	Yes		NA/TC	R (26FEB2021)	N/N
>55/ C4591001 1241 12411752	GASTR	Nausea/ Nausea	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ Headache	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	07OCT2020	2/2	2	Yes		NA/TCN	R (08OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pain/ Body pain	2	07OCT2020	2/1	2	Yes		NA/TC	R (07OCT2020)	N/N
>55/ C4591001 1241 12411761	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1241 12411770	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	1/4	1	Yes		NA	R (01FEB2021)	N/N
>55/ C4591001 1241 12411788	GENRL	Chills/ Chills#	3	29JAN2021	2/2	2	Yes		NA	R (30JAN2021)	N/N
		Fatigue/ Fatigue#	3	29JAN2021	2/2	2	Yes		NA	R (30JAN2021)	N/N
		Pyrexia/ Fever#	3	29JAN2021	2/2	2	Yes		NA	R (30JAN2021)	N/N
	NERV	Headache/ Headache#	3	29JAN2021	2/2	2	Yes		NA	R (30JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
>55/ C4591001 1241 12411789	GENRL	Fatigue/ Fatigue#	3	28JAN2021	1/5	1	Yes		NA	R (01FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	28JAN2021	1/5	1	Yes		NA/TCN	R (01FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1241 12411794	MUSC	Myalgia/ Myalgia	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
>55/ C4591001 1241 12411796	GENRL	Chills/ Chills	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ Headache	1	19SEP2020	3/3	2	Yes		NA/TC	R (21SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	22SEP2020	6/3	2	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	22FEB2021	1/4	3	Yes		NA/TC	R (25FEB2021)	N/N
		Fatigue/ Fatigue#	4	22FEB2021	1/4	3	Yes		NA/TC	R (25FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	22FEB2021	1/4	3	Yes		NA/TC	R (25FEB2021)	N/N
	NERV	Dizziness/ Dizziness#	4	22FEB2021	1/4	3	Yes		NA/TC	R (25FEB2021)	N/N
		Headache/ Headache#	4	22FEB2021	1/4	3	Yes		NA/TC	R (25FEB2021)	N/N
>55/ C4591001 1241 12411811	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Fatigue/ Prostration#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Pyrexia/ Fever#	4	25FEB2021	2/1	1	Yes		NA/TC	R (25FEB2021)	N/N	
>55/ C4591001 1241 12411821	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N	
>55/ C4591001 1241 12411825	INFEC	Pyelonephritis acute/ ACUTE PYELONEPHRITIS	2	02NOV2020	26/15	2	No	O	NA/TC	R (16NOV2020)	Y/N	
	BLOOD	Hypochromic anaemia/ HYPOCHROMIC ANEMIA / MICROCYTIC	2	04NOV2020	28/20	1	No	O	NA	R (23NOV2020)	N/N	
>55/ C4591001 1241 12411829	GASTR	Gastrointestinal haemorrhage/ High digestive bleeding#	4	12MAR2021	22/C	4	No	O	NA/W	N	Y/N	
>55/ C4591001 1241 12411831	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N	
>55/ C4591001 1241 12411844	GENRL	Chills/ Chills#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N	
	GENRL	Pyrexia/ Fever#	4	19FEB2021	2/1	1	Yes		NA/TC	R (19FEB2021)	N/N	
>55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/3	2	Yes		NA/TC	R (20SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411852	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	2/2	1	Yes		NA/TC	R (30JAN2021)	N/N
	NERV	Headache/ Headache#	3	29JAN2021	2/2	1	Yes		NA/TC	R (30JAN2021)	N/N
	NERV	Headache/ Headache#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
>55/ C4591001 1241 12411876	INJ&P	Tendon rupture/ Left shoulder tendon rupture	2	08JAN2021	93/1	2	No	O	NA/TC	R (08JAN2021)	N/N
>55/ C4591001 1241 12411883	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001 1241 12411896	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11OCT2020	3/1	1	Yes		NA	R (11OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ Headache#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
>55/ C4591001 1241 12411902	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
>55/ C4591001 1241 12411910	GENRL	Chills/ Chills	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
		Fatigue/ Fatigue	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
>55/ C4591001 1241 12411916	GENRL	Pyrexia/ Fever#	4	15FEB2021	1/3	1	Yes		NA	R (17FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
>55/ C4591001 1241 12411918	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1241 12411922	INJ&P	Foot fracture/ Fracture of the third right toe#	3	28JAN2021	1/1	1	No	O	NA/TC/TCN	R (28JAN2021)	N/N
>55/ C4591001 1241 12411934	GENRL	Fatigue/ Fatigue	2	10OCT2020	2/1	2	Yes		NA/TC	R (10OCT2020)	N/N
>55/ C4591001 1241 12411938	GENRL	Chills/ Chills	2	07OCT2020	1/4	2	Yes		NA	R (10OCT2020)	N/N
		Injection site pain/ Injection site pain	2	07OCT2020	1/4	2	Yes		NA	R (10OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	07OCT2020	1/4	2	Yes		NA	R (10OCT2020)	N/N
>55/ C4591001 1241 12411946	GENRL	Fatigue/ Fatigue#	3	30JAN2021	2/1	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N
		Pyrexia/ Fever#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N
	NERV	Headache/ Headache#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N
>55/ C4591001	MUSC	Back pain/ Backache	2	07OCT2020	1/1	1	No	O	NA/TC	R (07OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411959	GENRL	Chills/ Chills#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
>55/ C4591001 1241 12411976	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
>55/ C4591001 1241 12412017	GENRL	Injection site pain/ Injection site pain	2	21OCT2020	1/1	1	Yes		NA	R (21OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
		Pyrexia/ Fever#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1241 12412021	GASTR	Abdominal pain lower/ Abdominal pain in hypogastrium	2	23OCT2020	5/62	1	No	O	NA/TC	R (23DEC2020)	N/N
	INFEC	Urinary tract infection/ Urinary tract infection	2	23OCT2020	5/62	1	No	O	NA/TC	R (23DEC2020)	N/N
>55/ C4591001 1241 12412033	MUSC	Myalgia/ Myalgia	2	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1241 12412040	GENRL	Chills/ Chills#	3	30JAN2021	2/1	1	Yes		NA	R (30JAN2021)	N/N	
		Fatigue/ Prostration#	3	30JAN2021	2/1	1	Yes		NA	R (30JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N	
>55/ C4591001 1241 12412042	GENRL	Chills/ Chills	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N	
		Fatigue/ Fatigue	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N	
		Injection site pain/ Injection site pain	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N	
		Injection site pruritus/ Injection site itching	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N	
		Injection site swelling/ Injection site swelling	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N	
		NERV	Headache/ Headache	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Chills/ Chills	2	20OCT2020	1/2	1	Yes		NA/TC	R (21OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	20OCT2020	1/2	1	Yes		NA/TC	R (21OCT2020)	N/N	
>55/ C4591001	GENRL	Pyrexia/ Fever	2	20OCT2020	1/2	1	Yes		NA/TC	R (21OCT2020)	N/N	
		Fatigue/ Fatigue#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12412047		Injection site pain/ Injection site pain#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N	
>55/ C4591001 1241 12412075	GENRL	Chills/ Chills	1	01OCT2020	1/1	1	Yes		NA	R (01OCT2020)	N/N	
		Injection site pain/ Injection site pain	1	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N	
	GENRL	Chills/ Chills	2	20OCT2020	1/1	1	Yes		NA/TC	R (20OCT2020)	N/N	
		Injection site pain/ Injection site pain	2	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N	
>55/ C4591001 1241 12412077	GENRL	Chills/ Chills	2	22OCT2020	1/1	1	Yes		NA	R (22OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N	
>55/ C4591001 1241 12412079	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	19FEB2021	1/2	2	Yes		NA	R (20FEB2021)	N/N	
		Injection site pain/ Injection site pain#	4	19FEB2021	1/2	2	Yes		NA	R (20FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Pyrexia/ Fever#	4	19FEB2021	1/2	2	Yes		NA/TC	R (20FEB2021)	N/N	
>55/ C4591001 1241 12412085	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N	
>55/ C4591001 1241 12412115	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N	
		Pyrexia/ Fever#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N	
>55/ C4591001 1241 12412125	GENRL	Injection site pain/ Injection site pain	1	03OCT2020	2/4	1	Yes		NA/TCN	R (06OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N	
>55/ C4591001 1241 12412129	NERV	Headache/ Headache#	3	23JAN2021	2/1	1	Yes		NA/TC	R (23JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N	
	NERV	Headache/ Headache#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N	
>55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412145	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
>55/ C4591001 1241 12412164	GENRL	Fatigue/ Prostration#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
		Pyrexia/ Fever#	4	19FEB2021	2/1	1	Yes		NA/TC	R (19FEB2021)	N/N
>55/ C4591001 1241 12412178	GENRL	Chills/ Chills	2	04NOV2020	1/1	1	Yes		NA/TC	R (04NOV2020)	N/N
		Injection site pain/ Injection site pain	2	04NOV2020	1/1	1	Yes		NA	R (04NOV2020)	N/N
		Pyrexia/ Fever	2	04NOV2020	1/1	1	Yes		NA/TC	R (04NOV2020)	N/N
>55/ C4591001 1241 12412189	GENRL	Chills/ Chills#	4	24FEB2021	2/3	1	Yes		NA	R (26FEB2021)	N/N
		Fatigue/ Fatigue#	4	24FEB2021	2/3	1	Yes		NA	R (26FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	24FEB2021	2/3	1	Yes		NA	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	4	24FEB2021	2/3	1	Yes		NA	R (26FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1241 12412191	NERV	Amnesia/ Transitional global amnesia	2	09NOV2020	4/3	3	No	O	NA/TC	R (11NOV2020)	N/N	
		Dizziness/ Dizziness	2	09NOV2020	4/2	3	No	O	NA/TC	R (10NOV2020)	N/N	
	PSYCH	Disorientation/ Disorientation to clarify	2	09NOV2020	4/4	3	No	O	NA/TC	R (12NOV2020)	Y/N	
>55/ C4591001 1241 12412196	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	
>55/ C4591001 1241 12412205	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N	
>55/ C4591001 1241 12412219	GENRL	Injection site pain/ Injection site pain	1	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	07NOV2020	2/2	2	Yes		NA	R (08NOV2020)	N/N	
>55/ C4591001 1241 12412220	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N	
>55/ C4591001	GENRL	Pyrexia/ Fever#	4	17FEB2021	2/1	1	Yes		NA/TC	R (17FEB2021)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412238 >55/ C4591001 1241 12412241	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	1/1	1	Yes		NA	R (16OCT2020)	N/N
1241 12412241	GENRL	Injection site pain/ Injection site pain	2	07NOV2020	2/2	1	Yes		NA	R (08NOV2020)	N/N
>55/ C4591001 1241 12412242	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	1/2	1	Yes		NA/TCN	R (17OCT2020)	N/N
>55/ C4591001 1241 12412263	INFEC	Respiratory tract infection viral/ Respiratory Tract Viral infection	2	10DEC2020	36/9	2	No	O	NA/TC	R (18DEC2020)	Y/N
>55/ C4591001 1241 12412266	GENRL	Injection site pain/ Injection site pain#	3	30JAN2021	2/3	1	Yes		NA	R (01FEB2021)	N/N
>55/ C4591001 1241 12412272	GENRL	Fatigue/ Fatigue	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
>55/ C4591001 1241 12412273	GENRL	Fatigue/ Fatigue	2	07NOV2020	2/3	2	Yes		NA/TC	R (09NOV2020)	N/N
	GENRL	Injection site pain/ Injection site tenderness#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Myalgia#	3	05FEB2021	2/7	1	Yes		NA/TC	R (11FEB2021)	N/N
>55/ C4591001 1241 12412297	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
>55/ C4591001 1241 12412300	GENRL	Fatigue/ Prostration	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
>55/ C4591001 1241 12412305	GENRL	Injection site pain/ Injection site pain	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
>55/ C4591001 1241 12412309	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	29JAN2021	1/2	1	Yes		NA/TC	R (30JAN2021)	N/N
>55/ C4591001 1241 12412310	GENRL	Fatigue/ Fatigue	2	10NOV2020	2/2	2	Yes		NA	R (11NOV2020)	N/N
>55/ C4591001 1241 12412319	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/4	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	1/4	1	Yes		NA	R (26FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1241 12412325	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N
>55/ C4591001 1241 12412340	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
>55/ C4591001 1241 12412349	GENRL	Injection site pain/ Injection site pain	2	12NOV2020	2/5	1	Yes		NA	R (16NOV2020)	N/N
		Injection site swelling/ Injection site swelling	2	12NOV2020	2/5	1	Yes		NA	R (16NOV2020)	N/N
>55/ C4591001 1241 12412356	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/4	1	Yes		NA	R (22OCT2020)	N/N
>55/ C4591001 1241 12412359	GENRL	Injection site pain/ Injection site pain	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N
>55/ C4591001 1241 12412384	GENRL	Fatigue/ Fatigue#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
>55/ C4591001	GASTR	Diarrhoea/ Diarrhea	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412483 >55/ C4591001 1241 12412484	GENRL	Fatigue/ Prostration	2	12NOV2020	1/2	2	Yes		NA	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	12NOV2020	1/2	2	Yes		NA	R (13NOV2020)	N/N
>55/ C4591001 1241 12412487	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Chills/ Chills#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
>55/ C4591001 1241 12412488	GENRL	Chills/ Chills	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
		Fatigue/ Fatigue	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Chills/ Chills	2	12NOV2020	1/2	1	Yes		NA/TC	R (13NOV2020)	N/N
		Injection site pain/ Injection site pain	2	12NOV2020	1/1	1	Yes		NA/TC	R (12NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1241 12412497	GENRL	Pyrexia/ Fever	2	12NOV2020	1/2	1	Yes		NA/TC	R (13NOV2020)	N/N
		Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
>55/ C4591001 1241 12412499	GENRL	Fatigue/ Fatigue	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
		Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
>55/ C4591001 1241 12412503	GENRL	Pyrexia/ Fever	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
		Injection site pain/ Injection site pain	2	12NOV2020	1/2	2	Yes		NA/TC	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	12NOV2020	1/2	2	Yes		NA/TC	R (13NOV2020)	N/N
>55/ C4591001 1241 12412503	GENRL	Chills/ Chills#	4	19FEB2021	2/1	1	Yes		NA/TC	R (19FEB2021)	N/N
>55/ C4591001 1241 12412511	MUSC	Myalgia/ Myalgia#	4	18FEB2021	1/1	1	Yes		NA/TC	R (18FEB2021)	N/N
>55/ C4591001 1241 12412521	GENRL	Fatigue/ Fatigue	2	12NOV2020	1/4	1	Yes		NA	R (15NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1241 12412522	SURG	Tooth extraction/ Dental extraction	2	08DEC2020	27/1	1	No	O	NA/TC	R (08DEC2020)	N/N
>55/ C4591001 1241 12412524	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
>55/ C4591001 1241 12412526	GENRL	Pain/ Body pain	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
>55/ C4591001 1241 12412533	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/1	2	Yes		NA/TC	R (11FEB2021)	N/N
>55/ C4591001 1241 12412541	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
>55/ C4591001 1241 12412542	GENRL	Injection site pain/ Injection site pain	1	24OCT2020	2/3	1	Yes		NA	R (26OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Injection site pain/ Injection site pain	2	13NOV2020	2/4	2	Yes		NA	R (16NOV2020)	N/N	
>55/ C4591001 1241 12412555	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	13NOV2020	2/3	2	Yes		NA/TC	R (15NOV2020)	N/N	
>55/ C4591001 1246 12461013	GENRL	Injection site pain/ Painfull Left arm at injection site#	3	02FEB2021	2/2	1	Yes		NA/TC	R (03FEB2021)	N/N	
>55/ C4591001 1246 12461035	GENRL	Non-cardiac chest pain/ REFERRED NON-CARDIAC CHEST PAIN	2	10NOV2020	22/3	3	No	O	NA/TCN	R (12NOV2020)	Y/N	
	GASTR	Gastroesophageal reflux disease/ Reflux esophagitis	2	12NOV2020	24/C	2	No	O	NA/TC	RG	N/N	
		Hiatus hernia/ Hiatus hernia	2	12NOV2020	24/C	2	No	O	NA/TC/TCN	RG	N/N	
>55/ C4591001 1247 12471007	GENRL	Chills/ Chills#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N	
		Injection site pain/ local injection site pain#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N	
	MUSC	Arthralgia/ Generalized joint pain#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N	
>55/ C4591001	INJ&P	Fall/ Fall	1	13OCT2020	19/1	2	No	O	NA	R (13OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1247 12471039		Rib fracture/ Right 9th rib fractured	1	13OCT2020	19/15	2	No	O	NA/TC	R (27OCT2020)	N/N	
	GENRL	Pyrexia/ Fever#	4	23FEB2021	1/2	1	Yes		NA/TC	R (24FEB2021)	N/N	
	PSYCH	Confusional state/ Acute Confusion#	4	23FEB2021	1/2	1	No	O	NA	R (24FEB2021)	N/N	
>55/ C4591001 1247 12471083	MUSC	Arthralgia/ Arthralgia (knees and Hips)#	4	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N	
		Myalgia/ muscle pain#	4	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N	
>55/ C4591001 1247 12471093	INFEC	Nasopharyngitis/ Common cold*		29SEP2020	-7/7	1	No	O	NA	R (05OCT2020)	N/N	
	PSYCH	Insomnia/ Insomnia	1	23OCT2020	18/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1247 12471094	INFEC	Oral herpes/ Herpes Simplex of the lip	1	09OCT2020	11/7	1	No	O	NA/TC	R (15OCT2020)	N/N	
	GENRL	Chills/ Chills#	4	03MAR2021	1/1	1	Yes		NA/TC	R (03MAR2021)	N/N	
	RESP	Rhinorrhoea/ Runny nose#	4	05MAR2021	3/2	1	Yes		NA	R (06MAR2021)	N/N	
>55/ C4591001	GENRL	Injection site pain/ Local injection site pain#	3	29JAN2021	2/7	1	Yes		NA	R (04FEB2021)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1247 12471095 >55/ C4591001 1247 12471135	NERV	Cerebral infarction/ Left Middle Cerebral Artery Infarct	1	21OCT2020	22/C	3	No	O	P/TC/TCN	N	Y/N
	NERV	Cerebellar infarction/ Chronic cerebelar infarcts	1	23OCT2020	24/C	1	No	O	NA	N	N/N
		Cerebral atrophy/ Cerebral atrophy	1	23OCT2020	24/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ Local injection site pain#	3	17FEB2021	2/C	1	Yes		NA	RG	N/N
>55/ C4591001 1247 12471180	GENRL	Chills/ Chills	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
		Fatigue/ Fatigue	1	07OCT2020	2/6	2	Yes		NA	R (12OCT2020)	N/N
			1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
		Pyrexia/ Fever	1	07OCT2020	2/2	2	Yes		NA/TC	R (08OCT2020)	N/N
	MUSC	Arthralgia/ Generalised joint pain	1	07OCT2020	2/2	3	Yes		NA/TC	R (08OCT2020)	N/N
	NERV	Headache/ Headache	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
		Headache/ headache	1	07OCT2020	2/6	2	Yes		NA/TC	R (12OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	08OCT2020	3/4	1	Yes		NA	R (11OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1247 12471187			1	08OCT2020	3/2	1	Yes		NA	R (09OCT2020)	N/N
	MUSC	Arthralgia/ Generalized joint pain	1	08OCT2020	3/3	2	Yes		NA	R (10OCT2020)	N/N
	NERV	Headache/ Headache	1	08OCT2020	3/5	1	Yes		NA/TC	R (12OCT2020)	N/N
	MUSC	Arthralgia/ Generalized joint pain	1	11OCT2020	6/3	1	Yes		NA	R (13OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ Headache	1	08OCT2020	3/2	1	Yes		NA/TC	R (09OCT2020)	N/N
	NERV	Headache/ Headache	2	28OCT2020	2/2	2	Yes		NA	R (29OCT2020)	N/N
>55/ C4591001 1247 12471188	MUSC	Myalgia/ Muscle Pain	2	29OCT2020	3/2	2	Yes		NA	R (30OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain#	2	08MAR2021	133/2	1	Yes		NA	R (09MAR2021)	N/N
	GENRL	Fatigue/ Fatigue	1	08OCT2020	3/1	1	Yes		NA	R (08OCT2020)	N/N
>55/ C4591001 1247 12471216	GASTR	Diarrhoea/ Diarrhea	1	12OCT2020	7/2	2	Yes		NA	R (13OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	08OCT2020	2/3	2	Yes		NA	R (10OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1247 12471219	MUSC	Injection site pain/ Injection site pain	1	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N	
		Myalgia/ Muscle pain	1	09OCT2020	3/1	1	Yes		NA	R (09OCT2020)	N/N	
	GENRL	Chills/ Chills	1	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N	
		Injection site erythema/ injection site redness	1	09OCT2020	2/3	1	Yes		NA	R (11OCT2020)	N/N	
		Injection site pain/ Injection site pain	1	09OCT2020	2/3	1	Yes		NA	R (11OCT2020)	N/N	
	MUSC	Injection site swelling/ Injection site swelling	1	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N	
		Arthralgia/ Joint pain	1	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N	
>55/ C4591001 1247 12471229	GENRL	Myalgia/ Muscle pain	1	09OCT2020	2/3	1	Yes		NA	R (11OCT2020)	N/N	
		Injection site pain/ Injection site pain	2	29OCT2020	1/2	1	Yes		NA/TC	R (30OCT2020)	N/N	
>55/ C4591001 1247 12471249	GASTR	Abnormal faeces/ Change in bowel habits (change in stool consistency)	2	NOV2020	4/C	1	No	O	NA	N	N/N	
		Frequent bowel movements/ Change in bowel habits (increase in number of stools per day)	2	NOV2020	4/C	1	No	O	NA	N	N/N	
>55/ C4591001	GENRL	Injection site pain/ Injection Site Reaction (pain)	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1248 12481002 >55/ C4591001 1248 12481015	GENRL	Chills/ Chills#	4	05FEB2021	1/2	2	Yes		NA	R (06FEB2021)	N/N
		Fatigue/ fatigue#	4	05FEB2021	1/3	2	Yes		NA/TC	R (07FEB2021)	N/N
		Pyrexia/ Fever#	4	05FEB2021	1/2	2	Yes		NA/TC	R (06FEB2021)	N/N
>55/ C4591001 1248 12481020	GENRL	Injection site pain/ Injection site reaction (pain)	1	29AUG2020	2/3	2	Yes		NA	R (31AUG2020)	N/N
>55/ C4591001 1248 12481021	MUSC	Pain in extremity/ Left arm pain	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
>55/ C4591001 1248 12481027	GENRL	Chills/ Chills	2	20SEP2020	1/2	1	Yes		NA	R (21SEP2020)	N/N
		Injection site pain/ Injection site Pain	2	20SEP2020	1/2	1	Yes		NA/TC	R (21SEP2020)	N/N
		Pain/ Bodyaches	2	20SEP2020	1/2	1	Yes		NA/TC	R (21SEP2020)	N/N
>55/ C4591001 1248 12481028	MUSC	Myalgia/ Muscle Soreness#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1248 12481029	GENRL	Injection site pain/ Left Arm Pain at Injection Site Reaction	1	29AUG2020	1/4	2	Yes		NA	R (01SEP2020)	N/Y
>55/ C4591001 1248 12481040	GENRL	Injection site pruritus/ Injection Site Reaction Itching Mild	1	31AUG2020	2/3	1	Yes		NA	R (02SEP2020)	N/N
		Injection site swelling/ Injection Site Reaction Swelling	1	31AUG2020	2/3	1	No	O	NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Injection site (pain)	2	20SEP2020	1/1	1	Yes		NA/TC	R (20SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	21SEP2020	2/1	1	Yes		NA/TC	R (21SEP2020)	N/N
>55/ C4591001 1248 12481041	GASTR	Diarrhoea/ Diarrhea	1	02SEP2020	4/1	2	No	O	NA	R (02SEP2020)	N/N
>55/ C4591001 1248 12481047	GENRL	Injection site pain/ Injection Site Reaction Pain	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Reaction(pain)	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Fatigue/ Fatigue	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
>55/ C4591001	GENRL	Injection site haemorrhage/ Injection Site Reaction(ecchymosis)	2	19SEP2020	2/23	1	Yes		NA	R (11OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1248 12481049		Injection site mass/ Injection Site Reaction (Lump/Knot)	2	19SEP2020	2/7	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Dizziness/ Dizziness	2	13OCT2020	26/C	1	No	O	NA	RG	N/N
>55/ C4591001 1248 12481058	MUSC	Arthralgia/ Right Knee Pain	1	12SEP2020	12/7	1	No	O	NA/TC	R (18SEP2020)	N/N
>55/ C4591001 1248 12481064	INV	Blood pressure increased/ Elevated Blood Pressure#	3	13JAN2021	22/52	1	No	O	NA/TC	R (05MAR2021)	N/N
>55/ C4591001 1248 12481083	GASTR	Abdominal pain upper/ Stomachache	1	23SEP2020	19/2	1	No	O	NA/TC	R (24SEP2020)	N/N
>55/ C4591001 1248 12481084	GENRL	Chills/ Chills	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		Injection site pain/ Injection Site pain	2	25SEP2020	1/3	1	Yes		NA/TC	R (27SEP2020)	N/N
		Pain/ Body aches	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ Headache	2	25SEP2020	1/3	1	Yes		NA/TC	R (27SEP2020)	N/N
>55/ C4591001	GENRL	Injection site pain/ Right Arm soreness(Injection Site)	1	06SEP2020	1/2	1	Yes		NA	R (07SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1248 12481090 >55/ C4591001 1248 12481105	NERV	Burning sensation/ Burning Sensation in Leg	1	28SEP2020	20/2	1	No	O	NA	R (29SEP2020)	N/N
>55/ C4591001 1248 12481120	CARD	Cardiac failure acute/ Acute Heart Failure	1	23SEP2020	13/C	3	No	O	NA	RG	Y/N
>55/ C4591001 1248 12481124	GENRL	Injection site pain/ injection Site Pain	2	03OCT2020	1/2	2	Yes		NA/TC	R (04OCT2020)	N/N
>55/ C4591001 1248 12481128	NERV	Headache/ Headache	1	12SEP2020	1/2	1	Yes		NA/TC	R (13SEP2020)	N/N
>55/ C4591001 1248 12481132	GENRL	Fatigue/ Tiredness	1	12SEP2020	1/3	1	Yes		NA	R (14SEP2020)	N/N
		Injection site pain/ Injection Site Reaction Pain	1	12SEP2020	1/3	1	Yes		NA	R (14SEP2020)	N/Y
	METAB	Decreased appetite/ Decreased Appetite	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	15SEP2020	4/3	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	1	15SEP2020	4/3	1	Yes		NA/TC	R (17SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	NERV	Hypoaesthesia/ Facial numbness#	4	29JAN2021	1/11	1	No	O	NA	R (08FEB2021)	N/N
		Paraesthesia/ Facial Tingling#	4	29JAN2021	1/11	1	No	O	NA	R (08FEB2021)	N/N
>55/ C4591001 1248 12481139	NERV	Headache/ Headache	1	13SEP2020	2/2	1	Yes		NA/TC	R (14SEP2020)	N/N
>55/ C4591001 1248 12481140	GENRL	Injection site pain/ injection site reaction-Left upper arm pain	1	12SEP2020	1/3	1	Yes		NA	R (14SEP2020)	N/N
>55/ C4591001 1248 12481142	INV	Body temperature increased/ Increase Temperature	1	14SEP2020	2/2	1	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ Headache	1	14SEP2020	2/1	1	Yes		NA	R (14SEP2020)	N/N
>55/ C4591001 1248 12481148	GENRL	Injection site pain/ Injection site Pain	1	13SEP2020	1/4	1	Yes		NA	R (16SEP2020)	N/N
>55/ C4591001 1248 12481163	NERV	Headache/ Headache (R sided headache around R eye)	1	03OCT2020	20/3	1	No	O	NA/TC	R (05OCT2020)	N/N
	INFEC	Brain abscess/ Brain abscess	2	10OCT2020	6/C	4	No	O	NA/TCN	RG	Y/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Sinusitis/ Sinusitis	2	10OCT2020	6/C	3	No	O	NA/TCN	RG	N/N	
>55/ C4591001 1248 12481184	GENRL	Injection site reaction/ Injection Site Reaction	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N	
>55/ C4591001 1248 12481203	GENRL	Fatigue/ fatigue#	4	13JAN2021	2/11	1	Yes		NA	R (23JAN2021)	N/N	
		Injection site pain/ Injection site soreness#	4	13JAN2021	2/14	1	Yes		NA	R (26JAN2021)	N/N	
	MUSC	Myalgia/ muscle pain#	4	13JAN2021	2/11	1	Yes		NA	R (23JAN2021)	N/N	
	NERV	Headache/ Headache#	4	13JAN2021	2/11	1	Yes		NA	R (23JAN2021)	N/N	
>55/ C4591001 1248 12481207	GENRL	Injection site pain/ Left Arm Pain at injection	1	18SEP2020	1/33	1	Yes		NA	R (20OCT2020)	N/N	
>55/ C4591001 1248 12481241	GENRL	Injection site pain/ Pain in site of injection right arm	2	14OCT2020	2/56	1	Yes		NA	R (08DEC2020)	N/N	
>55/ C4591001 1251 12511028	INJ&P	Foot fracture/ broken right foot	2	23SEP2020	13/C	3	No	O	NA/TC/TCN	RG	N/N	
>55/ C4591001	INJ&P	Ankle fracture/ Shattered Ankle/Tibia#	2	24FEB2021	154/2	3	No	O	NA/TC/TCN	RS (25FEB2021)	Y/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1251 12511029 >55/ C4591001	VASC	Hypertension/ exacerbation of hypertension	1	04SEP2020	11/C	3	No	O	NA	RG	Y/N
1251 12511050 >55/ C4591001	MUSC	Arthralgia/ B/L knee soreness	1	28AUG2020	4/1	1	Yes		NA	R (28AUG2020)	N/N
1251 12511055 >55/ C4591001	GENRL	Chills/ Chills	1	26AUG2020	2/1	1	No	O	NA	R (26AUG2020)	N/N
1251 12511056 >55/ C4591001	GASTR	Nausea/ nausea	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
1251 12511063	GENRL	Chills/ chills	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ headache	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1251 12511071	GENRL	Chills/ Chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
>55/ C4591001 1251 12511072	NEOPL	Uterine cancer/ Uterine Cancer	2	28JAN2021	134/1	4	No	O	NA/TC/TCN	R (28JAN2021)	Y/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1251 12511087	MUSC	Arthralgia/ worsening of left shoulder pain	1	02SEP2020	3/C	2	Yes		NA/TC	N	N/N
	MUSC	Exostosis/ Bone spur left shoulder	1	06OCT2020	37/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1251 12511110	GENRL	Vaccination site swelling/ Left arm swelling at injection site after flu shot	2	15OCT2020	23/4	1	No	O	NA/TC	R (18OCT2020)	N/N
>55/ C4591001 1251 12511116	MUSC	Myalgia/ muscle aches	1	10SEP2020	8/5	1	Yes		NA	R (14SEP2020)	N/N
>55/ C4591001 1251 12511145	INJ&P	Spinal fracture/ Broken Vertebrae#	3	08MAR2021	13/3	3	No	O	NA/TCN	R (10MAR2021)	Y/N
>55/ C4591001 1251 12511151	EYE	Retinal detachment/ Detached Retina	2	09OCT2020	10/6	3	No	O	NA/TCN	RS (14OCT2020)	N/N
>55/ C4591001 1251 12511158	GENRL	Injection site pain/ Pain at Injection Site Left Deltoid	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Chills/ Chills	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
		Fatigue/ Fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1251 12511167	GENRL	Malaise/ Malaise	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
		Chills/ chills	2	06OCT2020	2/1	1	Yes		NA/TCN	R (06OCT2020)	N/N
	RESP	Oropharyngeal pain/ sore throat	2	06OCT2020	2/3	1	Yes		NA/TC	R (08OCT2020)	N/N
>55/ C4591001 1251 12511186	IMMUN	Drug hypersensitivity/ Allergic Reaction to Investigational product	2	11OCT2020	3/28	2	Yes		NA/TC	R (07NOV2020)	N/N
	SKIN	Rash/ Rash Chin Elbows Knees Neck back	2	11OCT2020	3/30	1	Yes		NA/TC	R (09NOV2020)	N/N
	GASTR	Swollen tongue/ Tongue Swelling	2	30OCT2020	22/9	2	Yes		NA	R (07NOV2020)	N/N
	RESP	Pharyngeal swelling/ Throat Swelling	2	30OCT2020	22/9	2	Yes		NA	R (07NOV2020)	N/N
>55/ C4591001 1251 12511200	GENRL	Injection site pain/ pain at injection site left deltoid	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	INV	Blood pressure systolic increased/ Elevated systolic blood pressure (142)	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C4591001 1251 12511203	GASTR	Diarrhoea/ Diarrhea	1	28SEP2020	6/1	1	Yes		NA/TC	R (28SEP2020)	N/N
>55/ C4591001	GASTR	Abdominal pain/ Abdominal Pain	1	30OCT2020	17/1	3	No	O	NA/TC	R (30OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1251 12511243		Nausea/ nausea	1	30OCT2020	17/1	3	No	O	NA/TC	R (30OCT2020)	N/N	
>55/ C4591001 1251 12511244	RESP	Epistaxis/ worsening of epistaxis right nostril	1	27OCT2020	13/1	1	Yes		NA	R (27OCT2020)	N/N	
>55/ C4591001 1251 12511250	RESP	Epistaxis/ worsening of epistaxis right nostril	1	02NOV2020	19/1	1	Yes		NA	R (02NOV2020)	N/N	
>55/ C4591001 1251 12511250	MUSC	Arthralgia/ increased pain with activities-right knee	2	02DEC2020	22/C	4	No	O	NA/TC/TCN	RG	Y/N	
>55/ C4591001 1252 12521010	INJ&P	Skin laceration/ Scalp Laceration	2	08DEC2020	92/1	1	No	O	NA/TC	R (08DEC2020)	N/N	
	INFEC	COVID-19 pneumonia/ Pneumonia due to COVID-19	2	25DEC2020	109/2	4	No	O	NA/TC/W	F (26DEC2020)	Y/N	
	RENAL	Acute kidney injury/ Acute Renal failure	2	25DEC2020	109/2	2	No	O	NA/TC	R (26DEC2020)	N/N	
>55/ C4591001 1252 12521011	BLOOD	Anaemia/ Anemia	2	06JAN2021	120/5	1	No	O	NA	R (10JAN2021)	N/N	
	INFEC	Sepsis/ Sepsis	2	06JAN2021	120/5	2	No	O	NA/TC	R (10JAN2021)	N/N	
	INV	Lymphocyte count decreased/ Low Lymphocytes	2	06JAN2021	120/5	1	No	O	NA	R (10JAN2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1254 12541001	METAB	Platelet count decreased/ Low platelets	2	06JAN2021	120/5	1	No	O	NA	R (10JAN2021)	N/N
		Troponin increased/ Elevated Troponin	2	06JAN2021	120/5	2	No	O	NA	R (10JAN2021)	N/N
		Hyperkalaemia/ Hyperkalemia	2	06JAN2021	120/5	1	No	O	NA	R (10JAN2021)	N/N
		Chronic obstructive pulmonary disease/ COPD exacerbation	2	06JAN2021	120/5	3	No	O	NA/TC	R (10JAN2021)	Y/N
		Respiratory failure/ Chronic Hypoxic respiratory failure	2	06JAN2021	120/5	2	No	O	NA	R (10JAN2021)	N/N
	GENRL	Injection site pain/ Soreness at injection site#	3	16JAN2021	1/2	1	Yes		NA	R (17JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Injection site pain/ injection site soreness	1	26AUG2020	1/2	2	Yes		NA	R (27AUG2020)	N/N
	GENRL	Fatigue/ fatigue	1	31AUG2020	6/5	2	Yes		NA	R (04SEP2020)	N/N
>55/ C4591001 1254 12541006	GENRL	Chills/ Chills#	4	17FEB2021	2/2	1	Yes		NA/W	R (18FEB2021)	N/N
>55/ C4591001 1254 12541009	INFEC	Urinary tract infection/ Urinary Tract Infection	2	15DEC2020	91/32	1	No	O	NA/TC	R (15JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection Site Soreness#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
>55/ C4591001 1254 12541010	GASTR	Diarrhoea/ diarrhea	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
	GASTR	Diarrhoea/ diarrhea	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1254 12541011	GENRL	Fatigue/ Fatigue	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ chills	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		Fatigue/ fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Pain/ bodyache	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C4591001 1254 12541012	SKIN	Rash/ LEFT LOWER EXTREMITY RASH	1	02SEP2020	7/18	1	No	O	NA	R (19SEP2020)	N/N
	SKIN	Blister/ ONE BLISTER (2.5 INCHES BELOW INJECTION SITE)	2	16SEP2020	1/4	1	No	O	NA	R (19SEP2020)	N/N
	INJ&P	Fall/ fall	2	23DEC2020	99/1	2	No	O	NA	R (23DEC2020)	N/N
	MUSC	Musculoskeletal chest pain/ unilateral rib cage pain	2	23DEC2020	99/43	2	No	O	NA/TC	R (03FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Soreness at injection site#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
		Injection site swelling/ Swelling at injection site#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	24FEB2021	1/4	2	Yes		NA	R (27FEB2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	24FEB2021	1/4	1	Yes		NA	R (27FEB2021)	N/N
	GENRL	Pain/ Body ache#	4	25FEB2021	2/3	2	Yes		NA	R (27FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/3	2	Yes		NA	R (27FEB2021)	N/N
>55/ C4591001 1254 12541014	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	INFEC	Clostridium difficile colitis/ Clostridium Difficile Colitis#	2	21JAN2021	126/12	4	No	O	NA/TC	R (01FEB2021)	Y/N
>55/ C4591001 1254 12541015	GENRL	Injection site pain/ Soreness at Injection Site#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	04FEB2021	2/3	1	Yes		NA	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
>55/ C4591001	GENRL	Fatigue/ Fatigue#	3	20JAN2021	2/3	1	Yes		NA	R (22JAN2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1254 12541017		Injection site pain/ Injection site soreness#	3	20JAN2021	2/3	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1254 12541018	GENRL	Fatigue/ Fatigue	1	28AUG2020	1/6	2	Yes		NA	R (02SEP2020)	N/N
	RESP	Rhinorrhoea/ Runny Nose	1	31AUG2020	4/3	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	19SEP2020	1/4	2	Yes		NA	R (22SEP2020)	N/N
		Pain/ bodyache	2	19SEP2020	1/4	1	Yes		NA/TC	R (22SEP2020)	N/N
	NERV	Headache/ headache	2	20SEP2020	2/3	1	Yes		NA/TC	R (22SEP2020)	N/N
>55/ C4591001 1254 12541021	GENRL	Injection site pain/ Injection Site Soreness#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
>55/ C4591001 1254 12541022	GENRL	Fatigue/ Fatigue#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001	GENRL	Injection site pain/ Injection site soreness#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine Subject	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1254 12541024	GENRL	Fatigue/ Fatigue#	4	05FEB2021	2/2	2	Yes	NA	NA	R (06FEB2021)	N/N
>55/ C4591001 1254 12541025	GENRL	Injection site pain/ SORENESS OF INJECTION SITE	2	19SEP2020	2/4	1	Yes	NA	NA	R (22SEP2020)	N/N
>55/ C4591001 1254 12541026	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	18SEP2020	1/3	1	Yes	NA/TC	NA/TC	R (20SEP2020)	N/N
>55/ C4591001 1254 12541037	GENRL	Fatigue/ FATIGUE	2	19SEP2020	2/3	1	Yes	NA	NA	R (21SEP2020)	N/N
>55/ C4591001 1254 12541045	GENRL	Injection site pain/ Injection site pain	1	29AUG2020	1/2	1	Yes	NA	NA	R (30AUG2020)	N/N
>55/ C4591001 1254 12541047	GENRL	Injection site pain/ Soreness at Injection Site#	3	21JAN2021	1/2	1	Yes	NA	NA	R (22JAN2021)	N/N
>55/ C4591001 1254 12541047	GENRL	Injection site pain/ INJECTION SITE PAIN	1	31AUG2020	1/4	1	Yes	NA	NA	R (03SEP2020)	N/N
	GENRL	Chills/ chills	2	23SEP2020	1/2	1	Yes	NA	NA	R (24SEP2020)	N/N
		Injection site pain/ soreness at injection site	2	23SEP2020	1/3	1	Yes	NA	NA	R (25SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1254 12541048		Pain/ bodyache	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	VASC	Hypertension/ hypertension	2	02OCT2020	10/C	2	No	O	NA/TC	RG	N/N
	MUSC	Psoriatic arthropathy/ worsening of psoriatic arthritis	2	09OCT2020	17/22	2	No	O	NA/TC	R (30OCT2020)	N/N
	GASTR	Gastroesophageal reflux disease/ gastric reflux	2	16OCT2020	24/15	2	No	O	NA/TC	R (30OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
		Injection site pain/ SORENESS AT INJECTION SITE	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
		Injection site swelling/ SWELLING SLIGHTLY BELOW INJECTION SITE	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Paraesthesia/ TINGLING SENSATION IN BOTH ARMS	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Injection site soreness#	3	15JAN2021	1/3	1	Yes		NA	R (17JAN2021)	N/N
NERV	Headache/ Mild Headache#	4	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N	
GENRL	Fatigue/ Fatigue#	4	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N	
	Injection site pain/ Injection Site Soreness#	4	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1254 12541059	GENRL	Fatigue/ Worsening of Fatigue	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	NERV	Headache/ Headache	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ worsening of fatigue	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ headache	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
>55/ C4591001 1254 12541065	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
	INFEC	Cellulitis/ RIGHT FIRST TOE CELLULITIS	1	10SEP2020	9/31	1	No	O	NA	R (10OCT2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
	MUSC	Tendonitis/ L hand tendonitis	2	NOV2020	38/C	2	No	O	NA/TC	N	N/N
>55/ C4591001 1254 12541074	GENRL	Injection site pain/ Injection site soreness#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
	GASTR	Nausea/ Nausea#	3	23JAN2021	4/1	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	10FEB2021	1/4	1	Yes		NA/TC	R (13FEB2021)	N/N
	GENRL	Pain/ Body Ache#	4	11FEB2021	2/1	1	Yes		NA/TC	R (11FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1254 12541076	GENRL	Injection site pain/ left arm pain at injection site	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
		Injection site pain/ Soreness at Injection Site#	3	23DEC2020	2/3	1	Yes		NA	R (25DEC2020)	N/N
	NERV	Headache/ Headache#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
	NERV	Dizziness/ Dizziness#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	13JAN2021	2/33	1	Yes		NA	R (14FEB2021)	N/N
>55/ C4591001 1254 12541078	GENRL	Fatigue/ Fatigue#	3	30JAN2021	2/2	1	No	O	NA	R (31JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
>55/ C4591001 1254 12541085	GENRL	Injection site pain/ Soreness at Injection Site#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1254 12541088	GENRL	Fatigue/ FATIGUE	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of Vaccine	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1254 12541093	GENRL	Injection site pain/ injection site soreness L arm#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	19FEB2021	3/2	2	Yes		NA	R (20FEB2021)	N/N
		Pain/ bodyache#	4	19FEB2021	3/2	2	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ headache#	4	19FEB2021	3/2	2	Yes		NA/TC	R (20FEB2021)	N/N
>55/ C4591001 1254 12541095	GENRL	Injection site pain/ Left upper extremity pain at injection site	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
	INFEC	Tooth infection/ dental infection	1	05SEP2020	2/8	2	No	O	NA/TC	R (12SEP2020)	N/N
>55/ C4591001 1254 12541096	GENRL	Injection site pain/ soreness at injection site in left arm	1	04SEP2020	1/5	1	Yes		NA	R (08SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
>55/ C4591001 1254 12541097	GENRL	Injection site pain/ soreness at injection site	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
	METAB	Hyperlipidaemia/ Worsening Hyperlipidemia	2	01DEC2020	68/C	2	No	O	NA/TC	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1254 12541098	GENRL	Injection site pain/ Pain at the Injection Site#	4	09JAN2021	1/2	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Pyrexia/ Fever at 100.7 F#	4	10JAN2021	2/1	2	Yes		NA/TC	R (10JAN2021)	N/N
	GENRL	Fatigue/ fatigue	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
	INJ&P	Skin laceration/ right hand laceration	1	24SEP2020	21/22	1	No	O	NA/TC	R (15OCT2020)	N/N
	GENRL	Chills/ chills	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		Fatigue/ fatigue	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		Injection site pain/ soreness at injection site	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
		Pain/ bodyache	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		Pyrexia/ fever at 101.0F	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
>55/ C4591001 1254 12541103	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	06SEP2020	2/3	1	Yes		NA	R (08SEP2020)	N/N
	GASTR	Nausea/ nausea	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Dizziness/ dizziness	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1254 12541106	GENRL	Headache/ headache	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		Pyrexia/ fever 102F	2	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N
>55/ C4591001 1254 12541106	GENRL	Injection site pain/ injection site soreness	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
>55/ C4591001 1254 12541108	GASTR	Abdominal discomfort/ Abdominal Discomfort	2	27OCT2020	29/8	2	No	O	NA/TC	R (03NOV2020)	N/N
>55/ C4591001 1254 12541122	GENRL	Injection site pain/ Soreness at Injection Site#	3	16JAN2021	1/3	1	Yes		NA	R (18JAN2021)	N/N
>55/ C4591001 1254 12541125	GENRL	Chills/ Chills#	4	04FEB2021	1/1	1	Yes		NA	R (04FEB2021)	N/Y
	GENRL	Injection site pain/ Injection Site Pain#	4	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N
		Pain/ Body ache#	4	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N
		Fatigue/ Fatigue#	4	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
		Pyrexia/ Fever of 101.4F#	4	05FEB2021	2/1	2	Yes		NA/TC	R (05FEB2021)	N/N
		Injection site pain/ Mild Injection Site Soreness#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1254 12541127	GENRL	Injection site pain/ INJECTION SITE TENDERNESS	1	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	02OCT2020	1/3	2	Yes		NA	R (04OCT2020)	N/N
		Injection site pain/ Soreness at injection site	2	02OCT2020	1/2	2	Yes		NA/TC	R (03OCT2020)	N/N
		Pyrexia/ Fever of 100.6F	2	02OCT2020	1/2	2	Yes		NA/TC	R (03OCT2020)	N/N
>55/ C4591001 1254 12541128	GENRL	Fatigue/ FATIGUE	1	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	12SEP2020	2/3	2	Yes		NA/TC	R (14SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at Injection Site#	3	16JAN2021	1/2	1	Yes		NA	R (17JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1254 12541130	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	02OCT2020	1/3	2	Yes		NA/TC	R (04OCT2020)	N/N
>55/ C4591001 1254 12541132	GENRL	Injection site pain/ Injection Site Soreness#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1254 12541137	INV	Body temperature increased/ Elevated Body Temperature of 100.2F#	4	06FEB2021	2/1	2	Yes		NA/TC	R (06FEB2021)	N/N
	GENRL	Injection site pain/ injection site soreness#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	13FEB2021	1/2	1	Yes		NA	R (14FEB2021)	N/N
>55/ C4591001 1254 12541138	INV	Body temperature increased/ Elevated Temperature of 99.2F#	4	14FEB2021	2/2	1	Yes		NA	R (15FEB2021)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	12SEP2020	2/2	2	Yes		NA	R (13SEP2020)	N/N
	GASTR	Nausea/ nausea	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Chills/ chills	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
		Fatigue/ fatigue	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
		Injection site pain/ pain at injection site	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
>55/ C4591001		Pain/ bodyache	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
		Pyrexia/ fever at 100.5F	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	2	23JAN2021	113/1	1	Yes		NA	R (23JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1254 12541141	GASTR	Dyspepsia/ indigestion	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)	N/N
>55/ C4591001 1254 12541143	GENRL	Fatigue/ MILD FATIGUE	1	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N
1254 12541146		Injection site pain/ INJECTION SITE SORENESS	1	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at Injection Site#	3	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ Soreness at Injection Site#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
>55/ C4591001 1254 12541149	GENRL	Injection site pain/ pain at injection site	1	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
		Pain/ bodyache	1	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
	NERV	Headache/ headache	1	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	06OCT2020	1/3	1	Yes		NA/TC	R (08OCT2020)	N/N
	GENRL	Pain/ generalized body ache	2	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N
	NERV	Headache/ headache	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1254 12541156	GENRL	Chills/ Chills#	4	12FEB2021	2/2	2	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1254 12541160	GENRL	Chills/ Chills#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N
		Fatigue/ Fatigue#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N
		Injection site pain/ Soreness at Injection Site#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N
	NERV	Headache/ Headache#	3	23JAN2021	1/2	2	Yes		NA/TC	R (24JAN2021)	N/N
	GENRL	Chills/ Chills#	4	14FEB2021	2/1	1	Yes		NA	R (14FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	4	14FEB2021	2/1	1	Yes		NA	R (14FEB2021)	N/N
		Pain/ Body Ache#	4	14FEB2021	2/1	1	Yes		NA	R (14FEB2021)	N/N
>55/ C4591001 1254 12541192	GENRL	Injection site pain/ injection site soreness	1	18OCT2020	2/20	1	Yes		NA	R (06NOV2020)	N/N
	GASTR	Diarrhoea/ diarrhea	2	08NOV2020	2/2	1	Yes		NA	R (09NOV2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE SORENESS	2	08NOV2020	2/3	1	Yes		NA	R (10NOV2020)	N/N
	NERV	Headache/ Headaches	2	08NOV2020	2/2	2	Yes		NA/TC	R (09NOV2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1254 12541197	GENRL	Fatigue/ Fatigue#	3	16JAN2021	1/3	1	Yes		NA	R (18JAN2021)	N/N
		Injection site pain/ Injection Site Soreness#	3	16JAN2021	1/3	2	Yes		NA/TC	R (18JAN2021)	N/N
	MUSC	Back pain/ Back Pain#	3	16JAN2021	1/1	1	Yes		NA	R (16JAN2021)	N/N
	MUSC	Musculoskeletal stiffness/ Stiff Neck#	3	02FEB2021	18/4	1	No	O	NA	R (05FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	4	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N
	MUSC	Back pain/ Lower Back Pain#	4	04FEB2021	1/2	2	Yes		NA/TC	R (05FEB2021)	N/N
>55/ C4591001 1254 12541200	GENRL	Pyrexia/ Fever at 100.3F	1	22OCT2020	2/1	1	Yes		NA/TC	R (22OCT2020)	N/N
>55/ C4591001 1254 12541203	GENRL	Injection site erythema/ redness at injection site	1	24OCT2020	1/3	1	Yes		NA	R (26OCT2020)	N/N
		Injection site pain/ soreness at injection site	1	24OCT2020	1/2	1	Yes		NA	R (25OCT2020)	N/N
	NERV	Headache/ headache	1	24OCT2020	1/2	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Chills/ Chills#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1254 12541207	NERV	Fatigue/ Fatigue#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
		Headache/ Headache#	3	26JAN2021	1/2	2	Yes		NA	R (27JAN2021)	N/N	
	PSYCH	Insomnia/ Insomnia#	3	JAN2021	1/C	2	No	O	NA/TC	N	N/N	
	GENRL	Pyrexia/ Fever of 101.4F#	4	16FEB2021	1/2	2	Yes		NA/TC	R (17FEB2021)	N/N	
	GASTR	Nausea/ Nausea#	4	17FEB2021	2/1	2	Yes		NA	R (17FEB2021)	N/N	
	GENRL	Injection site pain/ Injection Site Soreness#	Pain/ Body ache#	4	17FEB2021	2/5	2	Yes		NA/TC	R (21FEB2021)	N/N
			Headache/ Headache#	4	17FEB2021	2/3	2	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	17FEB2021	2/2	2	Yes		NA/TC	R (18FEB2021)	N/N	
	GENRL	Injection site pain/ injection site soreness	1	24OCT2020	1/2	1	Yes		NA	R (25OCT2020)	N/N	
	GENRL	Injection site pain/ soreness at injection site	2	14NOV2020	1/4	2	Yes		NA	R (17NOV2020)	N/N	
	MUSC	Pain in extremity/ general soreness in both arms	2	14NOV2020	1/3	2	Yes		NA	R (16NOV2020)	N/N	
	GENRL		Chills/ chills	2	15NOV2020	2/1	1	Yes		NA	R (15NOV2020)	N/N
			Pain/ body ache	2	15NOV2020	2/3	2	Yes		NA/TC	R (17NOV2020)	N/N
Pyrexia/ Fever 101.7F			2	15NOV2020	2/2	2	Yes		NA/TC	R (16NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1260 12601003	GENRL	Injection site pain/ soreness at injection site	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C4591001 1260 12601008	GENRL	Chills/ chills	1	27AUG2020	2/2	2	Yes		NA	R (28AUG2020)	N/N
		Fatigue/ fatigue	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
		Injection site pain/ soreness at injection site	1	27AUG2020	2/5	2	Yes		NA	R (31AUG2020)	N/N
	MUSC	Arthralgia/ increased aches in joints	1	27AUG2020	2/2	2	Yes		NA/TC	R (28AUG2020)	N/N
		Myalgia/ muscle pain	1	27AUG2020	2/2	2	Yes		NA	R (28AUG2020)	N/N
	NERV	Headache/ headache	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	NERV	Headache/ headache	1	30AUG2020	5/2	1	Yes		NA	R (31AUG2020)	N/N
	GASTR	Diarrhoea/ diarrhea	2	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
	GENRL	Pain/ generalized body aches	2	17SEP2020	1/2	2	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ headache	2	17SEP2020	1/2	2	Yes		NA/TC	R (18SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Arm soreness at injection site only when exposed to cold temperature	2	04NOV2020	49/9	1	Yes		NA	R (12NOV2020)	N/N
>55/ C4591001 1260 12601015	GENRL	Injection site pain/ mild arm pain injection site/soreness at the injection site#	3	23JAN2021	2/1	1	Yes		NA/TC	R (23JAN2021)	N/N
>55/ C4591001 1260 12601019	GENRL	Injection site pain/ Soreness at injection site	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/N
>55/ C4591001 1260 12601020	MUSC	Myalgia/ generalized muscle aches	2	19SEP2020	2/5	2	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
>55/ C4591001 1260 12601021	NERV	Headache/ headache	1	30AUG2020	3/2	1	Yes		NA	R (31AUG2020)	N/N
	NERV	Headache/ headache	1	02SEP2020	6/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ shoulder soreness at injection site#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/Y
	RESP	Rhinorrhoea/ runny nose#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/Y
	GENRL	Injection site pain/ soreness at the injection site#	4	04FEB2021	1/1	1	Yes		NA	R (04FEB2021)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1260 12601025	GENRL	Fatigue/ fatigue#	4	05FEB2021	2/1	1	Yes		NA/TC	R (05FEB2021)	N/N
	MUSC	Myalgia/ muscle soreness#	4	05FEB2021	2/1	1	Yes		NA/TC	R (05FEB2021)	N/N
	GASTR	Nausea/ nausea#	4	07FEB2021	4/1	1	Yes		NA	R (07FEB2021)	N/N
	MUSC	Arthralgia/ joint pain#	4	07FEB2021	4/1	1	Yes		NA	R (07FEB2021)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	31AUG2020	1/4	2	Yes		NA	R (03SEP2020)	N/N
	GASTR	Nausea/ nausea	1	01SEP2020	2/1	2	Yes		NA	R (01SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	01SEP2020	2/1	2	Yes		NA	R (01SEP2020)	N/N
	NERV	Headache/ headache	1	01SEP2020	2/1	2	Yes		NA	R (01SEP2020)	N/N
	GASTR	Nausea/ nausea	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
>55/ C4591001 1260 12601026	NERV	Headache/ headache	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	01SEP2020	2/2	2	Yes		NA	R (02SEP2020)	N/N
		Injection site pain/ soreness at injection site	1	01SEP2020	2/2	2	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1260 12601027	GENRL	Injection site pain/ soreness at the injection site	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
		Pain/ generalized aches	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
	NERV	Headache/ headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Injection site pain/ soreness at injection site	1	03SEP2020	4/1	1	Yes		NA	R (03SEP2020)	N/N	
	GENRL	Chills/ chills	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
		Pyrexia/ fever	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
	MUSC	Myalgia/ generalized muscle aches	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N	
	NERV	Headache/ sporadic intense headache in the back of his head	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N	
	>55/ C4591001 1260 12601030	GENRL	Injection site pain/ soreness at the injection site#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	>55/ C4591001 1260 12601031	GENRL	Injection site pain/ soreness at the injection site#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1260 12601033	GENRL	Injection site pain/ left arm slightly tender at area of injection	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1260 12601035	GENRL	Injection site erythema/ redness at injection site	2	24SEP2020	4/5	1	Yes		NA	R (28SEP2020)	N/N
		Injection site pain/ soreness at injection site	2	24SEP2020	4/8	1	Yes		NA	R (01OCT2020)	N/N
		Injection site warmth/ warmth at injection site	2	24SEP2020	4/5	1	Yes		NA	R (28SEP2020)	N/N
	NERV	Headache/ headache	1	01SEP2020	2/28	2	Yes		NA/TC	R (28SEP2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	INJ&P	Fall/ fall from walking dog#	3	31JAN2021	19/3	1	No	O	NA/TC	R (02FEB2021)	N/N
		Lip injury/ lip laceration#	3	31JAN2021	19/3	1	No	O	NA/TC	R (02FEB2021)	N/N
		Subdural haematoma/ traumatic subdural hemorrhage#	3	31JAN2021	19/3	3	No	O	NA/TC	R (02FEB2021)	N/N
		Tooth fracture/ chipped teeth#	3	31JAN2021	19/5	1	No	O	NA/TC	R (04FEB2021)	N/N
		Traumatic intracranial haemorrhage/ traumatic subarachnoid hemorrhage#	3	31JAN2021	19/3	3	No	O	NA/TC	R (02FEB2021)	Y/N
>55/ C4591001 1260 12601037	NEOPL	Meningioma/ calcified meningioma#	3	31JAN2021	19/3	2	No	O	NA/TC	R (02FEB2021)	N/N
	NERV	Arachnoid cyst/ arachnoid cyst#	3	31JAN2021	19/3	2	No	O	NA/TC	R (02FEB2021)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	02SEP2020	2/3	1	Yes		NA	R (04SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Soreness at injection site	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	GASTR	Small intestinal obstruction/ small bowel obstruction	2	29OCT2020	38/8	3	No	O	NA/TC/TCN	R (05NOV2020)	Y/N
>55/ C4591001 1260 12601039	GENRL	Injection site pain/ soreness at injection site	1	01SEP2020	1/4	2	Yes		NA/TC	R (04SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	23SEP2020	2/8	1	Yes		NA	R (30SEP2020)	N/N
		Pain/ Generalized Body Aches	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C4591001 1260 12601040	GENRL	Fatigue/ exhausted/fatigued#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
		Injection site pain/ soreness at the injection site#	4	13FEB2021	2/3	1	Yes		NA	R (15FEB2021)	N/N
>55/ C4591001 1260 12601041	GENRL	Injection site pain/ soreness at injection site	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ soreness at injection site	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N
		Injection site swelling/ swollen at injection site	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1260 12601046	NERV	Headache/ headache	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	VASC	Flushing/ flushed all over	2	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Chills/ chills	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ muscle aches in thighs	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Pain/ soreness around left axillary area	2	24SEP2020	3/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Chills/ chills	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Injection site erythema/ redness at injection site	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Pyrexia/ fever 100.4	2	23SEP2020	2/2	2	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C4591001 1260 12601051	NERV	Headache/ headache	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	16OCT2020	26/2	1	No	O	NA/TC	R (17OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1260 12601052	GENRL	Injection site pain/ soreness at the injection site#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1260 12601053	GENRL	Injection site pain/ soreness at injection site	2	07OCT2020	17/3	1	No	O	NA	R (09OCT2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	18DEC2020	1/4	1	Yes		NA	R (21DEC2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
>55/ C4591001 1260 12601054	GENRL	Injection site pain/ soreness at the injection site#	3	11JAN2021	1/11	1	Yes		NA/TC	R (21JAN2021)	N/N
	GENRL	Injection site pain/ arm soreness at injection site#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
>55/ C4591001 1260 12601056	GENRL	Injection site pain/ soreness at injection site	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ Soreness in injected arm	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	PSYCH	Sleep disorder/ Unsettled sleep	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Musculoskeletal stiffness/ Generalized body stiffness	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1260 12601060	NERV	Headache/ Mild Headache	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	05SEP2020	2/2	2	Yes		NA/TC	R (06SEP2020)	N/N
	MUSC	Injection site pain/ left arm pain at injection site	1	05SEP2020	2/2	2	Yes		NA/TC	R (06SEP2020)	N/N
>55/ C4591001 1260 12601062	MUSC	Back pain/ back pain	2	01OCT2020	9/4	1	No	O	NA/TC	R (04OCT2020)	N/N
	MUSC	Pain in extremity/ left leg pain	2	01OCT2020	9/4	1	No	O	NA/TC	R (04OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C4591001 1260 12601064	GENRL	Chills/ chills#	2	12FEB2021	143/2	1	Yes		NA/TC	R (13FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	2	12FEB2021	143/2	1	Yes		NA/TC	R (13FEB2021)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	2	12FEB2021	143/2	1	Yes		NA/TC	R (13FEB2021)	N/N
	GENRL	Injection site erythema/ redness at injection site	1	06SEP2020	3/4	1	Yes		NA	R (09SEP2020)	N/N
	NERV	Injection site pain/ soreness at injection site	1	06SEP2020	3/4	1	Yes		NA	R (09SEP2020)	N/N
	NERV	Migraine without aura/ intermittent migraines without aura	1	06SEP2020	3/4	2	Yes		NA	R (09SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue	1	08SEP2020	5/2	2	Yes		NA	R (09SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	25SEP2020	2/5	1	Yes		NA	R (29SEP2020)	N/N
		Injection site pain/ Soreness at injection site	2	25SEP2020	2/5	1	Yes		NA	R (29SEP2020)	N/N
	NERV	Headache/ Headache	2	25SEP2020	2/5	1	Yes		NA	R (29SEP2020)	N/N
>55/ C4591001 1260 12601066	GENRL	Fatigue/ fatigue#	4	11FEB2021	2/4	1	Yes		NA	R (14FEB2021)	N/N
		Injection site pain/ soreness at the injection site#	4	11FEB2021	2/4	1	Yes		NA	R (14FEB2021)	N/N
>55/ C4591001 1260 12601069	INFEC	Appendicitis/ acute appendicitis	2	05OCT2020	12/3	2	No	O	NA/TC/TCN	R (07OCT2020)	Y/N
	VASC	Aortic aneurysm/ abdominal aortic aneurysm	2	07OCT2020	14/C	2	No	O	NA	N	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	20JAN2021	2/3	1	Yes		NA/TC	R (22JAN2021)	N/N
	MUSC	Back pain/ lower back soreness#	3	20JAN2021	2/3	1	Yes		NA/TC	R (22JAN2021)	N/N
	MUSC	Back pain/ slight backache#	4	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N
>55/ C4591001 1260 12601071	GENRL	Fatigue/ fatigue	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1260 12601072	GENRL	Injection site pain/ soreness at injection site	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
		Fatigue/ fatigue	2	24SEP2020	1/4	2	Yes		NA	R (27SEP2020)	N/N
		Pain/ body aches	2	24SEP2020	1/3	2	Yes		NA/TC	R (26SEP2020)	N/N
	NERV	Headache/ headache	1	24SEP2020	21/1	1	No	O	NA	R (24SEP2020)	N/N
			2	24SEP2020	1/3	2	Yes		NA/TC	R (26SEP2020)	N/N
		Injection site pain/ soreness at the injection site	1	05SEP2020	2/1	2	Yes		NA/TC	R (05SEP2020)	N/N
>55/ C4591001 1260 12601073	NERV	Headache/ headache	1	05SEP2020	2/1	2	Yes		NA/TC	R (05SEP2020)	N/N
	MUSC	Arthralgia/ Soreness Left Knee	1	21SEP2020	18/12	2	No	O	NA/TC	R (02OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	3	12JAN2021	2/3	1	Yes		NA	R (14JAN2021)	N/N
>55/ C4591001 1260 12601078	GENRL	Injection site pain/ soreness at the injection site#	3	12JAN2021	2/3	1	Yes		NA	R (14JAN2021)	N/N
		Fatigue/ fatigue	1	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N
		Injection site discomfort/ arm heaviness at injection area	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1260 12601079	GENRL	Pain/ body aches	1	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N	
		Pain/ Body aches (generalized)	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N	
	GENRL	Injection site pain/ soreness at injection site	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
	GASTR	Nausea/ nausea#	4	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N	
	GENRL	Chills/ chills#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N	
	NERV	Pyrexia/ fever#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N	
		Headache/ headache#	4	11FEB2021	2/4	1	Yes		NA/TC	R (14FEB2021)	N/N	
		GENRL	Injection site pain/ Soreness at the injection site	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	>55/ C4591001 1260 12601080	GENRL	Injection site pain/ soreness at injection site	1	08SEP2020	1/4	2	Yes		NA	R (11SEP2020)	N/N
	>55/ C4591001 1260 12601081	GENRL	Fatigue/ fatigue	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
>55/ C4591001 1260 12601087	GASTR	Nausea/ nausea#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ tired/fatigue#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
		Injection site pain/ soreness at the injection site#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
>55/ C4591001 1260 12601090	GENRL	Injection site pain/ soreness at injection site	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
>55/ C4591001 1260 12601093	NERV	Headache/ headache	1	02OCT2020	24/1	1	No	O	NA/TC	R (02OCT2020)	N/N
	SKIN	Rash/ facial rash	2	04OCT2020	3/8	1	Yes		NA/TC	R (11OCT2020)	N/N
>55/ C4591001 1260 12601095	GENRL	Injection site pain/ soreness at injection site	1	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N
	IMMUN	Food allergy/ allergic reaction to swedish ice cream	1	21SEP2020	13/2	2	No	O	NA/TC	R (22SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
>55/ C4591001 1260 12601101	GENRL	Injection site pain/ Soreness at injection site#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Chills/ chills#	4	10FEB2021	1/4	1	Yes		NA	R (13FEB2021)	N/N
		Fatigue/ fatigue#	4	10FEB2021	1/4	1	Yes		NA	R (13FEB2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1260 12601102	GENRL	Injection site pain/ pain at injection site#	4	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Injection site pain/ Soreness at injection site#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Chills/ chills#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
>55/ C4591001 1260 12601103		Fatigue/ fatigue#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ headache#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	1/5	2	Yes		NA	R (14SEP2020)	N/N
>55/ C4591001 1260 12601109	NERV	Migraine without aura/ migraine (no aura)	1	30SEP2020	21/2	2	No	O	NA/TC	R (01OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Chills/ chills	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/Y
	GENRL	Fatigue/ fatigue	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1260 12601124	GENRL	Pain/ generalized body aches	2	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
		Injection site pain/ soreness at injection site	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Fatigue/ fatigue	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ fever	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Myalgia/ generalized myalgia	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
	MUSC	Pyrexia/ Fever (max 100.4)	2	08OCT2020	2/2	2	Yes		NA/TC	R (09OCT2020)	N/N
Myalgia/ Muscle Ache (generalized)		2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N	
>55/ C4591001 1260 12601131	GENRL	Injection site pain/ soreness at injection site	1	19SEP2020	2/1	2	Yes		NA/TC	R (19SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
>55/ C4591001 1261 12611003	GENRL	Pyrexia/ Fever	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1261 12611012	MUSC	Myalgia/ Diffuse myalgia	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site pain#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N
	NERV	Paraesthesia/ Left arm parasthesia#	3	30DEC2020	1/C	1	Yes		NA	N	N/N
	GENRL	Fatigue/ Fatigue#	4	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
	NERV	Headache/ Headache#	4	20JAN2021	2/1	1	Yes		NA/TC	R (20JAN2021)	N/N
>55/ C4591001 1261 12611014	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	MUSC	Muscular weakness/ Left Arm weakness	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	NERV	Dizziness/ Dizziness	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
>55/ C4591001 1261 12611019	GENRL	Fatigue/ Fatigue#	4	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N
	MUSC	Myalgia/ Diffuse myalgia#	4	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N
>55/ C4591001 1261 12611021	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/4	1	Yes		NA	R (26SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1261 12611037	NERV	Headache/ Headache	2	23SEP2020	2/4	1	Yes		NA	R (26SEP2020)	N/N	
	GENRL	Pyrexia/ Fever	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N	
	INJ&P	Vaccination complication/ Vaccine reaction	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N	
	MUSC	Myalgia/ Diffuse Myalgia	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N	
	NERV	Headache/ Headache	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N	
>55/ C4591001 1261 12611048	GASTR	Hiatus hernia/ Heartburn r/t hiatal hernia	2	23OCT2020	29/C	2	No	O	NA/TC	N	N/N	
	METAB	Hyperlipidaemia/ Hyperlipidemia	2	24OCT2020	30/C	2	No	O	NA/TC	N	N/N	
	GASTR	Aphthous ulcer/ Canker sore	2	25OCT2020	31/4	2	No	O	NA/TC	R (28OCT2020)	N/N	
	GASTR	Hiatus hernia/ Hiatal hernia#	2	19JAN2021	117/C	2	No	O	NA/TC	N	N/N	
	MUSC	Arthralgia/ Left shoulder pain	2	29SEP2020	2/C	2	No	O	NA/TC/TCN	N	N/N	
>55/ C4591001 1261 12611055		Neck pain/ Neck pain	2	29SEP2020	2/C	2	No	O	NA/TC/TCN	N	N/N	
	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site pain	2	30SEP2020	1/5	1	Yes		NA	R (04OCT2020)	N/N
>55/ C4591001 1261 12611066	GENRL	Fatigue/ Fatigue#	4	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001 1261 12611068	MUSC	Myalgia/ Myalgia - lower back and neck	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
>55/ C4591001 1261 12611069	GENRL	Chills/ CHILLS - ADVERSE REACTION TO VACCINATION 2	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		Pyrexia/ FEVER SECONDARY TO VACCINATION 2	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
	MUSC	Myalgia/ MYALGIA - ADVERSE REACTION TO VACCINATION 2	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
>55/ C4591001 1261 12611072	GENRL	Fatigue/ Fatigue#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
>55/ C4591001 1261 12611073	GENRL	Pyrexia/ Fever	1	13SEP2020	3/3	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Injection site pain/ Injection site arm pain	2	02OCT2020	1/4	1	Yes		NA/TC	R (05OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pyrexia/ fever	2	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
>55/ C4591001 1261 12611075	GENRL	Injection site pain/ Injection site arm pain#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
	GENRL	Chills/ Chills#	4	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
		Fatigue/ Fatigue#	4	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	4	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
>55/ C4591001 1261 12611076	GENRL	Injection site pain/ Left arm injection site pain	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C4591001 1261 12611079	GENRL	Injection site pain/ Injection site arm pain	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
>55/ C4591001 1261 12611081	GENRL	Injection site pain/ Injection site arm tenderness/pain	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
	CARD	Coronary artery disease/ Worsening coronary artery disease	2	28OCT2020	24/23	2	No	O	NA/TCN	R (19NOV2020)	N/N
	GENRL	Injection site pain/ Injection site arm pain#	3	27JAN2021	13/1	1	Yes		NA	R (27JAN2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1264 12641030	INJ&P	Tendon rupture/ Quadriceps tendon tear	1	01SEP2020	10/C	2	No	O	NA/TC	N	N/N	
>55/ C4591001 1264 12641031	MUSC	Arthralgia/ Shoulder pain	2	09OCT2020	27/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1264 12641038	GENRL	Feeling hot/ Warm sensation in the body (no fever when measured)	1	26AUG2020	3/2	2	Yes		NA/TC	R (27AUG2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N	
>55/ C4591001 1264 12641039	GENRL	Injection site pain/ injection site pain*		24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/N	
>55/ C4591001 1264 12641054	GENRL	Injection site pain/ Injection site tenderness	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N	
>55/ C4591001 1264 12641057	GENRL	Injection site pain/ Injection site pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N	
>55/ C4591001 1264 12641059	GASTR	Toothache/ Tooth pain	1	13SEP2020	19/C	2	No	O	NA/TC	RG	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Pain in jaw/ Jaw pain	1	13SEP2020	19/C	2	No	O	NA/TC	RG	N/N	
>55/ C4591001 1264 12641063	MUSC	Psoriatic arthropathy/ Psoriatic arthritis flare	1	28AUG2020	2/21	2	Yes		NA/TC	R (17SEP2020)	N/N	
	EYE	Blepharospasm/ Right eyelid muscle spasm	1	13SEP2020	18/C	1	No	O	NA	N	N/N	
>55/ C4591001 1264 12641077	GENRL	Injection site pain/ Injection site pain*		28AUG2020	1/3	1	No	O	NA	R (30AUG2020)	N/N	
>55/ C4591001 1264 12641097	GENRL	Fatigue/ Fatigue	2	21SEP2020	1/4	2	Yes		NA	R (24SEP2020)	N/N	
		Pyrexia/ Fever	2	21SEP2020	1/4	1	Yes		NA	R (24SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	21SEP2020	1/4	2	Yes		NA/TC	R (24SEP2020)	N/N	
>55/ C4591001 1264 12641099	SKIN	Rash/ Skin rash on left hip	1	17SEP2020	16/9	2	No	O	NA/TC	R (25SEP2020)	N/N	
	GASTR	Eructation/ Burps with fishy after taste	1	19SEP2020	18/34	1	No	O	NA	R (22OCT2020)	N/N	
	NERV	Dizziness/ Dizziness	2	18OCT2020	25/1	1	No	O	NA	R (18OCT2020)	N/N	
>55/ C4591001	NERV	Disturbance in attention/ Concentration impairment	2	26SEP2020	2/1	2	Yes		NA	R (26SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1264 12641112 >55/ C4591001 1264 12641117	RESP	Throat irritation/ Scratchy throat	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
	GASTR	Diarrhoea/ diarrhea	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N
	METAB	Hyperglycaemia/ Hyperglycemia	2	27SEP2020	4/8	1	No	O	NA	R (04OCT2020)	N/N
>55/ C4591001 1264 12641121	GENRL	Injection site pain/ Pain at injection site	2	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
		Malaise/ Malaise	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C4591001 1264 12641133	GASTR	Nausea/ Nausea	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
	NERV	Headache/ Headache	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
	CARD	Myocardial infarction/ Myocardial Infarction#	2	20FEB2021	146/9	4	No	O	NA/TC	RG (28FEB2021)	Y/N
>55/ C4591001 1264 12641137	VASC	Hypertension/ Hypertension	1	17SEP2020	9/C	2	No	O	NA/TC	RG	N/N
>55/ C4591001	GENRL	Fatigue/ Fatigue	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1264 12641149 >55/ C4591001 1264 12641155	GENRL	Injection site pain/ Pain at injection site	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
	RESP	Dyspnoea exertional/ Shortness of breath with minor exertion	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
>55/ C4591001 1264 12641174	GASTR	Abdominal pain upper/ Stomachache	2	06OCT2020	1/2	1	No	O	NA	R (07OCT2020)	N/N
>55/ C4591001 1264 12641180	GENRL	Injection site pain/ Injection site pain	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
	NERV	Headache/ Headache	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
		Lethargy/ Lethargy	2	12OCT2020	1/4	1	Yes		NA	R (15OCT2020)	N/N
>55/ C4591001 1264 12641195	GASTR	Cheilitis/ Cheilitis	1	07OCT2020	16/34	2	Yes		NA/TC	R (09NOV2020)	N/N
		Dry mouth/ Dry mouth	1	07OCT2020	16/C	2	Yes		P	N	N/N
	NERV	Dysgeusia/ Dysgeusia	1	07OCT2020	16/38	1	Yes		NA	R (13NOV2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	SKIN	Parosmia/ Hyperosmia	1	07OCT2020	16/38	1	Yes		NA	R (13NOV2020)	N/N	
		Eczema/ Worsening eczema	1	07OCT2020	16/C	2	Yes		P	N	N/N	
		Pruritus/ Pruritus, abdomen	1	07OCT2020	16/C	2	Yes		P/TCN	N	N/N	
		Rash maculo-papular/ Rash maculo-papular, abdomen	1	07OCT2020	16/C	1	Yes		P/TCN	N	N/N	
>55/ C4591001 1264 12641198	GENRL	Chills/ Chills	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N	
>55/ C4591001 1264 12641217	GENRL	Injection site pain/ Injection site pain	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N	
		Fatigue/ Fatigue	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N	
>55/ C4591001 1264 12641222	GENRL	Pyrexia/ Fever	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	09NOV2020	1/4	1	Yes		NA	R (12NOV2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N	
	MUSC	Myalgia/ Myalgia (generalized)	2	17NOV2020	5/2	1	Yes		NA/TC	R (18NOV2020)	N/N	
	PSYCH	Listless/ listlessness	2	18DEC2020	36/2	1	No	O	NA	R (19DEC2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1264 12641223	GENRL	Injection site warmth/ Heat at injection site	1	23OCT2020	1/1	1	Yes		NA	R (23OCT2020)	N/N
	NERV	Headache/ Headache	1	23OCT2020	1/1	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	13NOV2020	1/3	1	Yes		NA	R (15NOV2020)	N/N
			2	13NOV2020	1/3	1	Yes		NA	R (15NOV2020)	N/N
	NERV	Headache/ Headache	2	13NOV2020	1/3	1	Yes		NA	R (15NOV2020)	N/N
>55/ C4591001 1264 12641229	RESP	Pulmonary embolism/ Pulmonary embolism	2	07DEC2020	22/C	4	No	O	NA/TC	RG	Y/N
>55/ C4591001 1264 12641230	GENRL	Injection site pain/ Injection site pain	2	16NOV2020	1/2	1	Yes		NA	R (17NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	20JAN2021	2/3	1	No	O	NA	R (22JAN2021)	N/N
>55/ C4591001 1265 12651005	GENRL	Chills/ Chills#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
		Fatigue/ Fatigue#	4	11JAN2021	1/2	2	Yes		NA	R (12JAN2021)	N/N
		Injection site pain/ Muscle pain at injection site#	4	11JAN2021	1/3	2	Yes		NA	R (13JAN2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1265 12651011	GENRL	Pain/ Body aches#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
		Fatigue/ Fatigue	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
>55/ C4591001 1265 12651012	GENRL	Pyrexia/ Fever	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ Muscle pain at injection site#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
>55/ C4591001 1265 12651019	SURG	Dental implantation/ Dental implant	1	17SEP2020	21/1	1	No	O	NA/TCN	R (17SEP2020)	N/N
>55/ C4591001 1265 12651026	GENRL	Pyrexia/ Fever	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
	GASTR	Diverticulum/ Diverticulosis	1	16SEP2020	17/1	1	No	O	NA	R (16SEP2020)	N/N
>55/ C4591001 1265 12651048	NEOPL	Haemorrhoids/ Internal hemorrhoids	1	16SEP2020	17/1	1	No	O	NA	R (16SEP2020)	N/N
	MUSC	Adenoma benign/ Tubular adenoma	1	16SEP2020	17/1	1	No	O	NA/TCN	R (16SEP2020)	N/N
		Myalgia/ Muscle pain	2	24SEP2020	2/6	1	Yes		NA	R (29SEP2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1265 12651051	GENRL	Injection site pain/ Pain at injection site, left deltoid#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	NERV	Headache/ Headache#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	02FEB2021	2/C	2	Yes		NA	N	N/N
	GENRL	Chills/ Chills#	4	22FEB2021	1/C	2	Yes		NA	N	N/N
		Pyrexia/ Fever#	4	22FEB2021	1/4	2	Yes		NA	R (25FEB2021)	N/N
	MUSC	Myalgia/ Muscle ache#	4	22FEB2021	1/C	2	Yes		NA	N	N/N
	NERV	Headache/ Headache#	4	22FEB2021	1/C	2	Yes		NA	N	N/N
	RESP	Nasal congestion/ Nasal congestion#	4	22FEB2021	1/8	2	Yes		NA	R (01MAR2021)	N/N
>55/ C4591001 1265 12651056	SKIN	Hyperhidrosis/ Sweating#	4	22FEB2021	1/4	2	Yes		NA	R (25FEB2021)	N/N
	GENRL	Asthenia/ Sensation of generalized weakness	2	26SEP2020	3/2	1	Yes		NA	R (27SEP2020)	N/N
		Fatigue/ Fatigue	2	26SEP2020	3/2	1	Yes		NA	R (27SEP2020)	N/N
>55/ C4591001 1265 12651068	GENRL	Pyrexia/ Fever	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1265 12651069	GENRL	Chills/ chills#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N	
		Pyrexia/ fever#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N	
>55/ C4591001 1265 12651071	GASTR	Diarrhoea/ Diarrhea#	4	12JAN2021	2/2	2	Yes		NA	R (13JAN2021)	N/N	
	GENRL	Nausea/ Nausea#	4	12JAN2021	2/2	2	Yes		NA	R (13JAN2021)	N/N	
		Chills/ Chills#	4	12JAN2021	2/2	2	Yes		NA	R (13JAN2021)	N/N	
		METAB	Decreased appetite/ Loss of appetite#	4	12JAN2021	2/2	2	Yes		NA	R (13JAN2021)	N/N
		MUSC	Myalgia/ Muscle aches#	4	12JAN2021	2/7	2	Yes		NA	R (18JAN2021)	N/N
>55/ C4591001 1265 12651080	MUSC	Neck pain/ NECK PAIN	1	22SEP2020	14/C	2	No	O	NA	N	N/N	
		Pain in extremity/ RIGHT ARM PAIN	1	22SEP2020	14/C	2	No	O	NA	N	N/N	
>55/ C4591001 1265 12651085	GENRL	Injection site pain/ Pain at injection site	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup> AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1265 12651087	MUSC	Malaise/ Malaise, mild	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
		Pyrexia/ Fever	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
		Myalgia/ New or increased muscle pain	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
	MUSC	Myalgia/ New or increased muscle pain	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
	RESP	Nasal congestion/ Sniffling	1	12SEP2020	3/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Sneezing/ Sneezing	1	12SEP2020	3/2	1	Yes		NA	R (13SEP2020)	N/N
		Pyrexia/ Fever	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Malaise/ Malaise	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
Headache/ Headache		2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N	
>55/ C4591001 1265 12651100	GENRL	Injection site pain/ Muscle pain at injection site	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
>55/ C4591001	EYE	Eye irritation/ Irritated eyes	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1265 12651103	GENRL	Chills/ Chills	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
		Fatigue/ Fatigue	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
		Pyrexia/ Fever	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	METAB	Decreased appetite/ Anorexia	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ Headache	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	MUSC	Myalgia/ New or increased muscle pain	1	13SEP2020	3/1	1	Yes		NA	R (13SEP2020)	N/N
>55/ C4591001 1265 12651107	EAR	Cerumen impaction/ Bilateral cerumen impaction	2	07OCT2020	2/1	1	No	O	NA/TCN	R (07OCT2020)	N/N
	MUSC	Musculoskeletal discomfort/ Right neck fullness	2	07OCT2020	2/1	1	No	O	NA	R (07OCT2020)	N/N
>55/ C4591001 1265 12651109	GENRL	Injection site pain/ Injection site pain (left deltoid)#	3	28DEC2020	1/3	1	Yes		NA/TC	R (30DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain (left deltoid)#	4	18JAN2021	1/4	1	Yes		NA/TC	R (21JAN2021)	N/N
>55/ C4591001 1265 12651113	GENRL	Injection site discomfort/ Injection site discomfort	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1265 12651118	GENRL	Fatigue/ FATIGUE	2	07OCT2020	2/12	1	No	O	NA	R (18OCT2020)	N/N	
	MUSC	Myalgia/ MUSCLE PAIN	2	07OCT2020	2/12	1	No	O	NA	R (18OCT2020)	N/N	
>55/ C4591001 1265 12651119	METAB	Type 2 diabetes mellitus/ Worsening of type 2 diabetes mellitus	1	28SEP2020	14/C	1	No	O	NA/TC/TCN	N	N/N	
>55/ C4591001 1265 12651120	MUSC	Myalgia/ Muscle pain	1	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N	
>55/ C4591001 1265 12651121	EAR	Vertigo/ Vertigo#	4	18FEB2021	11/5	1	No	O	NA	R (22FEB2021)	N/N	
>55/ C4591001 1265 12651122	GENRL	Fatigue/ Fatigue	1	17SEP2020	2/3	1	No	O	NA	R (19SEP2020)	N/N	
	EYE	Cataract/ Worsening of cataracts, bilateral	2	08OCT2020	2/C	2	No	O	NA	N	N/N	
		Dry eye/ Bilateral dry eye syndrome	2	08OCT2020	2/C	1	No	O	NA	N	N/N	
>55/ C4591001 1265 12651129	GENRL	Pyrexia/ Fever#	4	02FEB2021	2/1	1	Yes		NA/TC	R (02FEB2021)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1265 12651130	MUSC	Myalgia/ Muscle aches#	4	02FEB2021	2/1	1	Yes		NA/TC	R (02FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
>55/ C4591001 1265 12651137	NERV	Headache/ Headache#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	GASTR	Abdominal discomfort/ Abdominal pressure sensation	1	18SEP2020	2/8	1	No	O	NA	R (25SEP2020)	N/N
>55/ C4591001 1265 12651150†	GENRL	Pain/ Minor body aches	1	20SEP2020	4/1	1	No	O	NA	R (20SEP2020)	N/N
	EYE	Vitreous detachment/ Acute posterior vitreous detachment (left eye)	1	29SEP2020	9/C	2	No	O	NA	RG	N/N
>55/ C4591001 1265 12651152	RESP	Rhinorrhoea/ Rhinorrhea	2	06NOV2020	26/4	1	No	O	NA	R (09NOV2020)	N/N
	INFEC	Oral herpes/ Cold sores	1	08OCT2020	18/33	1	Yes		NA/TC	R (09NOV2020)	N/N
>55/ C4591001 1265 12651158	GENRL	Fatigue/ Mild fatigue	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Injection site discomfort/ Injection site discomfort	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1265 12651163	GENRL	Fatigue/ Fatigue#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
		Injection site pain/ pain at injection site, left deltoid#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
	NERV	Headache/ headache#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
>55/ C4591001 1265 12651171	GENRL	Injection site pain/ Injection site pain with radiation to elbow	2	16OCT2020	2/9	1	Yes		NA	R (24OCT2020)	N/N
	MUSC	Tendonitis/ Left tendonitis	2	24OCT2020	10/1	1	No	O	NA	R (24OCT2020)	N/N
	INFEC	Orchitis/ Right orchitis	2	25OCT2020	11/6	1	No	O	NA/TC	R (30OCT2020)	N/N
	MUSC	Myalgia/ New or increased muscle pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
>55/ C4591001 1265 12651176	MUSC	Myalgia/ Muscle pain#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
	NERV	Headache/ Headache#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
>55/ C4591001 1265 12651178	GENRL	Fatigue/ Fatigue	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
		Injection site pain/ Injection site muscle pain	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1265 12651179	NERV	Pyrexia/ Fever	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N	
		Headache/ Headache	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N	
	INV	Body temperature increased/ Elevated temperature	2	16OCT2020	1/4	1	Yes		NA/TC	R (19OCT2020)	N/N	
	MUSC	Myalgia/ Muscle ache	2	16OCT2020	1/4	1	Yes		NA/TC	R (19OCT2020)	N/N	
	SKIN	Hyperhidrosis/ Sweating	2	16OCT2020	1/4	1	Yes		NA/TC	R (19OCT2020)	N/N	
>55/ C4591001 1265 12651183	MUSC	Arthralgia/ Right shoulder pain#	4	09FEB2021	2/C	2	Yes		NA	N	N/N	
>55/ C4591001 1265 12651184	GENRL	Pyrexia/ FEVER	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N	
>55/ C4591001 1269 12691009	MUSC	Myalgia/ MUSCLE PAIN	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N	
	SKIN	Pruritus/ lower back itching	2	15SEP2020	6/2	1	No	O	NA/TC	R (16SEP2020)	N/N	
>55/ C4591001 1269 12691019	GENRL	Chills/ chills	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1269 12691028	MUSC	Fatigue/ fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		Pyrexia/ fever	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
		Arthralgia/ joint aches	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
		Myalgia/ muscle aches	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
	NERV	Headache/ headache	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
	MUSC	Arthralgia/ Joint pains	2	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Myalgia/ muscle pains	2	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		Headache/ headaches	2	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
>55/ C4591001 1269 12691035	GENRL	Pyrexia/ fever	2	12SEP2020	1/3	1	Yes		NA	R (14SEP2020)	N/N
>55/ C4591001 1269 12691036	MUSC	Pain in extremity/ left arm soreness	2	12SEP2020	1/3	1	Yes		NA	R (14SEP2020)	N/N
	GASTR	Diarrhoea/ diarrhea	1	26AUG2020	5/1	1	No	O	NA	R (26AUG2020)	N/N
	GASTR	Diarrhoea/ worsening of diarrhea*		24AUG2020	1/1	1	No	O	NA	R (24AUG2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1269 12691043 >55/ C4591001 1269 12691046	MUSC	Muscle spasms/ worsening of leg cramps	2	20SEP2020	5/1	1	No	O	NA	R (20SEP2020)	N/N
1269 12691046 >55/ C4591001 1269 12691053	GASTR	Diarrhoea/ diarrhea	2	11OCT2020	26/1	1	No	O	NA/TC	R (11OCT2020)	N/N
1269 12691053 >55/ C4591001 1269 12691053	GENRL	Chills/ chills	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
1269 12691053 >55/ C4591001 1269 12691053		Fatigue/ fatigue	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
1269 12691053 >55/ C4591001 1269 12691053		Pyrexia/ fever	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
1269 12691053 >55/ C4591001 1269 12691053	MUSC	Myalgia/ muscle aches	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
1269 12691053 >55/ C4591001 1269 12691066	GENRL	Chills/ chills	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
1269 12691066 >55/ C4591001 1269 12691066		Injection site pain/ soreness at injection site	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
1269 12691066 >55/ C4591001 1269 12691066		Pyrexia/ fever	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
1269 12691066 >55/ C4591001 1269 12691066	MUSC	Joint stiffness/ stiff joints	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
1269 12691066 >55/ C4591001 1269 12691066		Myalgia/ muscle aches	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1269 12691071	NERV	Headache/ headache	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N	
	RESP	Upper respiratory tract congestion/ mild head congestion	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N	
	GENRL	Chills/ chills	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N	
			Fatigue/ fatigue	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N	
	GASTR	Abdominal pain upper/ stomach cramps	2	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N	
>55/ C4591001 1269 12691082	RENAL	Micturition urgency/ increased urge to urinate	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N	
	NERV	Headache/ headaches	2	22SEP2020	5/3	1	Yes		NA/TC	R (24SEP2020)	N/N	
	MUSC	Myalgia/ muscle aches	2	23SEP2020	6/2	1	Yes		NA/TC	R (24SEP2020)	N/N	
>55/ C4591001 1269 12691109	RESP	Oropharyngeal pain/ sore throat	1	15SEP2020	13/3	1	No	O	NA	R (17SEP2020)	N/N	
	SKIN	Pruritus/ lower back itching	1	15SEP2020	13/2	1	No	O	NA/TC	R (16SEP2020)	N/N	
>55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1270 12701002	GENRL	Pyrexia/ Fever	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	17SEP2020	3/1	1	Yes		NA	R (17SEP2020)	N/N
	RESP	Epistaxis/ Intermittent Epistaxis	2	01NOV2020	48/116	1	No	O	NA/TC/TCN	R (24FEB2021)	N/N
>55/ C4591001 1270 12701006	SKIN	Dermatitis contact/ Poison Oak Rash	1	01SEP2020	7/30	2	No	O	NA	R (30SEP2020)	N/N
>55/ C4591001 1270 12701012	GENRL	Chills/ Chills	1	27AUG2020	2/7	1	Yes		NA	R (02SEP2020)	N/N
		Injection site pain/ Injection site pain	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
		Pyrexia/ Fever	2	15SEP2020	2/1	2	Yes		NA/TC	R (15SEP2020)	N/N
	SKIN	Actinic keratosis/ Actinic Keratosis on Forehead	2	21JAN2021	130/C	1	No	O	NA/TC	RG	N/N
>55/ C4591001 1270 12701017	EYE	Dry eye/ Bilateral Dry Eye Syndrome	2	15DEC2020	89/C	1	No	O	NA/TC	N	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	INFEC	Urinary tract infection/ Urinary Tract Infection	2	15DEC2020	89/8	1	No	O	NA/TC	R (22DEC2020)	N/N	
>55/ C4591001 1270 12701019	GENRL	Chills/ Chills	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N	
	GENRL	Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N	
>55/ C4591001 1270 12701024	GENRL	Injection site pain/ Pain at injection site	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N	
	GENRL	Chills/ Chills	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N	
>55/ C4591001 1270 12701026	GENRL	Fatigue/ Fatigue#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	
		Injection site pain/ Injection site pain#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	
	EAR	Ear pain/ Bilateral Otalgia#	4	13MAR2021	26/C	1	No	O	NA/TCN	N	N/N	
>55/ C4591001 1270 12701028	NERV	Headache/ Headache	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N	
>55/ C4591001 1270 12701032	GASTR	Diverticulum intestinal/ Diverticulosis of colon	1	17SEP2020	18/C	1	No	O	NA	N	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Haemorrhoids/ Internal Hemorrhoids	1	17SEP2020	18/C	1	No	O	NA	N	N/N
	NEOPL	Colon adenoma/ Adenomatous polyps of colon	1	17SEP2020	18/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ Injection site pain#	3	19JAN2021	1/3	1	Yes		NA	R (21JAN2021)	N/N
>55/ C4591001 1270 12701036	GENRL	Injection site pain/ Pain at Injection Site	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
>55/ C4591001 1270 12701038	EYE	Eye irritation/ Burning Eyes	1	02SEP2020	2/2	1	No	O	NA	R (03SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches	1	02SEP2020	2/2	2	Yes		NA	R (03SEP2020)	N/N
	RESP	Throat irritation/ Scratchy throat	1	02SEP2020	2/2	1	No	O	NA	R (03SEP2020)	N/N
>55/ C4591001 1270 12701042	GENRL	Fatigue/ Fatigue#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
>55/ C4591001 1270 12701043	GENRL	Injection site pain/ Pain at injection site	1	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
	GENRL	Chills/ CHILLS	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Bone pain/ LEFT THUMB METACARPOMETACARPAL PAIN	1	16SEP2020	16/C	2	No	O	NA	N	N/N	
	GENRL	Chills/ Chills	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N	
		Injection site pain/ Pain at injection site	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N	
	MUSC	Myalgia/ MUSCLE ACHES	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N	
	NERV	Headache/ Headache	2	23SEP2020	2/2	2	Yes		NA/TC	R (24SEP2020)	N/N	
>55/ C4591001 1270 12701047	GASTR	Nausea/ Nausea	1	02SEP2020	1/1	2	Yes		NA/TCN	R (02SEP2020)	N/N	
	NERV	Headache/ Headache	1	02SEP2020	1/1	3	Yes		NA/TC/TCN	R (02SEP2020)	N/N	
	SKIN	Actinic keratosis/ Actinic Keratosis	2	05OCT2020	13/C	1	No	O	NA/TC	RG	N/N	
		Stasis dermatitis/ Chronic Venous Stasis Dermatitis	2	05OCT2020	13/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1270 12701050	GENRL	Injection site pain/ Left arm pain at injection site	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N	
	NERV	Headache/ Headache	1	24SEP2020	23/1	1	No	O	NA	R (24SEP2020)	N/N	
>55/ C4591001 1270 12701054	GENRL	Injection site pain/ left arm pain at injection site	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1270 12701055	GENRL	Injection site pain/ Pain at Injection Site	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
>55/ C4591001 1270 12701057	RESP	Pulmonary embolism/ Pulmonary embolism	1	23SEP2020	21/C	3	No	O	P/TC	RG	Y/N
>55/ C4591001 1270 12701058	INFEC	Conjunctivitis/ Right Conjunctivitis#	4	01MAR2021	19/2	1	No	O	NA/TC/TCN	R (02MAR2021)	N/N
>55/ C4591001 1270 12701059	GASTR	Nausea/ Nausea	1	09SEP2020	7/2	1	No	O	NA	R (10SEP2020)	N/N
>55/ C4591001 1270 12701061	INJ&P	Fall/ Fall	2	22NOV2020	60/1	1	No	O	NA/TC/TCN	R (22NOV2020)	N/N
	MUSC	Musculoskeletal chest pain/ Left Rib Pain	2	22NOV2020	60/27	1	No	O	NA/TC/TCN	R (18DEC2020)	N/N
>55/ C4591001 1270 12701063	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Arthralgia/ Joint pain	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1270 12701067	NERV	Headache/ Headache	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
	MUSC	Pain in extremity/ Left Foot Pain	2	02OCT2020	8/80	1	No	O	NA/TC/TCN	R (20DEC2020)	N/N
	INV	High density lipoprotein increased/ Increased High Density Lipoproteins	2	03OCT2020	9/C	1	No	O	NA	RG	N/N
	GENRL	Fatigue/ Fatigue#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	27JAN2021	1/5	2	Yes		NA/TC	R (31JAN2021)	N/N
>55/ C4591001 1270 12701070	GENRL	Fatigue/ Fatigue#	4	19FEB2021	1/2	2	Yes		NA	R (20FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	19FEB2021	1/2	2	Yes		NA/TC	R (20FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	08SEP2020	1/3	2	Yes		NA/TC	R (10SEP2020)	N/N
>55/ C4591001 1270 12701073	NEOPL	Haemangioma of skin/ Cherry Angioma#	2	03FEB2021	128/C	1	No	O	NA/TCN	N	N/N
	EYE	Cataract/ Bilateral Cataract	2	07JAN2021	102/C	1	No	O	NA	N	N/N
>55/ C4591001 1270 12701077	INFEC	Rhinitis/ Chronic Rhinitis	2	06NOV2020	40/C	1	No	O	NA/TC	N	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	RESP	Nasal polyps/ Nasal Polyposis	2	06NOV2020	40/C	1	No	O	NA/TC/TCN	RG	N/N
		Nasal valve collapse/ Nasal Valve Incompetence	2	06NOV2020	40/C	1	No	O	NA	N	N/N
	RESP	Nasopharyngeal polyp/ Nasopharyngeal Polyp	2	09NOV2020	43/C	1	No	O	NA	N	N/N
	RESP	Nasal septum deviation/ Deviated Nasal Septum	2	16NOV2020	50/C	1	No	O	NA	N	N/N
	GENRL	Injection site hypoaesthesia/ Injection Site Numbness#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
>55/ C4591001 1270 12701079	GENRL	Pyrexia/ Fever#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
>55/ C4591001 1270 12701081	SKIN	Skin lesion/ Skin Lesions Buttocks	2	08OCT2020	10/9	1	No	O	NA	R (16OCT2020)	N/N
>55/ C4591001 1270 12701093	NEOPL	Basal cell carcinoma/ Right Lateral Lower Eyelid Basal Cell Carcinoma, Nodular Type	1	28SEP2020	18/C	2	No	O	NA	N	N/N
	NEOPL	Basal cell carcinoma/ Basal Cell Carcinoma Right Lateral Lower Eyelid	1	29SEP2020	19/70	1	No	O	NA	R (07DEC2020)	N/N
	GENRL	Chills/ Chills#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1270 12701094	GENRL	Fatigue/ Fatigue#	4	17FEB2021	1/2	2	Yes		NA	R (18FEB2021)	N/N	
		Pyrexia/ Fever#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N	
	MUSC	Injection site pain/ Injection site pain	1	11SEP2020	1/4	2	Yes		NA/TC	R (14SEP2020)	N/N	
		Myalgia/ Muscle aches	1	12SEP2020	2/3	1	Yes		NA/TC	R (14SEP2020)	N/N	
>55/ C4591001 1270 12701095	INV	Platelet count increased/ Elevated Platlett	2	26OCT2020	25/C	1	No	O	NA	N	N/N	
	INV	Blood thyroid stimulating hormone increased/ Elevated Thyroid Stimulating Hormone	2	27OCT2020	26/C	1	No	O	NA	N	N/N	
		Low density lipoprotein increased/ Elevated low-density lipoprotein	2	27OCT2020	26/C	1	No	O	NA	N	N/N	
>55/ C4591001 1270 12701101	GASTR	Abdominal pain upper/ Epigastric Abdominal Pain	2	19OCT2020	15/C	1	No	O	NA/TC	N	N/N	
>55/ C4591001 1270 12701102	GENRL	Injection site pain/ Injection site pain, left arm	1	15SEP2020	2/5	2	Yes		NA/TC	R (19SEP2020)	N/N	
	MUSC	Myalgia/ Muscle pain	1	15SEP2020	2/5	2	Yes		NA/TC	R (19SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/5	2	Yes		NA/TC	R (09OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1270 12701103	MUSC	Muscle fatigue/ Muscle Fatigue	2	05OCT2020	1/4	2	Yes		NA	R (08OCT2020)	N/N	
		Myalgia/ Muscle Aches	2	05OCT2020	1/2	2	Yes		NA/TC	R (06OCT2020)	N/N	
	GASTR	Nausea/ Nausea#	4	10FEB2021	2/1	1	Yes		NA/TC	R (10FEB2021)	N/N	
	GENRL	Chills/ Chills#	4	10FEB2021	2/1	1	Yes		NA/TC	R (10FEB2021)	N/N	
		Fatigue/ Fatigue#	4	10FEB2021	2/8	1	Yes		NA	R (17FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain	1	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N	
	>55/ C4591001 1270 12701104	NERV	Dizziness/ Dizziness	2	05NOV2020	32/1	2	No	O	NA	R (05NOV2020)	N/N
		SKIN	Hyperhidrosis/ Diaphoretic	2	05NOV2020	32/1	2	No	O	NA	R (05NOV2020)	N/N
		VASC	Pallor/ Pale	2	05NOV2020	32/1	2	No	O	NA	R (05NOV2020)	N/N
		INJ&P	Fall/ Fall from tripping	2	31DEC2020	88/1	1	No	O	NA	R (31DEC2020)	N/N
		Joint dislocation/ Left shoulder dislocation	2	31DEC2020	88/C	2	No	O	NA/TC/TCN	N	N/N	
	MUSC	Rotator cuff syndrome/ Left Rotator Cuff Tear	2	31DEC2020	88/C	2	No	O	NA/TC/TCN	N	N/N	
	CARD	Atrial flutter/ Atrial Flutter#	4	07MAR2021	25/1	1	No	O	NA/TC	R (07MAR2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Peripheral swelling/ Left Foot Swelling#	4	07MAR2021	25/C	1	No	O	NA	N	N/N	
	MUSC	Pain in extremity/ Left Foot Pain#	4	07MAR2021	25/C	1	No	O	NA	N	N/N	
>55/ C4591001 1270 12701106	GENRL	Injection site pain/ Injection site pain	1	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N	
	EAR	Ear pain/ RIGHT OTALGIA	2	10NOV2020	37/4	1	No	O	NA	R (13NOV2020)	N/N	
>55/ C4591001 1270 12701110	REPRO	Prostatomegaly/ Prostatomegaly#	2	17JAN2021	104/C	1	No	O	NA	N	N/N	
>55/ C4591001 1270 12701111	GENRL	Injection site pain/ Pain at inject site	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N	
>55/ C4591001 1270 12701112	GENRL	Injection site pain/ Injection site pain#	4	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N	
>55/ C4591001 1270 12701113	RENAL	Dysuria/ Dysuria	2	11OCT2020	3/6	1	No	O	NA/TC	R (16OCT2020)	N/N	
>55/ C4591001	GENRL	Fatigue/ Fatigue	1	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1270 12701114		Injection site pain/ Injection site pain	1	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	1	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C4591001 1270 12701126	GENRL	Fatigue/ Fatigue#	4	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
>55/ C4591001 1270 12701127	GASTR	Nausea/ Nausea	1	19SEP2020	3/1	2	Yes		NA	R (19SEP2020)	N/N
		Vomiting/ Vomiting	1	19SEP2020	3/1	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	1	19SEP2020	3/1	1	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ Fever (Highest 101.5°F)	1	19SEP2020	3/1	2	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ Headache	1	19SEP2020	3/1	1	Yes		NA	R (19SEP2020)	N/N
	REPRO	Breast pain/ Right Mastodynia	1	20SEP2020	4/7	2	No	O	NA	R (26SEP2020)	N/N
	GASTR	Diverticulum/ Diffuse diverticulosis	1	21SEP2020	5/C	2	No	O	NA	N	N/N
		Haemorrhoids/ Small internal hemorrhoids	1	21SEP2020	5/C	1	No	O	NA	N	N/N
	NEOPL	Colon adenoma/ Colonic Polyps tubular adenomas	1	21SEP2020	5/1	2	No	O	NA/TCN	R (21SEP2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1270 12701130	VASC	Hypertension/ Worsening Hypertension	2	28OCT2020	20/C	1	No	O	NA/TC	N	N/N
>55/ C4591001 1270 12701138	GASTR	Diarrhoea/ Diarrhea, once	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	MUSC	Arthritis/ Arthritis of left knee#	3	02FEB2021	19/C	2	No	O	NA/TC/TCN	N	N/N
>55/ C4591001 1270 12701139	GENRL	Injection site pain/ Injection site pain#	3	19JAN2021	2/2	2	Yes		NA	R (20JAN2021)	N/N
	NERV	Headache/ Headache#	3	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
	INJ&P	Fall/ Fall from slipping#	3	09FEB2021	23/1	1	No	O	NA	R (09FEB2021)	N/N
	MUSC	Arthralgia/ Right shoulder joint pain#	3	09FEB2021	23/C	1	No	O	NA/TC	RG	N/N
	RENAL	Dysuria/ Dysuria#	4	18FEB2021	9/4	1	No	O	NA/TC	R (21FEB2021)	N/N
>55/ C4591001 1270 12701140	GENRL	Injection site pain/ Injection site arm pain	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	22SEP2020	2/1	2	Yes		NA	R (22SEP2020)	N/N
		Nausea/ Nausea	1	22SEP2020	2/1	2	Yes		NA	R (22SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills	1	22SEP2020	2/1	2	Yes		NA	R (22SEP2020)	N/N
	NERV	Headache/ Headache	1	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
>55/ C4591001 1270 12701144	EYE	Meibomianitis/ Left lower eyelid meibomitis#	3	20JAN2021	6/8	1	No	O	NA/TCN	R (27JAN2021)	N/N
>55/ C4591001 1270 12701145	MUSC	Bursitis/ Pes Anserine Bursitis of Left Knee	1	01OCT2020	10/C	1	No	O	NA/TC	RG	N/N
	MUSC	Arthralgia/ Right Sacroiliac Joint Pain	2	15OCT2020	4/C	1	No	O	NA/TC	RG	N/N
	INJ&P	Contusion/ Chest wall contusion	2	12DEC2020	62/15	1	No	O	NA/TCN	R (26DEC2020)	N/N
	EAR	Eustachian tube dysfunction/ Bilateral Eustachian tube dysfunction#	4	26FEB2021	10/C	1	No	O	NA	N	N/N
	INFEC	Urinary tract infection/ Urinary tract infection#	4	02MAR2021	14/C	1	No	O	NA/TC/TCN	N	N/N
	SKIN	Ingrowing nail/ Left ingrown toe nail#	4	08MAR2021	20/C	1	No	O	NA/TC/TCN	N	N/N
>55/ C4591001 4444 44441001	GENRL	Asthenia/ asthenia	2	12OCT2020	1/3	2	Yes		NA	R (14OCT2020)	N/N
	MUSC	Myalgia/ left arm muscle pain	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
>55/ C4591001	INFEC	Tooth infection/ Odontogenic infection	2	22OCT2020	11/6	1	No	O	NA/TC	R (27OCT2020)	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
4444 44441002	GENRL	Pyrexia/ fever	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N	
>55/ C4591001 4444 44441006	GENRL	Asthenia/ asthenia	1	21SEP2020	1/8	1	Yes		NA	R (28SEP2020)	N/N	
4444 44441010	MUSC	Pain in extremity/ pain in left upper limb	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N	
	GENRL	Pyrexia/ fever	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N	
	MUSC	Myalgia/ right arm muscle pain	2	12OCT2020	1/2	1	Yes		NA/TC/TCN	R (13OCT2020)	N/N	
>55/ C4591001 4444 44441035	EAR	Deafness/ Hearing loss	2	14JAN2021	95/C	1	No	O	NA	N	N/N	
>55/ C4591001 4444 44441041	INJ&P	Thermal burn/ Burn on right forearm. Classification AB	2	05NOV2020	24/32	2	No	O	NA/TCN	R (06DEC2020)	N/N	
>55/ C4591001 4444 44441042	METAB	Dyslipidaemia/ Dyslipidemia	1	22SEP2020	2/8	1	No	O	NA/TC/TCN	R (29SEP2020)	N/N	
	MUSC	Osteitis/ Right hip trochanteritis worsening	1	09OCT2020	19/C	2	No	O	NA/TC/TCN	RG	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 4444 44441050	CARD	Ventricular extrasystoles/ Frequent ventricular extrasystoles	2	13OCT2020	2/1	1	No	O	NA/TC/TCN	R (13OCT2020)	N/N	
	INFEC	Urinary tract infection/ Urinary infection	1	01OCT2020	11/10	2	No	O	NA/TC/TCN	R (10OCT2020)	N/N	
>55/ C4591001 4444 44441051	VASC	Hypertension/ Worsening high blood pressure#	3	04MAR2021	13/2	1	No	O	NA	R (05MAR2021)	N/N	
	GENRL	Injection site pain/ Injection site pain in right arm.	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N	
>55/ C4591001 4444 44441053	GASTR	Abdominal pain/ Abdominal pain	2	13OCT2020	2/2	2	Yes		NA	R (14OCT2020)	N/N	
	>55/ C4591001 4444 44441058	GENRL	Diarrhoea/ Diarrhea	2	13OCT2020	2/2	2	Yes		NA	R (14OCT2020)	N/N
GENRL		Injection site pain/ Pain on injection site	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N	
>55/ C4591001 4444 44441059	GENRL	Asthenia/ asthenia	2	13OCT2020	1/4	1	Yes		NA/TC	R (16OCT2020)	N/N	
	RESP	Nasal congestion/ Congestion nasal	2	13OCT2020	1/4	1	Yes		NA/TC	R (16OCT2020)	N/N	
	GASTR	Abdominal distension/ abdominal distention	1	22SEP2020	2/7	2	No	O	NA/TC	R (28SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 4444 44441074	GENRL	Proctalgia/ Pain in anus	1	22SEP2020	2/7	2	No	O	NA/TC	R (28SEP2020)	N/N	
		Asthenia/ asthenia	1	21SEP2020	1/7	2	Yes		NA	R (27SEP2020)	N/N	
		Conjunctivitis/ conjunctivitis of the left eye	2	12OCT2020	1/11	1	No	O	NA/TC	R (22OCT2020)	N/N	
>55/ C4591001 4444 44441078	INFEC	Conjunctivitis/ Recurrent conjunctivitis	2	26OCT2020	15/7	1	No	O	NA/TC	R (01NOV2020)	N/N	
		Dysuria/ burning when urinating	1	10OCT2020	20/2	1	No	O	NA	R (11OCT2020)	N/N	
		Hypertension/ Arterial Hypertension Exacerbation	1	24SEP2020	4/2	1	No	CD	NA	R (25SEP2020)	N/N	
>55/ C4591001 4444 44441080	VASC											
>55/ C4591001 4444 44441091	INJ&P	Fall/ fall from own height	2	11NOV2020	31/1	2	No	O	NA/TCN	R (11NOV2020)	N/N	
>55/ C4591001 4444 44441097	RESP	Ligament sprain/ right ankle sprain	2	11NOV2020	31/15	2	No	O	NA/TC/TCN	R (25NOV2020)	N/N	
		Bronchospasm/ bronchospasm	1	28SEP2020	8/1	1	No	O	NA/TC	R (28SEP2020)	N/N	
>55/ C4591001	EYE	Conjunctivitis allergic/ allergic conjunctivitis	1	29SEP2020	9/2	1	No	O	NA/TC	R (30SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44441107 >55/ C4591001 4444 44441112	SKIN	Erythema/ redness of both upper limbs	1	25SEP2020	5/8	1	No	O	NA/TC	R (02OCT2020)	N/N
4444 44441112 >55/ C4591001 4444 44441114	GASTR	Abdominal pain upper/ Epigastralgia	2	02NOV2020	21/1	1	No	O	NA/TC	R (02NOV2020)	N/N
4444 44441114 >55/ C4591001 4444 44441116	NERV	Headache/ Short-term headache	1	05OCT2020	15/2	1	No	O	NA	R (06OCT2020)	N/N
4444 44441116 >55/ C4591001 4444 44441122	REPRO	Vulvovaginal pruritus/ vaginal itching	2	05NOV2020	25/4	1	No	O	NA/TC	R (08NOV2020)	N/N
4444 44441122 >55/ C4591001 4444 44441127	INFEC	Tooth infection/ Tooth infection	2	04NOV2020	24/5	1	No	O	NA/TC/TCN	R (08NOV2020)	N/N
4444 44441127 >55/ C4591001 4444 44441122	GENRL	Asthenia/ asthenia#	3	01FEB2021	1/7	1	Yes		NA/TC	R (07FEB2021)	N/N
4444 44441122 >55/ C4591001 4444 44441127	GENRL	Injection site pain/ injection site pain#	3	01FEB2021	1/3	1	Yes		NA/TC	R (03FEB2021)	N/N
4444 44441127 >55/ C4591001 4444 44441122	GENRL	Asthenia/ Asthenia	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
4444 44441122 >55/ C4591001	SKIN	Blister/ blisters on the back of both hands	1	23SEP2020	3/12	1	No	O	NA/TC	R (04OCT2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
4444 44441130		Rash/ Rash on the back of both hands	1	23SEP2020	3/12	1	No	O	NA/TC	R (04OCT2020)	N/N	
	SKIN	Skin lesion/ erythematous lesions on both forearms	1	02OCT2020	12/3	1	No	O	NA/TC	R (04OCT2020)	N/N	
	INV	Body temperature increased/ Body temperature increased	2	14OCT2020	2/1	1	Yes		NA/TC/TCN	R (14OCT2020)	N/N	
>55/ C4591001 4444 44441136	MUSC	Back pain/ Low back pain	1	01OCT2020	11/1	1	No	O	NA/TC	R (01OCT2020)	N/N	
>55/ C4591001 4444 44441140	RESP	Dysphonia/ Dysphonia	1	02OCT2020	12/6	1	No	O	NA	R (07OCT2020)	N/N	
>55/ C4591001 4444 44441141	VASC	Hypertension/ Arterial hypertension	2	23OCT2020	12/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 4444 44441145	INFEC	Complicated appendicitis/ Acute gangrenous appendicitis	2	12DEC2020	61/24	3	No	O	NA/TC/TCN	R (04JAN2021)	Y/N	
>55/ C4591001 4444 44441148	GASTR	Gastritis/ Acute gastritis	1	22SEP2020	2/18	1	No	O	NA/TC	R (09OCT2020)	N/N	
>55/ C4591001	REPRO	Benign prostatic hyperplasia/ Benign prostatic hyperplasia#	2	25JAN2021	105/C	1	No	O	NA/TC	RG	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44441151 >55/ C4591001 4444 44441158	NERV	Tremor/ Unintentional fine tremor of the left hand lasting one to two minutes	1	01OCT2020	11/12	1	No	O	NA	R (12OCT2020)	N/N
4444 44441161 >55/ C4591001 4444 44441165	GASTR	Tooth disorder/ dental mobility	1	08OCT2020	18/2	1	No	O	NA/TC/TCN	R (09OCT2020)	N/N
4444 44441161 >55/ C4591001 4444 44441165	CARD	Coronary artery disease/ Coronary heart disease	1	01OCT2020	11/140	2	No	O	NA/TC/TCN	R (17FEB2021)	Y/N
4444 44441165 >55/ C4591001 4444 44441168	INFEC	Tooth infection/ Left lower first molar infection	2	14OCT2020	2/27	1	No	O	NA/TC	R (09NOV2020)	N/N
4444 44441168 >55/ C4591001 4444 44441178	INFEC	Herpes zoster/ Herpes zoster in the right anterior thoracic region	2	21OCT2020	9/25	1	No	O	NA/TC	R (14NOV2020)	N/N
4444 44441178 >55/ C4591001 4444 44441178	GENRL	Asthenia/ Asthenia	2	14OCT2020	2/5	1	Yes		NA	R (18OCT2020)	N/N
4444 44441178 >55/ C4591001 4444 44441178	GENRL	Injection site pain/ Injection site pain	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
4444 44441178 >55/ C4591001 4444 44441178	GENRL	Injection site pain/ Pain in the site of injection	2	13OCT2020	1/4	1	Yes		NA	R (16OCT2020)	N/N
4444 44441178 >55/ C4591001 4444 44441178	GENRL	Asthenia/ Asthenia	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 4444 44441196	GASTR	Abdominal pain/ nonspecific abdominal pain	1	09OCT2020	19/5	1	No	O	NA/TC	R (13OCT2020)	N/N
	MUSC	Back pain/ low back pain#	2	06FEB2021	117/1	1	No	O	NA/TC	R (06FEB2021)	N/N
>55/ C4591001 4444 44441215	MUSC	Myalgia/ Generalized myalgia	1	22SEP2020	2/6	3	Yes		NA/TC	R (27SEP2020)	N/N
>55/ C4591001 4444 44441221	GENRL	Injection site pain/ Injection site pain	2	14OCT2020	1/5	2	Yes		NA/TC	R (18OCT2020)	N/N
	GENRL	Asthenia/ Asthenia	2	16OCT2020	3/3	1	Yes		NA	R (18OCT2020)	N/N
>55/ C4591001 4444 44441227	MUSC	Myalgia/ Myalgia	2	12OCT2020	1/2	2	Yes		NA	R (13OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	13OCT2020	2/1	2	Yes		NA/TC	R (13OCT2020)	N/N
>55/ C4591001 4444 44441229	METAB	Type 2 diabetes mellitus/ Type 2 diabetes	1	30SEP2020	10/C	1	No	O	NA/TC/TCN	N	N/N
>55/ C4591001 4444 44441231	GENRL	Asthenia/ asthenia	2	13OCT2020	2/5	1	Yes		NA	R (17OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 4444 44441235	REPRO	Benign prostatic hyperplasia/ exacerbation of benign prostatic hyperplasia	2	28OCT2020	16/17	1	No	O	NA/TC	R (13NOV2020)	N/N
>55/ C4591001 4444 44441239	INJ&P	Tooth fracture/ Tooth breakage	2	05NOV2020	25/1	1	No	O	NA/TC/TCN	R (05NOV2020)	N/N
	SURG	Tooth extraction/ Tooth extraction	2	05NOV2020	25/1	1	No	O	NA/TC	R (05NOV2020)	N/N
>55/ C4591001 4444 44441242	NERV	Paraesthesia/ Paraesthesia	1	23SEP2020	3/C	1	No	O	NA	N	N/N
>55/ C4591001 4444 44441274	GENRL	Pyrexia/ Fever	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N
>55/ C4591001 4444 44441287	MUSC	Back pain/ Low back pain	1	26SEP2020	5/6	1	No	O	NA/TC	R (01OCT2020)	N/N
	GENRL	Asthenia/ Asthenia	2	17OCT2020	5/1	1	Yes		NA	R (17OCT2020)	N/N
>55/ C4591001 4444 44441303	GASTR	Dental caries/ dental caries	1	29SEP2020	8/5	1	No	O	NA/TC/TCN	R (03OCT2020)	N/N
>55/ C4591001	INFEC	Helicobacter gastritis/ Helicobacter pylori gastritis	2	26JAN2021	106/C	1	No	O	NA/TC/TCN	RG	N/N



16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
4444 44441305 >55/ C4591001 4444 44441309	INFEC	Cystitis/ Lower urinary tract infection (cystitis)	1	28SEP2020	7/13	2	No	O	NA/TC	R (10OCT2020)	N/N	
	NERV	Headache/ Headache	1	28SEP2020	7/3	1	No	O	NA/TC	R (30SEP2020)	N/N	
	RESP	Throat irritation/ pharyngeal burning	1	07OCT2020	16/1	1	No	O	NA	R (07OCT2020)	N/N	
	NERV	Headache/ Headache	2	20OCT2020	9/26	2	No	O	NA/TC	R (14NOV2020)	N/N	
>55/ C4591001 4444 44441313	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N	
>55/ C4591001 4444 44441318	NERV	Headache/ Headache	1	24SEP2020	3/2	1	Yes		NA/TC	R (25SEP2020)	N/N	
>55/ C4591001 4444 44441322	INJ&P	Ligament sprain/ right ankle sprain	2	13OCT2020	2/29	1	No	O	NA/TCN	R (10NOV2020)	N/N	
>55/ C4591001 4444 44441328	GENRL	Injection site pain/ Injection site pain#	3	19FEB2021	1/4	2	Yes		NA/TC	R (22FEB2021)	N/N	
	GENRL	Pyrexia/ FEVER#	3	20FEB2021	2/1	2	Yes		NA/TC	R (20FEB2021)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 4444 44441331	GENRL	Injection site pain/ injection site pain	1	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Pyrexia/ fever (38.5 C)	1	12OCT2020	21/3	1	Yes		NA/TC	R (14OCT2020)	N/N
	MUSC	Myalgia/ generalized myalgia	1	12OCT2020	21/3	1	Yes		NA/TC	R (14OCT2020)	N/N
>55/ C4591001 4444 44441338	GENRL	Asthenia/ Asthenia	2	13OCT2020	1/4	1	Yes		NA	R (16OCT2020)	N/N
		Injection site pain/ Injection site pain	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	NERV	Headache/ Headache	2	13OCT2020	1/4	1	Yes		NA/TC	R (16OCT2020)	N/N
	HEPAT	Cholelithiasis/ Gallstones	2	10NOV2020	29/C	1	No	O	NA	N	N/N
	INJ&P	Procedural hypotension/ Hypotension during blood sample collection	2	12NOV2020	31/1	1	No	O	NA	R (12NOV2020)	N/N
>55/ C4591001 4444 44441343	MUSC	Pain in extremity/ pain in left upper limb up to the middle finger of the hand.	1	22SEP2020	1/9	1	Yes		NA	R (30SEP2020)	N/N
>55/ C4591001 4444 44441367	GENRL	Asthenia/ Asthenia	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Myalgia/ Generalized myalgias	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 4444 44441369	GENRL	Discomfort/ General discomfort	1	12OCT2020	21/3	1	No	O	NA	R (14OCT2020)	N/N	
>55/ C4591001 4444 44441370	RESP	Rhinitis allergic/ worsening allergic rhinitis	1	02OCT2020	11/8	1	No	O	NA	R (09OCT2020)	N/N	
>55/ C4591001 4444 44441371	INFEC	COVID-19/ Covid-19 Illness	2	15JAN2021	95/20	3	No	O	NA/TC	R (03FEB2021)	Y/N	
>55/ C4591001 4444 44441372	INFEC	Tooth infection/ Dental infection	1	22SEP2020	1/15	1	No	O	NA/TC/TCN	R (06OCT2020)	N/N	
	NERV	Headache/ Headache	2	12OCT2020	1/2	2	Yes		NA/TC	R (13OCT2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	13OCT2020	2/2	2	Yes		NA	R (14OCT2020)	N/N	
	METAB	Vitamin D deficiency/ Vitamin D deficiency	2	19OCT2020	8/62	1	No	O	NA/TC	R (19DEC2020)	N/N	
>55/ C4591001 4444 44441375	MUSC	Back pain/ WORSENER LOW BACK PAIN	2	15OCT2020	3/1	2	No	O	NA/TC	R (15OCT2020)	N/N	
>55/ C4591001 4444 44441385	VASC	Aortic stenosis/ Severe Aortic Stenosis	2	27JAN2021	107/42	3	No	O	NA/TC/TCN	R (09MAR2021)	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 4444 44441422	CARD	Ischaemic cardiomyopathy/ Ischemic cardiomyopathy worsening#	3	05FEB2021	3/33	3	No	O	NA/TC/TCN	R (09MAR2021)	Y/N	
	VASC	Aortic aneurysm/ Abdominal Aortic Aneurysm#	3	08FEB2021	6/19	1	No	O	NA/TC	R (26FEB2021)	N/N	
	MUSC	Pain in extremity/ Pain in left heel	1	28SEP2020	7/1	1	No	O	NA/TC	R (28SEP2020)	N/N	
	NEOPL	Adenocarcinoma of colon/ Poorly differentiated colon adenocarcinoma	2	20JAN2021	101/C	3	No	O	NA/TC/TCN	N	Y/N	
	INFEC	Abscess limb/ Abscessed lesion in the middle finger of the right hand	1	05OCT2020	14/11	1	No	O	NA/TC/TCN	R (15OCT2020)	N/N	
	INFEC	Pyelonephritis/ Pyelonephritis	2	18NOV2020	37/13	2	No	O	NA/TC	R (30NOV2020)	N/N	
	SKIN	Hand dermatitis/ dermatitis on both hands	1	28SEP2020	7/4	1	No	O	NA/TC	R (01OCT2020)	N/N	
	INFEC	Erysipelas/ erysipelas on left leg	1	07OCT2020	16/21	1	No	O	NA/TC/TCN	R (27OCT2020)	N/N	
	INFEC	Pneumonia/ Community-acquired pneumonia	2	29JAN2021	109/33	3	No	O	NA/TC	R (02MAR2021)	Y/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 4444 44441473	HEPAT	Cholelithiasis/ Worsening of biliary lithiasis	2	02NOV2020	21/122	3	No	O	NA/TC/TCN	R (03MAR2021)	Y/N	
>55/ C4591001 4444 44441513	REPRO	Breast pain/ Mastalgia	1	05OCT2020	14/1	1	No	O	NA	R (05OCT2020)	N/N	
>55/ C4591001 4444 44441533	GASTR	Abdominal pain upper/ Epigastralgia	1	05OCT2020	14/1	1	No	O	NA/TC/TCN	R (05OCT2020)	N/N	
>55/ C4591001 4444 44441535	GENRL	Pyrexia/ Fever#	4	12MAR2021	2/1	1	Yes		NA/TC	R (12MAR2021)	N/N	
>55/ C4591001 4444 44441547	GENRL	Injection site pain/ Pain at the injection site	2	14OCT2020	1/1	1	Yes		NA	R (14OCT2020)	N/N	
>55/ C4591001 4444 44441548	INFEC	Tooth infection/ Dental infection	2	05NOV2020	23/C	1	No	O	NA/TC	RG	N/N	
>55/ C4591001 4444 44441551	NERV	Headache/ Frontal headache	1	13OCT2020	21/1	1	No	O	NA/TC	R (13OCT2020)	N/N	
	NERV	Headache/ frontal headache	2	21OCT2020	8/2	1	No	O	NA/TC	R (22OCT2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 4444 44441584	GENRL	Pyrexia/ Fever#	3	20FEB2021	2/5	1	Yes		NA/TC	R (24FEB2021)	N/N	
>55/ C4591001 4444 44441588	VASC	Hypertension/ Isolated arterial hypertension record	1	01OCT2020	9/1	1	No	O	NA	R (01OCT2020)	N/N	
>55/ C4591001 4444 44441592	GENRL	Pyrexia/ FEVER (38.5)	2	15OCT2020	1/2	2	Yes		NA	R (16OCT2020)	N/N	
	RESP	Dysphonia/ Dysphonia	2	17OCT2020	3/34	1	No	O	NA	R (19NOV2020)	N/N	
>55/ C4591001 4444 44441595	VASC	Hypertension/ arterial hypertension	2	28JAN2021	107/C	2	No	O	NA/TC	RG	N/N	
		Hypertensive emergency/ Hypertensive emergency	2	28JAN2021	107/8	3	No	O	NA/TC	R (04FEB2021)	Y/N	
	METAB	Hyponatraemia/ Hyponatremia	2	31JAN2021	110/5	2	No	O	NA/TCN	R (04FEB2021)	Y/N	
>55/ C4591001 4444 44441600	INJ&P	Foreign body aspiration/ Irritating cough associated with foreign body aspiration	1	15OCT2020	23/1	1	No	O	NA	R (15OCT2020)	N/N	
		Pharyngeal perforation/ Pharyngeal laceration	1	15OCT2020	23/1	1	No	O	NA	R (15OCT2020)	N/N	
>55/ C4591001	INFEC	Erysipelas/ Erysipelas in left leg	2	02NOV2020	20/5	1	No	O	NA/TC	R (06NOV2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
4444 44441607	MUSC	Back pain/ Low back pain	2	09NOV2020	27/4	1	No	O	NA/TC	R (12NOV2020)	N/N	
>55/ C4591001 4444 44441613	EAR	Vertigo/ Worsening of Peripheral Vertiginous Syndrome	1	12OCT2020	20/3	2	No	O	NA/TC/TCN	R (14OCT2020)	N/N	
>55/ C4591001 4444 44441625	MUSC	Myalgia/ myalgia	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N	
>55/ C4591001 4444 44441625	GASTR	Haemorrhoids/ Hemorrhoids	1	27SEP2020	5/12	1	No	O	NA/TC	R (08OCT2020)	N/N	
>55/ C4591001 4444 44441626	MUSC	Myalgia/ GENERALIZED MYALGY	1	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N	
>55/ C4591001 4444 44441631	GENRL	Pyrexia/ Fever#	4	12MAR2021	1/2	2	Yes		NA/TC	R (13MAR2021)	N/N	
>55/ C4591001 4444 44441641	NERV	Headache/ Headache#	4	12MAR2021	1/2	2	Yes		NA/TC	R (13MAR2021)	N/N	
>55/ C4591001 4444 44441641	MUSC	Rotator cuff syndrome/ Rotator cuff injury of the right shoulder	2	01NOV2020	19/121	2	No	O	NA/TCN	R (01MAR2021)	N/N	
>55/ C4591001	GENRL	Injection site pain/ pain at the injection site in the left arm	1	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N	

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
4444 44441645 >55/ C4591001 4444 44441646 >55/ C4591001 4444 44441656 >55/ C4591001 4444 44441665	INFEC	Urinary tract infection/ Lower urinary infection	2	22OCT2020	9/8	1	No	O	NA/TC	R (29OCT2020)	N/N	
4444 44441646 >55/ C4591001 4444 44441656 >55/ C4591001 4444 44441665	MUSC	Pain in extremity/ pain on mobilization in left arm	1	25SEP2020	3/3	1	Yes		NA	R (27SEP2020)	N/N	
4444 44441665 4444 44441666 >55/ C4591001 4444 44441667	GASTR	Diarrhoea/ Acute diarrhea	2	17OCT2020	4/3	1	No	O	NA	R (19OCT2020)	N/N	
4444 44441666 >55/ C4591001 4444 44441667	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	15JAN2021	94/25	1	No	O	NA/TC	R (08FEB2021)	N/N	
4444 44441667	RENAL	Renal failure/ Renal insufficiency	2	15JAN2021	94/34	1	No	O	NA	R (17FEB2021)	N/N	
4444 44441667	GENRL	Pelvic mass/ Pelvic mass#	3	06FEB2021	2/C	2	No	O	NA/TC/TCN	N	Y/N	
4444 44441667	EYE	Dry eye/ Dry Eye	1	30SEP2020	8/C	1	No	O	NA/TC/TCN	RG	N/N	
4444 44441667	EYE	Eye pain/ eye pain	1	26SEP2020	4/5	2	No	O	NA/TC	R (30SEP2020)	N/N	
4444 44441667	MUSC	Arthralgia/ arthralgias	1	26SEP2020	4/3	1	No	O	NA	R (28SEP2020)	N/N	



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 4444 44441690	SKIN	Rash/ skin rash on face and torso	1	26SEP2020	4/3	1	No	O	NA	R (28SEP2020)	N/N
	MUSC	Arthralgia/ arthralgias	1	04OCT2020	12/12	1	No	O	NA/TC/TCN	R (15OCT2020)	N/N
	MUSC	Arthralgia/ Left elbow pain	1	28SEP2020	6/3	1	No	O	NA/TCN	R (30SEP2020)	N/N
	GENRL	Oedema peripheral/ edema in the left upper limb, arm, forearm and left hand	1	26SEP2020	4/4	2	No	O	NA/TC	R (29SEP2020)	N/N
	MUSC	Myalgia/ Generalized myalgia	1	26SEP2020	4/4	2	Yes		NA/TC	R (29SEP2020)	N/N
	INFEC	Influenza/ Flu	1	07OCT2020	15/4	1	No	O	NA/TC	R (10OCT2020)	N/N
	MUSC	Synovial cyst/ Left hand ganglion	1	07OCT2020	15/125	1	No	O	NA/TCN	RS (08FEB2021)	N/N
	VASC	Hypotension/ arterial hypotension	1	13OCT2020	21/1	2	No	O	NA	R (13OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	14OCT2020	2/2	2	Yes		NA/TC	R (15OCT2020)	N/N
	NERV	Headache/ headache	1	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 4444 44441743	MUSC	Myalgia/ Mild generalized myalgia.	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C4591001 4444 44441774	GENRL	Pyrexia/ Fever	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
	MUSC	Myalgia/ Generalized myalgia	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N
>55/ C4591001 4444 44441787	MUSC	Arthralgia/ Knee arthralgia	2	01NOV2020	20/15	1	No	O	NA	R (15NOV2020)	N/N
>55/ C4591001 4444 44441803	GENRL	Asthenia/ asthenia	1	28SEP2020	4/4	2	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ myalgia	1	28SEP2020	4/4	2	Yes		NA/TC	R (01OCT2020)	N/N
	INFEC	Ophthalmic herpes zoster/ herpes zoster related keratitis in left eye	2	20OCT2020	5/4	1	No	O	NA/TC	R (23OCT2020)	N/N
>55/ C4591001 4444 44441811	INFEC	Tooth infection/ Odontogenic infection	2	26OCT2020	11/11	1	No	O	NA/TC/TCN	R (05NOV2020)	N/N
>55/ C4591001 4444 44441813	MUSC	Myalgia/ Generalized myalgia#	4	06FEB2021	2/30	2	Yes		NA/TC	R (07MAR2021)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 4444 44441822	INJ&P	Joint dislocation/ Right hip dislocation	2	16OCT2020	1/1	3	No	O	NA/TCN	R (16OCT2020)	N/N
>55/ C4591001 4444 44441831	GENRL	Sensation of foreign body/ Foreign body sensation in pharynx	1	27SEP2020	3/1	2	No	O	NA	R (27SEP2020)	N/N
	GASTR	Abdominal pain upper/ Pain in epigastrium	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
		Vomiting/ Vomiting	2	17OCT2020	2/1	2	Yes		NA	R (17OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	17OCT2020	2/3	1	Yes		NA/TC	R (19OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	17OCT2020	2/3	1	Yes		NA	R (19OCT2020)	N/N
	NERV	Hypersomnia/ Hypersomnia	2	17OCT2020	2/3	1	Yes		NA	R (19OCT2020)	N/N
>55/ C4591001 4444 44441865	NERV	Parosmia/ Hyperosmia	2	25OCT2020	11/17	1	No	O	NA	R (10NOV2020)	N/N
>55/ C4591001 4444 44441867	GASTR	Diarrhoea/ Diarrhea	2	16OCT2020	1/2	2	Yes		NA	R (17OCT2020)	N/N
>55/ C4591001 4444 44441873	HEPAT	Cholelithiasis/ Gallstones (gallbladder stones)	2	13DEC2020	60/26	4	No	O	NA/TCN	R (07JAN2021)	Y/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GASTR	Pancreatitis acute/ Acute pancreatitis	2	16DEC2020	63/23	3	No	O	NA/TC/TCN	R (07JAN2021)	Y/N	
>55/ C4591001 4444 44441876	SKIN	Hand dermatitis/ Dermatitis on the back of both hands	1	27SEP2020	3/130	1	No	O	NA	R (03FEB2021)	N/N	
>55/ C4591001 4444 44441884	GENRL	Pyrexia/ Fever#	4	13MAR2021	2/1	1	Yes		NA/TC	R (13MAR2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	13MAR2021	2/C	1	Yes		NA	N	N/N	
>55/ C4591001 4444 44441890	GENRL	Pyrexia/ Fever	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N	
>55/ C4591001 4444 44441894	EAR	Vertigo/ Worsening of vertiginous syndrome	1	28SEP2020	4/17	2	No	O	NA/TC	R (14OCT2020)	N/N	
>55/ C4591001 4444 44441905	GASTR	Diarrhoea/ acute diarrhea	2	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N	
	NERV	Headache/ headache	2	16OCT2020	1/2	2	Yes		NA	R (17OCT2020)	N/N	
>55/ C4591001 4444 44441922	RESP	Rhinitis allergic/ allergic rhinitis.	1	26SEP2020	2/2	1	No	O	NA/TC	R (27SEP2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 4444 44441941	INFEC	Vulvovaginal mycotic infection/ Fungal vulvovaginitis	1	04OCT2020	10/1	1	No	O	NA/TC	R (04OCT2020)	N/N
	REPRO	Vaginal haemorrhage/ Vaginal hemorrhage	1	04OCT2020	10/1	1	No	O	NA/TC	R (04OCT2020)	N/N
>55/ C4591001 4444 44442012	NERV	Facial paralysis/ Left peripheral facial palsy	1	31OCT2020	37/21	2	No	O	NA/TC/TCN	R (20NOV2020)	N/N
>55/ C4591001 4444 44442063	MUSC	Pain in extremity/ Left arm pain	1	13OCT2020	17/5	1	No	O	NA	R (17OCT2020)	N/N
>55/ C4591001 4444 44442096	GASTR	Nausea/ nausea	1	12OCT2020	16/1	1	No	O	NA/TC	R (12OCT2020)	N/N
>55/ C4591001 4444 44442108	INJ&P	Hand fracture/ Fracture of proximal phalanx of second finger of left hand	2	03NOV2020	20/9	2	No	O	NA/TC/TCN	R (11NOV2020)	N/N
>55/ C4591001 4444 44442110	NERV	Headache/ headache	2	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N
>55/ C4591001 4444 44442128	MUSC	Intervertebral disc protrusion/ Herniated disc.	1	08OCT2020	12/8	1	No	O	NA/TCN	R (15OCT2020)	N/N

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Diarrhoea/ Diarrhea	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	17OCT2020	2/1	3	Yes		NA/TC	R (17OCT2020)	N/N
>55/ C4591001 4444 44442134	GASTR	Diarrhoea/ Diarrhea*		27SEP2020	1/2	1	No	O	NA	R (28SEP2020)	N/N
	METAB	Hyperglycaemia/ Hyperglycemia	2	16OCT2020	2/1	1	No	O	NA/TCN	R (16OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	17OCT2020	3/2	1	Yes		NA/TC	R (18OCT2020)	N/N
>55/ C4591001 4444 44442139	NERV	Headache/ headache	1	29SEP2020	3/2	1	Yes		NA/TC	R (30SEP2020)	N/N
>55/ C4591001 4444 44442143	GASTR	Abdominal pain/ Abdominal pain	2	09NOV2020	25/2	1	No	O	NA/TC	R (10NOV2020)	N/N
>55/ C4591001 4444 44442153	NERV	Headache/ headache	1	28SEP2020	2/2	1	Yes		NA/TC	R (29SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	17OCT2020	2/1	2	Yes		NA/TC	R (17OCT2020)	N/N
>55/ C4591001 4444 44442166	GENRL	Fatigue/ fatigue#	4	12MAR2021	2/2	2	Yes		NA/TC	R (13MAR2021)	N/N

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	MUSC	Pyrexia/ fever#	4	12MAR2021	2/1	1	Yes		NA/TC	R (12MAR2021)	N/N	
		Myalgia/ generalized muscle pain#	4	12MAR2021	2/2	2	Yes		NA/TC	R (13MAR2021)	N/N	
>55/ C4591001 4444 44442175	INV	Body temperature increased/ Body temperature increased: thermal record 37.7 C	1	28SEP2020	2/1	1	Yes		NA/TC	R (28SEP2020)	N/N	
>55/ C4591001 4444 44442176	GENRL	Chills/ Chills	2	15OCT2020	1/8	1	Yes		NA	R (22OCT2020)	N/N	
	NERV	Injection site pain/ injection site pain	2	15OCT2020	1/6	2	Yes		NA/TC	R (20OCT2020)	N/N	
		Headache/ Headache	2	15OCT2020	1/6	2	Yes		NA/TC	R (20OCT2020)	N/N	
>55/ C4591001 4444 44442183	GENRL	Pyrexia/ fever	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N	
>55/ C4591001 4444 44442191	SKIN	Pruritus/ Itching in both legs	1	28SEP2020	2/6	1	No	O	NA/TC	R (03OCT2020)	N/N	
>55/ C4591001 4444 44442192	NERV	Headache/ Headache	2	23OCT2020	8/15	1	No	O	NA/TC	R (06NOV2020)	N/N	
>55/ C4591001	GENRL	Asthenia/ asthenia	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N	

## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44442240 >55/ C4591001 4444 44442243	GENRL	Injection site pain/ Pain at the injection site#	4	27FEB2021	2/1	1	Yes		NA/TC	R (27FEB2021)	N/N
4444 44442243	NERV	Headache/ Headache#	4	27FEB2021	2/1	1	Yes		NA/TC	R (27FEB2021)	N/N
4444 44442243	BLOOD	Lymphadenitis/ reactive adenitis#	4	02MAR2021	5/C	1	No	O	NA	RG	N/N
>55/ C4591001 4444 44442246	SKIN	Rash/ Exanthema located on thighs, groin and arms	2	17OCT2020	2/1	1	No	O	NA	R (17OCT2020)	N/N
>55/ C4591001 4444 44442271	GASTR	Diarrhoea/ Diarrhea	1	29SEP2020	3/2	2	Yes		NA	R (30SEP2020)	N/N
4444 44442289	MUSC	Myalgia/ generalized myalgia	2	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N
>55/ C4591001 4444 44442289	NERV	Headache/ headache	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
>55/ C4591001 4444 44442290	EYE	Cataract/ Cataracts	2	29OCT2020	15/C	1	No	O	NA	N	N/N
>55/ C4591001	GENRL	Injection site pain/ Pain at injection site	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N



## 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44442295 >55/ C4591001 4444 44442309	GASTR	Toothache/ Left first molar tooth pain	1	02OCT2020	6/3	1	No	O	NA/TC	R (04OCT2020)	N/N
	INFEC	Tooth infection/ 1st left molar infected cavity	1	02OCT2020	6/3	1	No	O	NA/TC	R (04OCT2020)	N/N
	IMMUN	Drug hypersensitivity/ Allergic reaction secondary to taking antibiotics	1	03OCT2020	7/1	2	No	O	NA/TC	R (03OCT2020)	N/N
	SKIN	Rash pruritic/ Generalized pruritic rash	1	03OCT2020	7/1	2	No	O	NA/TC	R (03OCT2020)	N/N
>55/ C4591001 4444 44442316	GENRL	Injection site pain/ Pain at injection site	1	27SEP2020	1/3	1	Yes		NA	R (29SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	28SEP2020	2/1	1	Yes		NA	R (28SEP2020)	N/N
>55/ C4591001 4444 44442320	GENRL	Pyrexia/ fever	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
	NERV	Headache/ headache	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v23.1) coding dictionary applied.

Note: \* = prevaccination AE, ^ = Phase 1 subjects, † = human immunodeficiency virus (HIV)-positive subject, # = AE occurring on or after unblinding.

a. Relative day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

**16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age**

<b>Age Group (Years)/ Subject</b>	<b>System Organ Class</b>	<b>Preferred Term/ AE Investigator Text</b>	<b>Dose No.</b>	<b>Onset Date</b>	<b>Rel Day<sup>a</sup>/ Dur (Days)<sup>b</sup></b>	<b>Toxicity Grade</b>	<b>Vax Rel<sup>c</sup> AE</b>	<b>Cause of Vaccine Subject</b>	<b>Action: Investigational Dose/ Subject</b>	<b>Outcome (End Date)</b>	<b>SAE/Imm AE (Yes/No)</b>
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c. Vaccine related (Vax Rel): relationship to investigational vaccine as assessed by the investigator.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 29MAR2021 (21:25)  
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adae\_1002\_all\_all

## 16.2.7.4.2 Listing of Adverse Events – Subjects Enrolled in Multiple Sites

Duplicate	Subject ID	Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1	10561101	16-55/ C4591001 1056 10561101		NO AE									
	11331382	16-55/ C4591001 1133 11331382	GENRL	Fatigue/ FATIGUE	2	26SEP2020	2/3	1	Yes		NA/TCN	R (28SEP2020)	N/N
				Injection site pain/ SORNESS AT INJECTION SITE	2	26SEP2020	2/5	1	Yes		NA/TC	R (30SEP2020)	N/N
				Pain/ BODYACHE	2	26SEP2020	2/4	2	Yes		NA/TC	R (29SEP2020)	N/N
				Pyrexia/ FEVER	2	26SEP2020	2/2	2	Yes		NA/TC	R (27SEP2020)	N/N
			NERV	Headache/ HEADACHE	2	26SEP2020	2/3	2	Yes		NA/TC/TCN	R (28SEP2020)	N/N
2	11101123	16-55/ C4591001 1110 11101123		NO AE									
	11331405	16-55/ C4591001 1133 11331405		NO AE									
3	11491117	>55/ C4591001		NO AE									

## 16.2.7.4.2 Listing of Adverse Events – Subjects Enrolled in Multiple Sites

Duplicate	Subject ID	Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	12691090	1149 11491117 >55/ C4591001 1269 12691090	GENRL	Injection site pain/ soreness at injection site	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
				Pyrexia/ fever	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
			MUSC	Myalgia/ muscle aches	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
			NERV	Headache/ headache	2	01OCT2020	10/2	1	No	O	NA	R (02OCT2020)	N/N
4	11351357	>55/ C4591001 1135 11351357		NO AE									
	12691070	>55/ C4591001 1269 12691070		NO AE									
5	10891112	>55/ C4591001 1089 10891112	INFEC	Fungal infection/ fungal infection bilateral axilla	2	18SEP2020	18/9	2	No	O	NA/TC	R (26SEP2020)	N/N
	11341006	>55/ C4591001 1134 11341006		NO AE									

## 16.2.7.4.2 Listing of Adverse Events – Subjects Enrolled in Multiple Sites

Duplicate	Subject ID	Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade Rel <sup>c</sup>	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
6	10711213	16-55/ C4591001	GENRL	Pyrexia/ FEVER	1	08OCT2020	2/2	1 Yes		NA	R (09OCT2020)	N/N
	1071 10711213											
	11231105	16-55/ C4591001		NO AE								
	1123 11231105											

Abbreviations: Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v23.1) coding dictionary applied.

a. Relative day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

c. Vaccine related (Vax Rel): relationship to investigational vaccine as assessed by the investigator.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (09:21)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adae\_l002\_menrol\_all

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
18-55/ C4591001 1003 10031038^	INFEC	Appendicitis/ appendicitis	2	19SEP2020	74/5	3	No	O	NA/TC/TCN	R (23SEP2020)	Y/N	
18-55/ C4591001 1003 10031065^	NERV	Neuritis/ neuritis	2	29JUL2020	15/C	3	No	O	NA	N	Y/N	
16-55/ C4591001 1003 10031111	MUSC	Psoriatic arthropathy/ psoriatic arthritis	2	26SEP2020	38/C	2	Yes		NA/TC	N	Y/N	
16-55/ C4591001 1003 10031197	CONG	Congenital ureteropelvic junction obstruction/ Congenital right ureteropelvic junction obstruction	2	01DEC2020	90/58	3	No	O	NA/TC/TCN	R (27JAN2021)	Y/N	
16-55/ C4591001 1003 10031207	VASC	Deep vein thrombosis/ bilateral lower extremity DVT	2	27DEC2020	115/48	3	No	O	NA/TC	R (12FEB2021)	Y/N	
	RESP	Pulmonary embolism/ pulmonary embolism	2	28DEC2020	116/15	3	No	O	NA/TC	R (11JAN2021)	Y/N	
16-55/ C4591001 1005 10051054	GENRL	Non-cardiac chest pain/ INTERMITTENT NON CARDIAC CHEST PAIN	2	09SEP2020	6/9	2	No	O	NA	R (17SEP2020)	Y/N	
16-55/ C4591001 1005 10051411	GASTR	Abdominal pain/ ABDOMINAL PAIN	2	29JAN2021	2/4	3	No	O	NA/TC	R (01FEB2021)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1006 10061176	RESP	Asthma/ Acute Asthma Exacerbation#	2	03FEB2021	77/8	3	No	O	NA/TC	R (10FEB2021)	Y/N	
16-55/ C4591001 1007 10071276	NEOPL	Chronic myeloid leukaemia/ chronic myelogenous leukemia	2	24SEP2020	8/C	4	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1008 10081152	NERV	Optic neuritis/ Optic neuritis left eye	2	09DEC2020	80/14	3	No	O	NA/TC	R (22DEC2020)	Y/N	
16-55/ C4591001 1013 10131084	GENRL	Vascular stent occlusion/ OBSTRUCTED RENAL STENT (ARTERY)	2	01SEP2020	7/C	2	No	O	NA	RG	Y/N	
16-55/ C4591001 1013 10131089	VASC	Deep vein thrombosis/ LEFT ARM DEEP VEIN THROMBOSIS	2	20DEC2020	116/C	3	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1013 10131165	RESP	Pulmonary embolism/ Pulmonary Embolism Bilateral	2	14DEC2020	104/C	3	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1013 10131190	RENAL	Nephrolithiasis/ kidney stones	2	04JAN2021	119/2	3	No	O	NA/TCN	R (05JAN2021)	Y/N	
16-55/ C4591001	PREG	Abortion spontaneous/ MISCARRIAGE	2	OCT2020	22/	3	No	O	NA	R	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1013 10131255 16-55/ C4591001 1013 10131653	VASC	Deep vein thrombosis/ RIGHT LOWER EXTREMITY DEEP VEIN THROMBOSIS	2	15NOV2020	20/C	3	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1013 10131656	METAB	Diabetic ketoacidosis/ DIABETIC KETOACIDOSIS	2	18JAN2021	84/4	3	No	O	NA/TC	R (21JAN2021)	Y/N	
16-55/ C4591001 1013 10131718	HEPAT	Cholecystitis/ CHOLECYSTITIS#	3	07MAR2021	12/4	2	No	O	NA/TC	R (10MAR2021)	Y/N	
16-55/ C4591001 1015 10151047	GENRL	Shoulder injury related to vaccine administration/ SIRVA - shoulder injury related to vaccine administration	2	09SEP2020	1/153	3	Yes		NA	R (08FEB2021)	Y/N	
16-55/ C4591001 1016 10161120	NERV	Brachial plexopathy/ left brachial nerve plexopathy#	3	11JAN2021	20/18	3	No	O	NA	R (28JAN2021)	Y/N	
16-55/ C4591001 1016 10161128	NEOPL	Intraductal proliferative breast lesion/ ductal carcinoma in situ, right breast	2	26OCT2020	48/45	2	No	O	NA/TCN	R (09DEC2020)	Y/N	
16-55/ C4591001 1016 10161277	CARD	Atrial fibrillation/ atrial fibrillation	2	09OCT2020	8/4	2	No	O	NA/TC	R (12OCT2020)	Y/N	



16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1016 10161289	INJ&P	Facial bones fracture/ facial fractures	2	31OCT2020	25/C	3	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1018 10181031	INFEC	Appendicitis/ Appendicitis	2	06JAN2021	136/3	4	No	O	NA/TC/TCN	R (08JAN2021)	Y/N	
16-55/ C4591001 1018 10181090	VASC	Deep vein thrombosis/ Deep Vein Thrombosis, left leg	2	27NOV2020	93/C	3	No	O	NA/TC	RG	Y/N	
	RESP	Pulmonary embolism/ Pulmonary Embolism, bilateral, segmental and sub segmental	2	14DEC2020	110/C	4	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1018 10181159	NERV	Paraesthesia/ Right Leg Paresthesia	2	20OCT2020	47/C	2	Yes		NA/TC	RG	Y/N	
16-55/ C4591001 1019 10191145	NEOPL	Breast cancer/ Ductal carcinoma right Breast	2	13NOV2020	52/C	3	No	O	NA/TC	N	Y/N	
		Invasive ductal breast carcinoma/ Ductal Carcinoma Left Breast	2	13NOV2020	52/C	3	No	O	NA/TC	N	Y/N	
		Metastases to lymph nodes/ Right Axillary Metastases	2	13NOV2020	52/C	3	No	O	NA/TC	N	Y/N	
	INJ&P	Intentional overdose/ Overdose Intentional#	2	09MAR2021	168/2	3	No	CD	NA	RS (10MAR2021)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	PSYCH	Suicide attempt/ Attempted Suicide#	2	09MAR2021	168/2	3	No	CD	NA	RS (10MAR2021)	Y/N	
16-55/ C4591001 1019 10191226	INFEC	COVID-19/ COVID-19 Illness	2	28DEC2020	76/27	3	No	O	NA	R (23JAN2021)	Y/N	
16-55/ C4591001 1019 10191254	INFEC	Urinary tract infection/ Urinary Tract Infection	1	15OCT2020	11/10	3	No	O	NA/TC	R (24OCT2020)	Y/N	
16-55/ C4591001 1021 10211127	CARD	Acute left ventricular failure/ NYHA Class IV Acute on Chronic Systolic Heart Failure	2	19OCT2020	27/3	3	No	O	NA/TC	R (21OCT2020)	Y/N	
	CARD	Cardiac failure congestive/ Acute on Chronic Combined Systolic and Diastolic Congestive Heart Failure	2	30NOV2020	69/20	4	No	O	NA/TC/W	F (19DEC2020)	Y/N	
16-55/ C4591001 1022 10221164	NEOPL	Plasma cell myeloma/ IGA Kappa Multiple Myeloma	2	27NOV2020	51/C	2	No	O	NA	N	Y/N	
16-55/ C4591001 1028 10281033	SOCCI	Miscarriage of partner/ miscarriage for pregnant partner	2	22DEC2020	103/1	2	No	O	NA	R (22DEC2020)	Y/N	
16-55/ C4591001 1028 10281059	NEOPL	Invasive ductal breast carcinoma/ invasive ductal carcinoma stage 1B, left breast	2	30SEP2020	15/C	2	No	O	NA/TC	N	Y/N	
16-55/ C4591001	INJ&P	Upper limb fracture/ Closed fracture of right elbow	2	28OCT2020	42/2	2	No	O	NA/TC/TCN	R (29OCT2020)	Y/N	

## 16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1028 10281060 16-55/ C4591001 1030 10301110	INFEC	Pharyngitis streptococcal/ pharyngitis streptococcal#	2	17JAN2021	101/14	2	No	O	NA/TC	R (30JAN2021)	Y/N
16-55/ C4591001 1037 10371052	RESP	Dyspnoea/ INCREASED SHORTNESS OF BREATH#	2	31JAN2021	140/C	3	No	O	NA/TC/TCN	N	Y/N
16-55/ C4591001 1042 10421034	HEPAT	Cholecystitis/ cholecystitis#	2	07FEB2021	167/3	3	No	O	NA/TC/TCN	R (09FEB2021)	Y/N
16-55/ C4591001 1044 10441152†	NEOPL	Breast cancer/ breast cancer initial diagnosis	2	28DEC2020	71/C	2	No	O	NA/TC	N	Y/N
16-55/ C4591001 1046 10461175	INFEC	COVID-19/ CoVid19	2	14JAN2021	115/12	3	No	O	NA/TC	R (25JAN2021)	Y/N
16-55/ C4591001 1048 10481032	GASTR	Gastritis/ Worsening of gastritis	2	14FEB2021	153/4	3	No	O	NA/TC	R (17FEB2021)	Y/N
		Impaired gastric emptying/ Worsening of gastroparesis	2	14FEB2021	153/4	3	No	O	NA/TC	R (17FEB2021)	Y/N
16-55/ C4591001	NERV	Seizure/ Seizure#	4	05FEB2021	11/1	1	No	O	NA/TC	R (05FEB2021)	Y/N

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1052 10521172 16-55/ C4591001 1055 10551176	CARD	Arteriospasm coronary/ Coronary vasospasm	2	25SEP2020	3/2	3	No	O	NA	R (26SEP2020)	Y/N	
16-55/ C4591001 1057 10571065	HEPAT	Cholecystitis acute/ ACUTE CHOLECYSTITIS#	2	05FEB2021	150/4	3	No	O	NA/TCN	R (08FEB2021)	Y/N	
	INFEC	Postoperative abscess/ POST CHOLECYSTECTOMY ABSCESS#	2	12FEB2021	157/C	3	No	O	NA/TC	N	Y/N	
16-55/ C4591001 1057 10571137	NEOPL	Uterine leiomyoma/ WORSENING OF UTERINE FIBROIDS	1	14SEP2020	14/6	2	No	O	NA/TCN	R (19SEP2020)	Y/N	
16-55/ C4591001 1066 10661242	RESP	Pulmonary embolism/ Pulmonary Embolism with bilateral lower lobe Pulmonary embolisms#	4	15FEB2021	6/2	3	No	O	NA/TC	RS (16FEB2021)	Y/N	
16-55/ C4591001 1077 10771137	INJ&P	Tibia fracture/ LEFT TIBIAL PLATEAU FRACTURE	2	28JAN2021	134/C	2	No	O	NA/TC/TCN	RG	Y/N	
16-55/ C4591001 1079 10791004	NEOPL	Adenocarcinoma gastric/ INFILTRATING, POORLY DIFFERENTIATED ADENOCARCINOMA - STOMACH	1	20AUG2020	23/C	3	No	O	P/W	N	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1079 10791199	NERV	Seizure/ Seizure#	2	03MAR2021	169/C	4	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1080 10801059	INFEC	Appendicitis/ Appendicitis	2	09FEB2021	153/1	3	No	O	NA/TCN	R (09FEB2021)	Y/N	
16-55/ C4591001 1081 10811036	INFEC	Appendicitis/ Appendicitis	1	21AUG2020	9/3	3	No	O	NA/TC/TCN	R (23AUG2020)	Y/N	
16-55/ C4591001 1081 10811046	METAB	Diabetic ketoacidosis/ Diabetic Ketoacidosis	2	17SEP2020	9/2	3	No	O	NA	R (18SEP2020)	Y/N	
16-55/ C4591001 1081 10811135	CARD	Myocardial infarction/ Myocardial Infarction	2	21OCT2020	30/8	4	No	O	NA/TC/TCN	RS (28OCT2020)	Y/N	
	METAB	Type 2 diabetes mellitus/ Type II Diabetes Mellitus	2	27OCT2020	36/C	3	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1081 10811194	CARD	Myocardial infarction/ Myocardial Infarction	2	04NOV2020	37/1	4	No	O	NA/W	F (04NOV2020)	Y/N	
16-55/ C4591001 1082 10821083	CARD	Myocardial infarction/ myocardial infarction	2	28OCT2020	62/8	4	No	O	NA	R (04NOV2020)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1082 10821149	NEOPL	Malignant melanoma/ Malignant Melanoma (etiology unknown)	2	24NOV2020	63/C	3	No	O	NA/W	N	Y/N	
16-55/ C4591001 1083 10831029	CARD	Atrial fibrillation/ Paroxysmal Atrial fibrillation with rapid ventricular response	1	23AUG2020	20/17	3	No	O	P/TC/TCN	R (08SEP2020)	Y/N	
16-55/ C4591001 1083 10831060	GASTR	Diverticular perforation/ Ruptured diverticulum	1	14AUG2020	9/11	4	No	O	P/TC/TCN	R (24AUG2020)	Y/N	
16-55/ C4591001 1083 10831162	PREG	Abortion spontaneous/ Miscarriage	2	04DEC2020	80/2	2	No	O	NA	R (05DEC2020)	Y/N	
16-55/ C4591001 1083 10831194	CARD	Atrial fibrillation/ New Onset Atrial Fibrillation with rapid ventricular response	2	26OCT2020	34/C	2	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1084 10841141	INFEC	Appendicitis/ Appendicitis	2	20DEC2020	110/3	3	No	O	NA/TC/TCN	R (22DEC2020)	Y/N	
16-55/ C4591001 1084 10841317	INFEC	Cellulitis/ Cellulitis in Left leg	1	08SEP2020	12/9	2	No	O	NA/TC/TCN	R (16SEP2020)	Y/N	
16-55/ C4591001	CARD	Acute myocardial infarction/ ST-segment elevated MYOCARDIAL INFARCTION	1	26OCT2020	13/1	2	No	O	NA/TC	R (26OCT2020)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1084 10841480 16-55/ C4591001	PSYCH	Bipolar I disorder/ Bipolar I#	2	31JAN2021	63/C	3	No	O	NA/TC/TCN	RG	Y/N	
1084 10841538 16-55/ C4591001	REPRO	Endometrial thickening/ Endometrial thickening#	2	09FEB2021	172/3	3	No	O	NA/TCN	R (11FEB2021)	Y/N	
1085 10851018		Endometriosis/ Endometriosis#	2	09FEB2021	172/3	3	No	O	NA/TCN	R (11FEB2021)	Y/N	
16-55/ C4591001	NEOPL	Meningioma/ right frontal meningioma	1	23SEP2020	6/C	2	No	O	NA	N	Y/N	
1088 10881220 16-55/ C4591001	INFEC	Diabetic foot infection/ Infection right pinky toe (secondary to diabetes)	2	17JAN2021	144/33	3	No	O	NA/TC/TCN	R (18FEB2021)	Y/N	
1089 10891065 16-55/ C4591001	INJ&P	Hip fracture/ Left Hip Closed Fracture	1	09SEP2020	16/17	3	No	O	NA/TC	R (25SEP2020)	Y/N	
1089 10891182	PSYCH	Psychotic disorder/ Psychosis	1	27SEP2020	34/C	3	No	O	NA/TC/TCN	N	Y/N	
16-55/ C4591001	HEPAT	Acute hepatic failure/ Acute Liver Failure#	2	19DEC2020	79/C	4	No	O	NA/W	N	Y/N	
1089 10891289												

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1090 10901140	INFEC	Appendicitis perforated/ acute appendicitis with perforation#	3	04FEB2021	9/8	4	No	O	NA/TC/TCN	R (11FEB2021)	Y/N	
		Focal peritonitis/ localized peritonitis#	3	04FEB2021	9/8	4	No	O	NA/TC/TCN	R (11FEB2021)	Y/N	
		Pelvic abscess/ pelvic abscess#	3	04FEB2021	9/8	4	No	O	NA/TC/TCN	R (11FEB2021)	Y/N	
16-55/ C4591001 1090 10901384	REPRO	Adnexal torsion/ Right ovarian torsion	2	07DEC2020	63/6	4	No	O	NA/TCN	R (12DEC2020)	Y/N	
16-55/ C4591001 1090 10901536	INFEC	Pyelonephritis/ pyelonephritis	2	11FEB2021	91/2	2	No	O	NA/TC	R (12FEB2021)	Y/N	
16-55/ C4591001 1091 10911197	INJ&P	Toxicity to various agents/ poisoning by cocaine	2	26SEP2020	10/2	4	No	O	NA/TC/TCN	R (27SEP2020)	Y/N	
	RESP	Hypoxia/ hypoxia	2	26SEP2020	10/2	3	No	O	NA/TC/TCN	R (27SEP2020)	Y/N	
		Pneumonia aspiration/ Aspiration Pneumonia	2	26SEP2020	10/11	3	No	O	NA/TC	R (06OCT2020)	Y/N	
16-55/ C4591001 1091 10911300	INFEC	Appendicitis/ Appendicitis	2	21OCT2020	16/2	4	No	O	NA/TCN	R (22OCT2020)	Y/N	



16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1093 10931067	INFEC	Subcutaneous abscess/ Cutaneous abscess of left upper extremity#	2	20FEB2021	158/17	1	No	O	NA/TC	R (08MAR2021)	Y/N	
16-55/ C4591001 1094 10941155	INJ&P	Colon injury/ colon injury	1	16OCT2020	22/8	3	No	O	NA/TC/TCN	RS (23OCT2020)	Y/N	
16-55/ C4591001 1095 10951009	REPRO	Adnexal torsion/ torsion of right ovary	2	23DEC2020	125/27	3	No	O	NA/TC/TCN	R (18JAN2021)	Y/N	
16-55/ C4591001 1095 10951173	CARD	Acute myocardial infarction/ STEMI: ST elevation Myocardial Infarction	1	05SEP2020	8/5	4	No	O	NA/TC/TCN	R (09SEP2020)	Y/N	
16-55/ C4591001 1095 10951197	MUSC	Intervertebral disc degeneration/ exacerbation of Degenerative Disc Disease	2	14JAN2021	88/2	3	No	O	NA/TC/TCN	R (15JAN2021)	Y/N	
16-55/ C4591001 1096 10961036	PSYCH	Depression suicidal/ worsening of depression with suicidal ideation	2	OCT2020	23/	3	No	O	P/TC	RS (14NOV2020)	Y/N	
16-55/ C4591001 1096 10961062	METAB	Hypokalaemia/ HYPOKALEMIA	2	SEP2020	1/	3	No	O	NA/TC	R	Y/N	
	MUSC	Muscular weakness/ bilateral lower extremity weakness	2	04OCT2020	26/2	3	No	O	NA	R (05OCT2020)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1101 11011115	PREG	Abortion spontaneous/ spontaneous abortion#	2	20FEB2021	101/1	3	No	O	NA	R (20FEB2021)	Y/N	
16-55/ C4591001 1107 11071031	GASTR	Colitis/ ASCENDING COLITIS	2	25NOV2020	73/19	3	No	O	NA/TC	R (13DEC2020)	Y/N	
16-55/ C4591001 1107 11071065	BLOOD	Microcytic anaemia/ MICROCYTIC ANEMIA	2	09NOV2020	75/C	3	No	O	NA/TC/TCN	N	Y/N	
	INV	Red blood cell morphology abnormal/ ABNORMAL RBC MORPHOLOGY INCLUDING SICKLE CELLS	2	09NOV2020	75/C	3	No	O	NA	N	Y/N	
16-55/ C4591001 1109 11091204	INFEC	Appendicitis/ ACUTE APPENDICITIS	1	17AUG2020	7/17	4	No	O	NA/TC	R (02SEP2020)	Y/N	
		Peritoneal abscess/ Peritoneal Abscess	1	17AUG2020	7/17	4	No	O	NA/TC	R (02SEP2020)	Y/N	
16-55/ C4591001 1109 11091448	NERV	Hemiplegic migraine/ Hemiplegic Migraine	2	20OCT2020	23/C	4	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1110 11101187	INFEC	Appendicitis/ Acute Appendicitis	2	07DEC2020	77/4	3	No	O	NA/TC/TCN	R (10DEC2020)	Y/N	
16-55/ C4591001	EYE	Visual impairment/ change in vision	2	06DEC2020	66/2	2	No	O	NA	R (07DEC2020)	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1110 11101236 16-55/ C4591001 1111 11111130	NERV	Subarachnoid haemorrhage/ Subarachnoid hemorrhage	1	26AUG2020	9/9	2	No	O	NA/TC/TCN	R (03SEP2020)	Y/N	
16-55/ C4591001 1112 11121122	NEOPL	Uterine leiomyoma/ Worsening INTRAMURAL AND SUBSEROUS LEIOMYOMA OF UTERUS	2	14SEP2020	14/66	3	No	O	NA/TCN	R (18NOV2020)	Y/N	
16-55/ C4591001 1116 11161059	GASTR	Obstructive pancreatitis/ Gall Stone Pancreatitis	1	13SEP2020	14/6	3	No	O	NA/TC/TCN	R (18SEP2020)	Y/N	
	HEPAT	Bile duct stone/ Cholecholithiasis	1	13SEP2020	14/7	3	No	O	NA/TC/TCN	R (19SEP2020)	Y/N	
16-55/ C4591001 1117 11171036	NERV	Syncope/ Syncopal Episode	1	26AUG2020	7/5	4	No	O	NA	R (30AUG2020)	Y/N	
	PSYCH	Suicidal ideation/ Suicidal ideation	1	27AUG2020	8/4	4	No	O	NA/TC	R (30AUG2020)	Y/N	
	PSYCH	Suicidal ideation/ SUICIDAL IDEATION	2	20NOV2020	72/6	4	No	O	NA/TC/TCN	R (25NOV2020)	Y/N	
	PSYCH	Major depression/ MODERATE EPISODE OF MAJOR DEPRESSIVE DISORDER W/ PSYCHOSIS	2	30DEC2020	112/3	3	No	O	NA/TC/TCN	R (01JAN2021)	Y/N	

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16-55/ C4591001 1117 11171186	PSYCH	Suicide attempt/ SUICIDAL IDEATION WITH ATTEMPT	1	19OCT2020	14/8	3	No	O	P/TC/TCN	R (26OCT2020)	Y/N	
16-55/ C4591001 1120 11201266	EYE	Blindness unilateral/ LOSS OF VISION LEFT EYE	2	04DEC2020	67/C	4	No	O	NA	N	Y/N	
	NEOPL	Lung cancer metastatic/ Metastatic Lung cancer	2	04DEC2020	67/47	4	No	O	NA/TC/W	F (19JAN2021)	Y/N	
16-55/ C4591001 1121 11211112	INFEC	COVID-19/ COVID-19	2	24OCT2020	26/C	3	No	O	NA/TC	RS	Y/N	
16-55/ C4591001 1124 11241106	CARD	Acute myocardial infarction/ ST elevation myocardial infarction	2	27SEP2020	12/17	4	No	O	NA	R (13OCT2020)	Y/N	
16-55/ C4591001 1125 11251020	INJ&P	Craniocerebral injury/ traumatic brain injury	2	23DEC2020	111/30	3	No	O	NA/TC	R (21JAN2021)	Y/N	
16-55/ C4591001 1127 11271112	CARD	Cardio-respiratory arrest/ Cardiopulmonary arrest	2	04DEC2020	86/1	4	No	O	NA/W	F (04DEC2020)	Y/N	
16-55/ C4591001 1128 11281103	INFEC	Escherichia urinary tract infection/ Escherichia coli urinary tract infection	2	03OCT2020	33/20	2	No	O	NA/TC	R (22OCT2020)	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	METAB	Hypokalaemia/ Severe Hypokalemia	2	03OCT2020	33/20	2	No	O	NA/TC	R (22OCT2020)	Y/N	
	RENAL	Nephrolithiasis/ Kidney Stones	2	03OCT2020	33/20	2	No	O	NA/TC	R (22OCT2020)	Y/N	
16-55/ C4591001 1128 11281123	INFEC	Appendicitis/ APPENDICITIS#	2	15JAN2021	129/2	3	No	O	NA/TC/TCN	R (16JAN2021)	Y/N	
16-55/ C4591001 1128 11281153	HEPAT	Hepatocellular injury/ Hepatocellular injury	2	04NOV2020	57/10	3	No	O	NA/TC	R (13NOV2020)	Y/N	
	INFEC	Sepsis/ Sepsis	2	04NOV2020	57/10	3	No	O	NA/TC	R (13NOV2020)	Y/N	
16-55/ C4591001 1128 11281267	REPRO	Vaginal prolapse/ Vaginal Prolapse	2	01DEC2020	70/18	3	No	O	NA/TCN	R (18DEC2020)	Y/N	
	REPRO	Rectocele/ Rectocele	2	17DEC2020	86/2	3	No	O	NA/TCN	R (18DEC2020)	Y/N	
16-55/ C4591001 1129 11291005	GASTR	Intestinal obstruction/ bowel obstruction	2	21JAN2021	157/2	4	No	O	NA/TC/TCN	RS (22JAN2021)	Y/N	
16-55/ C4591001 1129 11291045	INJ&P	Wrist fracture/ compound fracture left wrist	2	31JAN2021	160/C	2	No	O	NA/TCN	N	Y/N	
16-55/ C4591001	IMMUN	Anaphylactoid reaction/ Anaphylactoid Reaction#	3	27JAN2021	3/1	4	Yes		P/TC	R (27JAN2021)	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1129 11291260 16-55/ C4591001 1131 11311094	PSYCH	Anxiety/ Increased Anxiety#	3	02MAR2021	21/C	3	No	O	NA/TC	N	Y/N	
	PSYCH	Major depression/ Major Depressive Disorder, single episode#	3	03MAR2021	22/C	3	No	O	NA/TC	N	Y/N	
		Suicide attempt/ Suicidal Attempt#	3	03MAR2021	22/3	3	No	O	NA	R (05MAR2021)	Y/N	
16-55/ C4591001 1133 11331317	NEOPL	Brain cancer metastatic/ Metastatic Brain Tumor#	2	08FEB2021	139/17	3	No	O	NA/TC	R (24FEB2021)	Y/N	
16-55/ C4591001 1134 11341327	INFEC	Pneumonia/ DOUBLE PNEUMONIA#	2	10MAR2021	160/C	3	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1135 11351265	VASC	Accelerated hypertension/ accelerated hypertension	2	23JAN2021	121/5	3	No	O	NA/TC	R (27JAN2021)	Y/N	
16-55/ C4591001 1135 11351368	NERV	Guillain-Barre syndrome/ Guillain barre syndrome	2	29DEC2020	84/C	3	No	O	NA/TC/TCN	RG	Y/N	
16-55/ C4591001	GASTR	Pancreatitis acute/ acute pancreatitis	2	21NOV2020	2/4	2	No	O	NA/TC	R (24NOV2020)	Y/N	

## 16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age

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1135 11351563 16-55/ C4591001 1140 11401009	IMMUN	Anaphylactic reaction/ Anaphylaxis Status Post Bee Sting	2	28AUG2020	9/1	4	No	O	NA/TC	R (28AUG2020)	Y/N
16-55/ C4591001 1140 11401020	NEOPL	B-cell lymphoma/ B-Cell Lymphoma	2	03DEC2020	101/C	2	No	O	NA/TC	N	Y/N
16-55/ C4591001 1140 11401282	RESP	Pulmonary embolism/ Bilateral Pulmonary Embolisms#	4	15FEB2021	12/C	4	No	O	NA	RG	Y/N
	VASC	Deep vein thrombosis/ Deep Vein Thrombosis Left Leg#	4	15FEB2021	12/C	4	No	O	NA	RG	Y/N
16-55/ C4591001 1140 11401306	EYE	Visual impairment/ Change in Visual Perception	1	07NOV2020	17/3	3	No	O	P/W	R (09NOV2020)	Y/N
	NERV	Amnesia/ short term memory loss	1	07NOV2020	17/4	1	No	O	P/TC/TCN	R (10NOV2020)	Y/N
16-55/ C4591001 1141 11411153	CARD	Junctional ectopic tachycardia/ Junctional ectopic tachycardia	2	02OCT2020	12/97	4	No	O	NA/TC/TCN	RS (06JAN2021)	Y/N
16-55/ C4591001 1142 11421084	PSYCH	Suicidal ideation/ Suicidal Ideation	1	19AUG2020	8/3	4	No	O	NA/TC	R (21AUG2020)	Y/N

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16-55/ C4591001 1142 11421202	INFEC	Appendicitis/ Acute Appendicitis	2	05DEC2020	68/2	3	No	O	NA/TCN	R (06DEC2020)	Y/N	
16-55/ C4591001 1145 11451042	GASTR	Ileus/ Ileus	2	25DEC2020	102/4	3	No	O	NA	R (28DEC2020)	Y/N	
16-55/ C4591001 1145 11451059	INFEC	Appendicitis/ appendicitis	2	04JAN2021	109/4	3	No	O	NA/TC/TCN	R (07JAN2021)	Y/N	
16-55/ C4591001 1145 11451063	NERV	Paraesthesia/ Paresthesias of Skin	1	21SEP2020	22/8	3	No	CD	NA/TC	R (28SEP2020)	Y/N	
16-55/ C4591001 1146 11461133	PREG	Abortion spontaneous/ spontaneous abortion#	2	21JAN2021	126/1	3	No	O	NA	R (21JAN2021)	Y/N	
	REPRO	Vaginal haemorrhage/ Vaginal Bleeding#	2	21JAN2021	126/2	2	No	O	NA	R (22JAN2021)	Y/N	
16-55/ C4591001 1146 11461200	CARD	Bradycardia/ Acute Bradycardia	2	27SEP2020	3/2	3	No	O	NA/TC	R (28SEP2020)	Y/N	
	NERV	Syncope/ syncope	2	27SEP2020	3/3	2	No	O	NA	R (29SEP2020)	Y/N	
16-55/ C4591001	INFEC	COVID-19/ COVID-19	2	14JAN2021	66/7	2	No	O	NA	R (20JAN2021)	Y/N	



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1146 11461302 16-55/ C4591001 1150 11501001	GASTR	Pancreatitis/ Worsening Pancreatitis	1	21AUG2020	5/34	3	No	O	NA	R (23SEP2020)	Y/N	
16-55/ C4591001 1150 11501022	RENAL	Nephrolithiasis/ Kidney Stones	2	02DEC2020	86/7	3	No	O	NA/TC	R (08DEC2020)	Y/N	
16-55/ C4591001 1150 11501084	PREG	Abortion spontaneous/ Spontaneous Miscarriage	2	19FEB2021	142/1	2	No	O	NA	R (19FEB2021)	Y/N	
16-55/ C4591001 1150 11501153	PSYCH	Depression/ Worsening Depression- no prior hospitalizations for depression#	3	02MAR2021	7/C	4	No	O	NA	RG	Y/N	
16-55/ C4591001 1152 11521085	GENRL	Death/ UNDETERMINED CAUSE OF DEATH	1	26AUG2020	8/1	4	No	O	P/W	F (26AUG2020)	Y/N	
16-55/ C4591001 1156 11561006	VASC	Deep vein thrombosis/ DEEP VEIN THROMBOSIS	1	31AUG2020	12/10	3	No	O	NA/TC	R (09SEP2020)	Y/N	
16-55/ C4591001 1156 11561007	PREG	Abortion spontaneous incomplete/ INCOMPLETE SPONTANEOUS ABORTION	2	04OCT2020	25/4	3	No	O	NA/TCN	R (07OCT2020)	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1156 11561124	INJ&P	Overdose/ MULTIPLE DRUG OVERDOSE	2	02NOV2020	32/1	4	No	O	NA/W	F (02NOV2020)	Y/N	
	RESP	Respiratory arrest/ RESPIRATORY ARREST	2	02NOV2020	32/1	4	No	O	NA/W	F (02NOV2020)	Y/N	
16-55/ C4591001 1167 11671009	HEPAT	Cholecystitis acute/ Acute Cholecystitis	1	21AUG2020	5/2	3	No	O	NA/TC/TCN	R (22AUG2020)	Y/N	
	HEPAT	Hepatitis acute/ Acute hepatitis#	4	25FEB2021	53/C	2	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1167 11671175	NERV	Cerebrovascular accident/ Cerebrovascular accident	2	21OCT2020	23/C	3	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1170 11701121	INJ&P	Lower limb fracture/ Right Lower Extremity Fracture#	4	22JAN2021	3/C	3	No	O	NA/TCN	RG	Y/N	
16-55/ C4591001 1177 11771222	PREG	Abortion spontaneous/ Abortion Spontaneous#	2	23DEC2020	94/1		No	O	NA	R (23DEC2020)	Y/N	
16-55/ C4591001 1178 11781107	BLOOD	Lymphadenopathy/ right axilla lymphadenopathy	1	16SEP2020	13/66	2	Yes		P/TC	R (20NOV2020)	Y/N	
16-55/ C4591001	NEOPL	Breast cancer/ left breast carcinoma	2	13JAN2021	90/C	3	No	O	NA	N	Y/N	

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1178 11781257 16-55/ C4591001 1195 11951003	MUSC	Spondylolisthesis/ Spondylolisthesis L4/5#	2	05FEB2021	93/33	2	No	O	NA	R (09MAR2021)	Y/N	
16-55/ C4591001 1195 11951008	GASTR	Anal prolapse/ anal prolapse#	4	18FEB2021	10/10	3	No	O	NA	R (27FEB2021)	Y/N	
16-55/ C4591001 1195 11951017	MUSC	Spondylolisthesis/ worsening of Spondylolisthesis	2	19DEC2020	47/29	3	No	O	NA/TC	R (16JAN2021)	Y/N	
16-55/ C4591001 1195 11951023	MUSC	Intervertebral disc protrusion/ herniated disc cervical vertebra	2	16NOV2020	13/5	1	No	O	NA/TC/TCN	R (20NOV2020)	Y/N	
16-55/ C4591001 1203 12031026	GASTR	Inguinal hernia/ inguinal hernia left	1	09NOV2020	21/103	2	No	O	NA/TC/TCN	R (19FEB2021)	Y/N	
16-55/ C4591001 1205 12051075	INFEC	Anal abscess/ Anal Abscess	2	04JAN2021	35/3	2	No	O	NA/TC/TCN	R (06JAN2021)	Y/N	
16-55/ C4591001 1205 12051077	NEOPL	Lipoma/ Encapsulated Lipoma	2	11JAN2021	41/10	2	No	O	NA/TC	R (20JAN2021)	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	RESP	Nasal septum deviation/ Nasal Septum Deviation	2	11JAN2021	41/10	2	No	O	NA/TC/TCN	R (20JAN2021)	Y/N	
16-55/ C4591001 1210 12101026	INFEC	Upper respiratory tract infection/ Acute upper respiratory tract infections	1	16NOV2020	18/22	3	No	O	NA/TC	R (07DEC2020)	Y/N	
16-55/ C4591001 1212 12121024	CARD	Myocardial infarction/ Heart Attack#	2	03FEB2021	71/1	4	Yes		NA/TC/TCN	R (03FEB2021)	Y/N	
16-55/ C4591001 1214 12141018	MUSC	Intervertebral disc protrusion/ recurrence vertebral disc herniation	1	18NOV2020	17/15	2	No	O	NA/TC/TCN	R (02DEC2020)	Y/N	
	RESP	Pulmonary embolism/ pulmonary embolism	2	05DEC2020	13/1	2	No	O	NA/TC	R (05DEC2020)	Y/N	
16-55/ C4591001 1218 12181001	HEPAT	Cholecystitis acute/ Acute cholecystitis#	2	18JAN2021	69/4	3	No	O	NA/TC/TCN	R (21JAN2021)	Y/N	
16-55/ C4591001 1218 12181012	PSYCH	Alcohol abuse/ Alcohol abuse	2	09JAN2021	47/C	1	No	O	NA/TCN	RG	Y/N	
16-55/ C4591001 1218 12181023	PSYCH	Alcohol withdrawal syndrome/ Alcohol withdrawal#	4	03MAR2021	30/2	2	No	O	NA/TC	R (04MAR2021)	Y/N	
16-55/ C4591001	HEPAT	Cholecystitis acute/ Acute Cholecystitis	1	20DEC2020	19/3	2	No	O	NA/TC	R (22DEC2020)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1218 12181046 16-55/ C4591001	RESP	Asthma/ Asthma exacerbation#	2	16JAN2021	25/3	1	No	O	NA/TC	R (18JAN2021)	Y/N	
1218 12181051 16-55/ C4591001	GASTR	Oesophageal varices haemorrhage/ Esophageal varices hemorrhage	1	09JAN2021	33/1	4	No	O	NA/TC/TCN	R (09JAN2021)	Y/N	
1218 12181057 16-55/ C4591001	INFEC	Meningitis bacterial/ Meningitis Bacterial	1	10NOV2020	26/23	3	No	O	NA/TC	R (02DEC2020)	Y/N	
1221 12211007 16-55/ C4591001	INFEC	Appendicitis/ appendicitis	2	11JAN2021	116/4	4	No	O	NA/TC/TCN	R (14JAN2021)	Y/N	
1223 12231014 16-55/ C4591001	GASTR	Gastrointestinal necrosis/ Bowel necrosis#	4	04FEB2021	30/C	4	No	O	NA/TC/TCN	N	Y/N	
1223 12231075	INJ&P	Postoperative ileus/ Postoperative ileus#	4	11FEB2021	37/5	3	No	O	NA/TC	R (15FEB2021)	Y/N	
	GASTR	Small intestinal obstruction/ Small Bowel Obstruction#	4	16FEB2021	42/4	3	No	O	NA/TC	R (19FEB2021)	Y/N	
16-55/ C4591001 1223 12231166	VASC	Hypertensive urgency/ hypertensive urgency	2	28OCT2020	22/9	2	No	O	NA/TC	R (05NOV2020)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261043	INFEC	Herpes zoster oticus/ Ramsay Hunt Syndrome#	2	25JAN2021	153/21	4	No	O	NA/TC	RS (14FEB2021)	Y/N	
16-55/ C4591001 1226 12261067	RENAL	Nephrolithiasis/ Worsening of nephrolithiasis	2	09NOV2020	70/18	3	No	O	NA/TC	R (26NOV2020)	Y/N	
16-55/ C4591001 1226 12261094	RENAL	Nephrolithiasis/ Worsening of Nephrolithiasis	2	21DEC2020	112/33	3	No	O	NA/TC/TCN	R (22JAN2021)	Y/N	
16-55/ C4591001 1226 12261136	GASTR	Haemorrhoids/ Hemorrhoid Worsening	2	26JAN2021	145/2	4	No	O	NA/TC/TCN	R (27JAN2021)	Y/N	
16-55/ C4591001 1226 12261137	INJ&P	Forearm fracture/ Right forearm fracture	2	20SEP2020	18/10	3	No	O	NA/TC/TCN	R (29SEP2020)	Y/N	
16-55/ C4591001 1226 12261282	INFEC	Appendicitis/ Appendicitis	2	01OCT2020	22/3	3	No	O	NA/TC/TCN	R (03OCT2020)	Y/N	
16-55/ C4591001 1226 12261300	RENAL	Renal colic/ Renal colic	1	29AUG2020	10/2	4	No	O	NA/TC/TCN	R (30AUG2020)	Y/N	
16-55/ C4591001	INFEC	Gastroenteritis/ Gastroenterocolitis	2	20NOV2020	73/10	2	No	O	NA/TC	R (29NOV2020)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12261338 16-55/ C4591001 1226 12261571	INJ&P	Cervical vertebral fracture/ Fracture of the fourth cervical vertebra	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N	
		Road traffic accident/ hit by motorcycle	2	21OCT2020	27/1	3	No	O	NA	R (21OCT2020)	Y/N	
		Spinal cord injury cervical/ Cervical spinal cord contusion	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N	
	NERV	Subarachnoid haemorrhage/ Subarachnoid hemorrhage	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N	
	RENAL	Subcapsular renal haematoma/ Peri-renal hematoma	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N	
16-55/ C4591001 1226 12261583	RENAL	Ureterolithiasis/ Left ureteral stone	2	13NOV2020	46/3	2	No	O	NA/TCN	R (15NOV2020)	Y/N	
16-55/ C4591001 1226 12261745	NEOPL	Leydig cell tumour of the testis/ Leydig cell tumor in left testicle	1	23SEP2020	8/15	2	No	O	NA	R (07OCT2020)	Y/N	
16-55/ C4591001 1226 12261769	NERV	Idiopathic intracranial hypertension/ idiopathic intracranial hypertension	2	22OCT2020	16/9	3	No	O	NA/TC/TCN	R (30OCT2020)	Y/N	
	INFEC	Postoperative wound infection/ surgical site infection (Flank)	2	03NOV2020	28/39	3	No	O	NA/TC	R (11DEC2020)	Y/N	
16-55/ C4591001	MUSC	Myalgia/ Muscle pain#	3	12FEB2021	21/2	3	No	O	NA/TC	R (13FEB2021)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12261836 16-55/ C4591001 1226 12262000	INFEC	COVID-19/ COVID-19	2	20DEC2020	60/26	4	No	O	NA/TC/TCN	RS (14JAN2021)	Y/N	
16-55/ C4591001 1226 12262052	VASC	Deep vein thrombosis/ Deep vein thrombosis in right lower limb	2	05JAN2021	72/9	2	No	O	NA/TC/TCN	R (13JAN2021)	Y/N	
16-55/ C4591001 1226 12262089	INFEC	Urinary tract infection/ Urinary tract infection	1	18OCT2020	13/5	3	No	O	NA/TC	R (22OCT2020)	Y/N	
16-55/ C4591001 1226 12262129	NERV	Transient ischaemic attack/ Transient Ischemic Attack	2	04DEC2020	36/5	4	No	O	NA/TC	R (08DEC2020)	Y/N	
16-55/ C4591001 1229 12291083†	METAB	Diabetes mellitus/ Diabetes Mellitus	2	28DEC2020	68/C	4	No	O	NA	N	Y/N	
	INFEC	COVID-19 pneumonia/ Covid 19 Pneumonia	2	01JAN2021	72/5	4	No	O	NA/W	F (05JAN2021)	Y/N	
16-55/ C4591001 1231 12311081	INFEC	Arthritis bacterial/ septic arthritis of the right knee.	2	13DEC2020	104/C	3	No	O	NA/TC/TCN	RG	Y/N	
16-55/ C4591001	RENAL	Nephrolithiasis/ worsening of renal lithiasis	2	21NOV2020	79/7	3	No	O	NA/TC	R (27NOV2020)	Y/N	



16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12311118 16-55/ C4591001	NERV	Peripheral nerve lesion/ Right index finger collateral nerve lesion	2	08OCT2020	37/63	3	No	O	NA/TC/TCN	R (09DEC2020)	Y/N	
1231 12311128 16-55/ C4591001	INJ&P	Ulna fracture/ Left arm olecranon fracture	2	17SEP2020	15/149	3	No	O	NA/TC/TCN	R (12FEB2021)	Y/N	
1231 12311205 16-55/ C4591001	INFEC	Appendicitis/ acute appendicitis	2	18SEP2020	15/19	3	No	O	NA/TC/TCN	R (06OCT2020)	Y/N	
1231 12311281 16-55/ C4591001	HEPAT	Cholecystitis acute/ Acute cholecystitis	2	12DEC2020	97/33	3	No	O	NA/TC/TCN	R (13JAN2021)	Y/N	
1231 12311294 16-55/ C4591001	NEOPL	Malignant melanoma/ Pigmented epithelioid melanoma of the vagina	2	25SEP2020	23/C	2	No	O	NA/TC/TCN	RG	Y/N	
1231 12311315 16-55/ C4591001	GENRL	Influenza like illness/ Flu like syndrome	1	20AUG2020	6/9	3	No	O	NA	R (28AUG2020)	Y/N	
1231 12311352 16-55/ C4591001	INFEC	Urinary tract infection/ Complicated Urinary Tract Infection	2	04JAN2021	123/15	3	No	O	NA/TC	R (18JAN2021)	Y/N	
1231 12311387												

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311538	INFEC	Gangrene/ Rightfoot transmetatarsal limited gangrene	2	03DEC2020	88/77	3	No	O	NA/TC/TCN	RS (17FEB2021)	Y/N	
16-55/ C4591001 1231 12311556	INJ&P	Ligament rupture/ Rupture of the anterior cruciate ligament of the left knee	2	21NOV2020	76/75	2	No	O	NA/TCN	R (03FEB2021)	Y/N	
		Meniscus injury/ Rupture of the external meniscus of the left knee	2	21NOV2020	76/75	2	No	O	NA/TC/TCN	R (03FEB2021)	Y/N	
16-55/ C4591001 1231 12311635	NEOPL	Benign hydatidiform mole/ Molar pregnancy in partner	2	JAN2021	120/	3	No	O	NA	R	Y/N	
16-55/ C4591001 1231 12311711	INFEC	Urosepsis/ Urosepsis	2	15SEP2020	9/8	3	No	O	NA/TC	R (22SEP2020)	Y/N	
16-55/ C4591001 1231 12311730	NEOPL	Invasive ductal breast carcinoma/ Right breast invasive ductal carcinoma	2	15NOV2020	70/C	2	No	O	NA	N	Y/N	
16-55/ C4591001 1231 12311766	HEPAT	Biliary colic/ biliary colic	2	30OCT2020	54/5	3	No	O	NA/TC	R (03NOV2020)	Y/N	
16-55/ C4591001 1231 12311812	PREG	Abortion spontaneous/ Complete miscarriage	2	27FEB2021	174/12	3	No	O	NA/TC	R (10MAR2021)	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311834	INJ&P	Foot fracture/ Hallux fracture and second toe of the right foot	2	16SEP2020	10/35	3	No	O	NA/TC/TCN	R (20OCT2020)	Y/N	
16-55/ C4591001 1231 12311844	METAB	Hypoglycaemia/ severe hypoglycemia	2	16OCT2020	40/1	3	No	O	NA	R (16OCT2020)	Y/N	
16-55/ C4591001 1231 12311862	VASC	Aortic stenosis/ Severe aortic stenosis	2	13OCT2020	35/C	3	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1231 12311901	HEPAT	Cholecystitis chronic/ chronic lithiasic cholecystitis	2	27OCT2020	50/134	2	No	O	NA/TC/TCN	R (09MAR2021)	Y/N	
16-55/ C4591001 1231 12312125	INFEC	Appendicitis/ Acute appendicitis	2	06JAN2021	122/37	3	No	O	NA/TC/TCN	R (11FEB2021)	Y/N	
		Peritonitis/ Peritonitis	2	06JAN2021	122/37	3	No	O	NA/TC/TCN	R (11FEB2021)	Y/N	
16-55/ C4591001 1231 12312205	PREG	Abortion spontaneous/ Spontaneous abortion	2	26NOV2020	81/4	2	No	O	NA/TC/TCN	R (29NOV2020)	Y/N	
16-55/ C4591001 1231 12312335	METAB	Hypoglycaemia/ Severe hypoglycemia	2	16DEC2020	100/8	3	No	O	NA/TC	R (23DEC2020)	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12312390	MUSC	Osteochondritis/ Osteochondritis	1	05SEP2020	18/2	2	No	O	NA	R (06SEP2020)	Y/N	
16-55/ C4591001 1231 12312420	INFEC	Appendicitis/ Acute Appendicitis	2	28DEC2020	110/16	3	No	O	NA/TC/TCN	R (12JAN2021)	Y/N	
16-55/ C4591001 1231 12312476	HEPAT	Bile duct stone/ Choledochal lithiasis	2	23JAN2021	136/C	3	No	O	NA	N	Y/N	
	HEPAT	Biliary colic/ Biliary colic	2	25FEB2021	169/C	3	No	O	NA/TC	N	Y/N	
16-55/ C4591001 1231 12312576	RENAL	Nephrolithiasis/ nephrolithiasis	2	05NOV2020	58/47	3	No	O	NA/TC/TCN	R (21DEC2020)	Y/N	
16-55/ C4591001 1231 12312577	NEOPL	Metastases to central nervous system/ Brain metastasis	1	28AUG2020	9/C	2	No	O	P/TC	N	Y/N	
16-55/ C4591001 1231 12312593	CARD	Acute coronary syndrome/ Acute coronary syndrome without ST-T segment elevation	2	16SEP2020	6/4	2	No	O	NA/TC	R (19SEP2020)	Y/N	
16-55/ C4591001 1231 12312696	CARD	Acute coronary syndrome/ acute coronary syndrome	2	22NOV2020	74/48	3	No	O	NA/TC/TCN	R (08JAN2021)	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12312854	CARD	Arrhythmia supraventricular/ Arrhythmia supraventricular	2	17SEP2020	7/3	4	No	O	NA/TC/TCN	R (19SEP2020)	Y/N	
16-55/ C4591001 1231 12312868	NERV	Syncope/ syncope	2	08OCT2020	1/1	3	No	O	NA/TCN	R (08OCT2020)	Y/N	
16-55/ C4591001 1231 12312982	INFEC	Suspected COVID-19/ Suspected COVID-19 Illness	2	09SEP2020	1/6	3	No	O	NA/TC	R (14SEP2020)	Y/N	
16-55/ C4591001 1231 12312996	RESP	Asthmatic crisis/ SEVERE ASTHMATIC CRYISIS	2	21OCT2020	42/9	3	No	O	NA/TC/TCN	R (29OCT2020)	Y/N	
16-55/ C4591001 1231 12313028	NERV	Optic neuritis/ Optic Neuritis	2	01DEC2020	82/C	3	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1231 12313140	NEOPL	Papillary thyroid cancer/ Suspected papillary thyroid carcinoma	2	28JAN2021	137/C	3	No	O	NA/TCN	N	Y/N	
16-55/ C4591001 1231 12313184	NERV	Carpal tunnel syndrome/ right carpal tunnel syndrome	2	15OCT2020	36/128	2	No	O	NA/TCN	R (19FEB2021)	Y/N	
16-55/ C4591001	RENAL	Urinary bladder polyp/ Bladder polyp	2	18SEP2020	9/C	1	No	O	NA/TCN	RG	Y/N	

## 16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12313193 16-55/ C4591001	NEOPL	Clear cell renal cell carcinoma/ Clear cell renal cell carcinoma	2	12OCT2020	32/C	3	No	O	NA/TCN	N	Y/N
1231 12313345 16-55/ C4591001	INFEC	Renal abscess/ Right kidney abscess	2	07DEC2020	86/C	2	No	O	NA/TC/TCN	RG	Y/N
1231 12313437 16-55/ C4591001	HEPAT	Cholelithiasis/ cholelithiasis	2	24DEC2020	103/13	3	No	O	NA/TC/TCN	R (05JAN2021)	Y/N
1231 12313504 16-55/ C4591001	NERV	Ischaemic stroke/ Ischemic Stroke	2	06NOV2020	55/78	3	No	O	NA/TC	RS (22JAN2021)	Y/N
1231 12313653 16-55/ C4591001	HEPAT	Cholecystitis/ Cholecystitis	2	25DEC2020	104/35	2	No	O	NA/TC/TCN	R (28JAN2021)	Y/N
1231 12313689 16-55/ C4591001	INJ&P	Ankle fracture/ Right Ankle Fracture	2	02JAN2021	112/59	3	No	O	NA/TC/TCN	RS (01MAR2021)	Y/N
1231 12313715 16-55/ C4591001	INFEC	Appendicitis/ Acute appendicitis	2	22OCT2020	39/16	2	No	O	NA/TC/TCN	R (06NOV2020)	Y/N
1231 12313785											

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16-55/ C4591001 1231 12313879	INFEC	Urinary tract infection/ Supected Complicated Urinary Tract Infection	2	31JAN2021	141/18	3	No	O	NA/TC	R (17FEB2021)	Y/N	
16-55/ C4591001 1231 12313998	PREG	Abortion spontaneous complete/ Complete spontaneous abortion#	2	24JAN2021	132/16	3	No	O	NA/TC	R (08FEB2021)	Y/N	
16-55/ C4591001 1231 12314075	HEPAT	Cholelithiasis obstructive/ Cholestatic syndrome secondary to lithiasis#	2	05MAR2021	170/6	2	No	O	NA/TC	R (10MAR2021)	Y/N	
16-55/ C4591001 1231 12314134	PREG	Abortion incomplete/ incomplete abortion	1	11FEB2021	170/3	3	No	O	NA/TC/TCN	R (13FEB2021)	Y/N	
16-55/ C4591001 1231 12314407	INJ&P	Multiple injuries/ Polytrauma	2	20SEP2020	5/93	3	No	O	NA/TC/TCN	R (21DEC2020)	Y/N	
16-55/ C4591001 1231 12314494	GASTR	Food poisoning/ Food poisoning	2	03FEB2021	141/5	3	No	O	NA/TC	R (07FEB2021)	Y/N	
16-55/ C4591001 1231 12314531	INFEC	Urinary tract infection/ Complicated urinary infection	2	08JAN2021	103/47	3	No	O	NA/TC	R (23FEB2021)	Y/N	
16-55/ C4591001	GASTR	Pancreatitis acute/ acute pancreatitis	2	30NOV2020	77/15	2	No	O	NA/TC	R (14DEC2020)	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12314583 16-55/ C4591001 1231 12314813	MUSC	Intervertebral disc protrusion/ Worsening of herniated disc	2	21SEP2020	5/107	3	No	O	NA/TC/TCN	R (05JAN2021)	Y/N	
1231 12314813 16-55/ C4591001 1231 12314833	INFEC	Appendicitis/ Acute Appendicitis	2	16OCT2020	29/9	3	No	O	NA/TC/TCN	R (24OCT2020)	Y/N	
1231 12314833	INFEC	Abdominal abscess/ Intra-abdominal Abscess	2	29OCT2020	42/37	3	No	O	NA/TC/TCN	R (04DEC2020)	Y/N	
16-55/ C4591001 1231 12314921	INJ&P	Burns second degree/ Second degree burn of the right arm and forearm.#	2	27JAN2021	134/C	3	No	O	NA/TC/TCN	RG	Y/N	
1231 12314921		Burns third degree/ Third degree burn on the right hand#	2	27JAN2021	134/C	3	No	O	NA/TC/TCN	RG	Y/N	
16-55/ C4591001 1231 12314987	CARD	Cardio-respiratory arrest/ Non-traumatic cardiorespiratory arrest	2	05DEC2020	81/2	4	No	O	NA/W	F (06DEC2020)	Y/N	
1231 12314987 16-55/ C4591001 1231 12315186	NEOPL	Adenocarcinoma pancreas/ pancreatic ductal adenocarcinoma#	2	17FEB2021	154/C	3	No	O	NA/TC/TCN	RG	Y/N	
1231 12315186 16-55/ C4591001 1231 12315291	EYE	Choroidal neovascularisation/ Myopic choroidal neovascular membrane of the left eye	1	06SEP2020	9/83	1	No	O	NA/TC	R (27NOV2020)	Y/N	



16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12315473	CARD	Angina unstable/ Unstable Angina Pectoris	2	14OCT2020	26/3	3	No	O	NA/TCN	R (16OCT2020)	Y/N	
16-55/ C4591001 1231 12315498	RENAL	Nephrolithiasis/ Nephrolithiasis	2	05DEC2020	78/48	3	No	O	NA/TC	R (21JAN2021)	Y/N	
16-55/ C4591001 1231 12315622	INFEC	Gastroenteritis/ gastroenterocolitis	2	09JAN2021	113/3	2	No	O	NA/TC/TCN	R (11JAN2021)	Y/N	
16-55/ C4591001 1241 12411053	GASTR	Gastroesophageal reflux disease/ Non-erosive reflux esophagitis#	3	31JAN2021	7/C	3	No	O	NA/TC/TCN	RG	Y/N	
16-55/ C4591001 1241 12411206	REPRO	Breast hyperplasia/ Atypical intraductal hyperplasia in left breast	2	29SEP2020	21/2	2	No	O	NA/TC	R (30SEP2020)	Y/N	
16-55/ C4591001 1241 12411269	INJ&P	Fall/ Fall from own height#	4	06MAR2021	17/1	3	No	O	NA	R (06MAR2021)	Y/N	
		Scapula fracture/ Fracture of the anterior border of the right glenoid#	4	06MAR2021	17/C	3	No	O	NA/TCN	N	Y/N	
16-55/ C4591001 1241 12411279	PREG	Retained products of conception/ RETAINED PRODUCTS OF CONCEPTION	1	14OCT2020	57/1	3	No	O	NA/TC	R (14OCT2020)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411887	NEOPL	Teratoma/ High grade immature teratoma	2	18JAN2021	102/10	3	No	O	NA	R (27JAN2021)	Y/N	
16-55/ C4591001 1241 12411978	INFEC	Cellulitis/ Cellulitis on the right foot	2	27DEC2020	76/C	2	No	O	NA/TC	N	Y/N	
16-55/ C4591001 1241 12412053	INJ&P	Clavicle fracture/ Fracture of right clavicle#	2	31JAN2021	103/4	3	No	O	NA/TC/TCN	R (03FEB2021)	Y/N	
		Rib fracture/ Fracture of ribs#	2	31JAN2021	103/4	3	No	O	NA/TC/TCN	R (03FEB2021)	Y/N	
		Road traffic accident/ Motor Vehicle Accident#	2	31JAN2021	103/1	3	No	O	NA	R (31JAN2021)	Y/N	
16-55/ C4591001 1241 12412218	INFEC	Appendicitis/ APPENDICITIS	2	23NOV2020	18/3	3	No	O	NA/TC/TCN	R (25NOV2020)	Y/N	
16-55/ C4591001 1246 12461070	PSYCH	Depression/ Worsening of depression	2	25DEC2020	63/22	3	No	O	NA/TC/TCN	R (15JAN2021)	Y/N	
16-55/ C4591001 1246 12461131	REPRO	Endometriosis/ Worsening of Endometriosis left ovary	2	06JAN2021	68/15	3	No	O	NA/TC/TCN	R (20JAN2021)	Y/N	
16-55/ C4591001	INJ&P	Flail chest/ Flail Chest	2	30OCT2020	10/C	3	No	O	NA/TC/TCN	N	Y/N	

## 16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1247 12471121 16-55/ C4591001 1247 12471137	MUSC	Intervertebral disc protrusion/ Worsening pain related to L5/S1 and L4/L5 disc protrusion	2	09NOV2020	20/C	3	No	O	NA/TC/TCN	N	Y/N
16-55/ C4591001 1247 12471226	PSYCH	Depression/ Severe depressive episode	2	04FEB2021	98/5	2	No	O	NA	R (08FEB2021)	Y/N
16-55/ C4591001 1251 12511031	METAB	Diabetes mellitus inadequate control/ worsening diabetes type 11#	4	25FEB2021	14/C	4	No	O	NA/TC/TCN	N	Y/N
16-55/ C4591001 1251 12511033	NERV	Idiopathic intracranial hypertension/ Pseudotumor Cerebri	2	JAN2021	114/C	3	No	O	NA/TC	N	Y/N
16-55/ C4591001 1251 12511239	CARD	Myocardial ischaemia/ Myocardial ischemia	2	13NOV2020	12/4	4	No	O	NA/TC	R (16NOV2020)	Y/N
16-55/ C4591001 1260 12601075	INFEC	Appendicitis/ acute appendicitis	2	04DEC2020	64/5	2	No	O	NA/TC	R (08DEC2020)	Y/N
16-55/ C4591001 1260 12601108	INJ&P	Ankle fracture/ Closed trimalleolar fracture of right ankle#	4	09MAR2021	37/C	3	No	O	NA/TC	N	Y/N

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1261 12611006	INFEC	Abscess/ Lip Abscess	2	23SEP2020	7/9	3	No	O	NA/TC/TCN	R (01OCT2020)	Y/N	
		Cellulitis/ Lip cellulitis	2	23SEP2020	7/9	3	No	O	NA/TC	R (01OCT2020)	Y/N	
	IMMUN	Drug hypersensitivity/ Hypersensitivity to antibiotics	2	26SEP2020	10/2	3	No	CD	NA/TC	R (27SEP2020)	Y/N	
16-55/ C4591001 1265 12651101	METAB	Hypoglycaemia/ Hypoglycemia	1	12SEP2020	2/2	3	No	CD	NA/TC	R (13SEP2020)	Y/N	
16-55/ C4591001 1270 12701069	INFEC	Appendicitis/ APPENDICITIS	1	20SEP2020	17/3	3	No	O	NA/TC/TCN	R (22SEP2020)	Y/N	
16-55/ C4591001 4444 44441007	INJ&P	Procedural haemorrhage/ Intraoperative hemorrhage during an elective laparoscopic ovarian cystectomy	1	03OCT2020	13/5	3	No	O	NA/TC	R (07OCT2020)	Y/N	
16-55/ C4591001 4444 44441249	GASTR	Incarcerated inguinal hernia/ Incarcerated right inguinal hernia	1	05OCT2020	15/18	3	No	O	NA/TC/TCN	R (22OCT2020)	Y/N	
16-55/ C4591001 4444 44441297	INFEC	Postoperative wound infection/ Surgical site infection	2	16NOV2020	36/12	2	No	O	NA/TC	R (27NOV2020)	Y/N	
16-55/ C4591001	GASTR	Intestinal perforation/ Intestinal perforation	2	23DEC2020	70/22	3	No	O	NA/TC/TCN	R (13JAN2021)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
4444 44441550	INFEC	Pneumonia/ Hospital-acquired pneumonia	2	30DEC2020	77/15	3	No	O	NA/TC	R (13JAN2021)	Y/N	
16-55/ C4591001 4444 44441634	HEPAT	Cholecystitis acute/ Acute cholecystitis	2	28DEC2020	76/8	3	No	O	NA/TC/TCN	R (04JAN2021)	Y/N	
16-55/ C4591001 4444 44441748	GASTR	Oesophageal food impaction/ esophageal impaction with food	1	28SEP2020	6/2	3	No	O	NA/TCN	R (29SEP2020)	Y/N	
16-55/ C4591001 4444 44441771	MUSC	Back pain/ Exacerbation of low back pain	2	02NOV2020	19/C	3	No	O	NA/TC/TCN	N	Y/N	
16-55/ C4591001 4444 44442021	INJ&P	Ankle fracture/ Right ankle fracture	2	15NOV2020	32/68	3	No	O	NA/TC/TCN	R (21JAN2021)	Y/N	
16-55/ C4591001 4444 44442041	INJ&P	Humerus fracture/ Right displaced proximal humeral fracture	2	05DEC2020	51/41	2	No	O	NA/TC/TCN	R (14JAN2021)	Y/N	
16-55/ C4591001 4444 44442278	VASC	Hypertensive urgency/ Hypertensive urgency	2	04MAR2021	141/1	3	No	O	NA/TC	R (04MAR2021)	Y/N	
>55/ C4591001	GENRL	Chest pain/ Chest Pain	2	10JAN2021	145/6	2	No	O	NA/TC/TCN	R (15JAN2021)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1001 10011093 >55/ C4591001 1001 10011100	INJ&P	Foot fracture/ R 5th metatarsal fracture	2	12DEC2020	117/C	2	No	O	NA/TC/TCN	RG	Y/N	
		Radius fracture/ L radial head fracture	2	12DEC2020	117/C	2	No	O	NA/TC/TCN	RG	Y/N	
>55/ C4591001 1003 10031113	RESP	Interstitial lung disease/ worsening of interstitial lung disease	2	17OCT2020	59/C	4	No	O	NA/TC/TCN	RG	Y/N	
	RESP	Respiratory failure/ respiratory failure	2	11JAN2021	145/C	2	No	O	NA/TC	RG	Y/N	
>55/ C4591001 1003 10031149	GASTR	Small intestinal obstruction/ small bowel obstruction	1	08AUG2020	4/3	4	No	O	NA/TC/TCN	R (10AUG2020)	Y/N	
	PSYCH	Panic attack/ suspected panic attack	2	28DEC2020	125/2	3	No	O	NA	R (29DEC2020)	Y/N	
>55/ C4591001 1005 10051047	VASC	Aortic aneurysm/ AORTIC ANEURYSM	2	20NOV2020	81/70	3	No	O	NA/TC	R (28JAN2021)	Y/N	
>55/ C4591001 1005 10051069	NEOPL	Breast cancer/ LEFT BREAST CANCER	2	04SEP2020	3/131	2	No	O	NA/TC	R (12JAN2021)	Y/N	
>55/ C4591001	CARD	Cardiac arrest/ CARDIAC ARREST	1	08NOV2020	21/1	4	No	O	NA/TC	R (08NOV2020)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1005 10051293	INJ&P	Overdose/ Overdose	1	08NOV2020	21/1	4	No	O	NA	R (08NOV2020)	Y/N	
	RESP	Acute respiratory failure/ Acute Respiratory Failure	1	08NOV2020	21/C	4	No	O	NA	RG	Y/N	
>55/ C4591001 1006 10061020	CARD	Coronary artery occlusion/ CORONARY ARTERY OCCLUSION	1	25AUG2020	14/3	4	No	O	P/TC/TCN/W	R (27AUG2020)	Y/N	
>55/ C4591001 1006 10061098	CARD	Atrial fibrillation/ ATRIAL FIBRILLATION INTERMITTENT	2	06OCT2020	22/7	2	No	CD	NA/TC/TCN	R (12OCT2020)	Y/N	
>55/ C4591001 1007 10071101	CARD	Cardiac arrest/ Cardiac Arrest	2	18OCT2020	60/4	4	No	O	NA/W	F (21OCT2020)	Y/N	
>55/ C4591001 1007 10071192	GASTR	Gastrointestinal haemorrhage/ Gastrointestinal Bleed	2	09DEC2020	98/30	3	No	O	NA/TC/TCN	R (07JAN2021)	Y/N	
>55/ C4591001 1007 10071306	INFEC	Pneumonia/ left lower lobe pneumonia#	2	19FEB2021	110/C	3	No	O	NA/TC/TCN	RG	Y/N	
		Sepsis/ sepsis#	2	19FEB2021	110/16	3	No	O	NA/TC/TCN	R (06MAR2021)	Y/N	
>55/ C4591001	CARD	Atrial fibrillation/ atrial fibrillation	1	25OCT2020	11/2	3	No	O	P/TC	R (26OCT2020)	Y/N	

## 16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1007 10071347 >55/ C4591001 1008 10081056	RESP	Dyspnoea/ Shortness of breath#	4	MAR2021	20/C	3	No	O	NA/TC	N	Y/N
>55/ C4591001 1008 10081184	NEOPL	Prostate cancer/ Prostate cancer	2	30SEP2020	7/C	2	No	O	NA/TCN	N	Y/N
>55/ C4591001 1008 10081603	INFEC	Cellulitis/ CELLULITIS UPPER BACK	1	26OCT2020	13/8	3	No	O	NA/TC	R (02NOV2020)	Y/N
		Subcutaneous abscess/ SCALP ABCESS	1	26OCT2020	13/2	3	No	O	NA/TC/TCN	R (27OCT2020)	Y/N
>55/ C4591001 1008 10081667	NEOPL	Hepatic cancer/ liver cancer#	4	25FEB2021	23/C	3	No	O	NA/W	N	Y/N
>55/ C4591001 1009 10091123	NEOPL	Colon adenoma/ TUBULAR ADENOMA OF ASCENDING COLON	2	15DEC2020	92/3	2	No	O	NA/TC/TCN	R (17DEC2020)	Y/N
>55/ C4591001 1009 10091135	NEOPL	Intraductal proliferative breast lesion/ Right Breast Ductal Carcinoma In Situ	1	02SEP2020	3/C	1	No	O	NA/TCN	N	Y/N
>55/ C4591001	INFEC	Diverticulitis/ worsening of diverticulitis	2	31DEC2020	101/3	2	No	O	NA/TC/TCN	R (02JAN2021)	Y/N



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1009 10091149 >55/ C4591001 1011 10111029	INFEC	Appendicitis perforated/ Perforated Appendicitis	2	12SEP2020	13/4	3	No	O	NA/TC/TCN	R (15SEP2020)	Y/N	
	INFEC	Peritonitis/ Feculant Peritonitis	2	14SEP2020	15/5	3	No	O	NA/TC/TCN	R (18SEP2020)	Y/N	
>55/ C4591001 1012 10121097	EAR	Vertigo/ Vertigo#	4	03FEB2021	2/3	3	No	O	NA/TC/TCN	R (05FEB2021)	Y/N	
>55/ C4591001 1012 10121112	CARD	Atrial fibrillation/ PAROXYSMAL ATRIAL FIBRILLATION	2	09DEC2020	80/3	3	No	O	NA/TC	R (11DEC2020)	Y/N	
>55/ C4591001 1013 10131176	GASTR	Abdominal adhesions/ abdominal adhesions	1	29AUG2020	17/2	3	No	O	NA/TC	R (30AUG2020)	Y/N	
		Small intestinal obstruction/ SMALL BOWEL OBSTRUCTION	1	29AUG2020	17/2	2	No	O	NA/TCN	R (30AUG2020)	Y/N	
	RESP	Acute respiratory failure/ acute hypoxic respiratory failure	1	30AUG2020	18/13	3	No	O	NA	R (11SEP2020)	Y/N	
		Pneumonia aspiration/ ASPIRATION PNEUMONIA	1	30AUG2020	18/18	2	No	O	NA/TCN	R (16SEP2020)	Y/N	
>55/ C4591001 1013 10131386	VASC	Arterial occlusive disease/ ARTERY OCCLUSION#	2	13MAR2021	173/C	3	No	O	NA/TC	RG	Y/N	

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>55/ C4591001 1013 10131517	CARD	Acute myocardial infarction/ STEMI	2	08NOV2020	40/3	3	No	O	NA	R (10NOV2020)	Y/N	
>55/ C4591001 1013 10131554	RESP	Asthma/ acute exacerbation of asthma	2	16DEC2020	73/5	3	No	O	NA/TC	R (20DEC2020)	Y/N	
>55/ C4591001 1013 10131699	RENAL	Nephrolithiasis/ KKIDNEY STONES#	4	19FEB2021	16/C	3	No	O	NA/TC	RG	Y/N	
>55/ C4591001 1013 10131786	NERV	Syncope/ SYNCOPAL EPISODE#	3	30JAN2021	6/3	3	No	O	NA/TC	R (01FEB2021)	Y/N	
	INFEC	COVID-19 pneumonia/ COVID-19 PNEUMONIA#	3	02FEB2021	9/5	3	No	O	NA/TC	R (06FEB2021)	Y/N	
>55/ C4591001 1015 10151238†	INFEC	Pneumonia/ Pneumonia	2	20JAN2021	86/8	3	No	O	NA/TC	R (27JAN2021)	Y/N	
>55/ C4591001 1016 10161042	MUSC	Arthritis/ worsening arthritis of right hip	2	10OCT2020	45/75	3	No	O	NA/TCN	R (23DEC2020)	Y/N	
>55/ C4591001 1018 10181132	INV	Cardiac stress test abnormal/ CARDIAC STRESS TEST ABNORMAL, HOSPITALIZED	2	08SEP2020	8/C	3	No	O	NA	N	Y/N	

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>55/ C4591001 1019 10191010	GASTR	Diarrhoea/ Diarrhea	1	27AUG2020	17/3	4	No	O	NA/TC	R (29AUG2020)	Y/N	
>55/ C4591001 1019 10191021	GASTR	Pancreatitis/ Pancreatitis	2	30DEC2020	120/6	3	No	O	NA/TC	RS (04JAN2021)	Y/N	
	GASTR	Pancreatic cyst/ Pancreatic Cyst	2	04JAN2021	125/C	1	No	O	NA	N	Y/N	
>55/ C4591001 1019 10191037	GENRL	Asthenia/ Weakness	2	27OCT2020	54/3	2	No	O	NA	R (29OCT2020)	Y/N	
>55/ C4591001 1019 10191071	BLOOD	Anaemia/ Anemia	2	17DEC2020	98/3	3	No	O	NA/TCN	R (19DEC2020)	Y/N	
>55/ C4591001 1019 10191146	NEOPL	Biliary cancer metastatic/ Biliary Cancer Metastatic	2	27OCT2020	36/52	4	No	O	NA/W	F (17DEC2020)	Y/N	
		Metastases to liver/ Metastases to Liver	2	27OCT2020	36/52	4	No	O	NA/W	F (17DEC2020)	Y/N	
>55/ C4591001 1019 10191229	GASTR	Gastrointestinal mucosa hyperaemia/ Hyperemic Bowel	2	04NOV2020	21/2	4	No	O	NA	RS (05NOV2020)	Y/N	
		Volvulus/ Sigmoid Volvulus	2	04NOV2020	21/2	4	No	O	NA	RS (05NOV2020)	Y/N	

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	INJ&P	Rib fracture/ Bilateral Rib Fractures	2	04NOV2020	21/C	3	No	O	NA	N	Y/N	
		Road traffic accident/ Injury Secondary to Pedestrian-Car Accident	2	04NOV2020	21/C	4	No	O	NA	N	Y/N	
		Spinal column injury/ Severe T2 Distraction Injury	2	04NOV2020	21/C	3	No	O	NA	N	Y/N	
		Subdural haematoma/ Small Parafalcine Subdural hematoma	2	04NOV2020	21/30	3	No	O	NA	RS (03DEC2020)	Y/N	
		Traumatic haemothorax/ Right Hemopneumothorax	2	04NOV2020	21/31	4	No	O	NA	RS (04DEC2020)	Y/N	
	NERV	Spinal cord compression/ Spinal Cord Compression	2	04NOV2020	21/C	4	No	O	NA	N	Y/N	
	RESP	Pneumothorax/ Left Pneumothorax	2	04NOV2020	21/31	4	No	O	NA	RS (04DEC2020)	Y/N	
		Pulmonary embolism/ Left Pulmonary Emboli	2	04NOV2020	21/31	3	No	O	NA	RS (04DEC2020)	Y/N	
	VASC	Deep vein thrombosis/ Left Superficial Femoral Vein Deep Vein Thrombosis	2	04NOV2020	21/31	3	No	O	NA	RS (04DEC2020)	Y/N	
	CARD	Cardiac arrest/ Cardiac Arrest	2	21NOV2020	38/1	4	No	O	NA/TCN	RS (21NOV2020)	Y/N	
	CARD	Cardiac arrest/ Cardiac Arrest	2	23NOV2020	40/1	4	No	O	NA/TCN	RS (23NOV2020)	Y/N	
>55/ C4591001 1021 10211044	MUSC	Osteoarthritis/ Worsening of osteoarthritis (left shoulder)#	2	10FEB2021	155/C	2	No	O	NA/TC/TCN	RG	Y/N	

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>55/ C4591001 1021 10211081	MUSC	Osteoarthritis/ Worsening of osteoarthritis (right knee)#	4	12MAR2021	31/C	2	No	O	NA/TC/TCN	RG	Y/N	
>55/ C4591001 1021 10211084	GASTR	Haematemesis/ Vomiting blood#	2	06MAR2021	173/C	3	No	O	NA	RG	Y/N	
>55/ C4591001 1021 10211181	NEOPL	Breast cancer/ Breast Cancer (right breast)#	4	11FEB2021	2/C	3	No	O	NA	N	Y/N	
>55/ C4591001 1021 10211190	NERV	Cerebrovascular accident/ Stroke (CVA)	2	02NOV2020	33/44	3	No	O	NA	R (15DEC2020)	Y/N	
>55/ C4591001 1027 10271054	NEOPL	Acute myeloid leukaemia/ Acute Myeloid Leukemia	2	08NOV2020	58/C	3	No	O	NA/TC/TCN	N	Y/N	
>55/ C4591001 1027 10271191	INFEC	COVID-19/ COVID-19#	2	12JAN2021	103/33	4	No	O	NA/TC/TCN/W	F (13FEB2021)	Y/N	
	RESP	Acute respiratory failure/ Acute Hypoxic Respiratory Failure#	2	12JAN2021	103/33	4	No	O	NA/TC/TCN/W	F (13FEB2021)	Y/N	
>55/ C4591001 1028 10281083	MUSC	Intervertebral disc degeneration/ worsening cervical degenerative disc disease	2	05JAN2021	107/2	2	No	O	NA/TCN	R (06JAN2021)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1028 10281283	CARD	Atrial fibrillation/ atrial fibrillation with rapid ventricular response#	4	16FEB2021	13/2	2	No	O	NA/TC	R (17FEB2021)	Y/N	
>55/ C4591001 1030 10301059	NEOPL	Lung adenocarcinoma/ adenocarcinoma, right lung	2	02DEC2020	62/C	2	No	O	NA/TCN	RG	Y/N	
		Metastases to lymph nodes/ Metastasis to lymph Nodes	2	02DEC2020	62/C	2	No	O	NA/TC	RG	Y/N	
>55/ C4591001 1036 10361140	INJ&P	Injury/ Traumatic Injuries#	2	10FEB2021	91/1	4	No	O	NA/W	F (10FEB2021)	Y/N	
		Road traffic accident/ Motor Vehicle Accident#	2	10FEB2021	91/1	4	No	CND	NA/W	F (10FEB2021)	Y/N	
>55/ C4591001 1037 10371318	INV	Blood pressure increased/ ELEVATED BLOOD PRESSURE	2	15DEC2020	54/4	3	No	O	NA/TC	R (18DEC2020)	Y/N	
>55/ C4591001 1038 10381050	RESP	Chronic obstructive pulmonary disease/ COPD exacerbation#	3	07FEB2021	10/2	2	No	O	NA/TC	R (08FEB2021)	Y/N	
>55/ C4591001 1038 10381101	NERV	Ischaemic stroke/ Acute Ischemic Stroke	2	04OCT2020	7/3	2	No	O	NA	R (06OCT2020)	Y/N	
>55/ C4591001	CARD	Hypertensive heart disease/ hypertensive cardiovascular disease	2	18NOV2020	71/1	4	No	O	NA/W	F (18NOV2020)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1039 10391010	VASC	Arteriosclerosis/ arthroscloratic cardiovascular disease	2	18NOV2020	71/1	4	No	O	NA/W	F (18NOV2020)	Y/N	
>55/ C4591001 1039 10391012	NEOPL	Skin cancer/ sebaceous carcinoma of skin	2	10DEC2020	92/22	2	No	O	NA/TCN	R (31DEC2020)	Y/N	
>55/ C4591001 1039 10391038	INJ&P	Pelvic fracture/ PELVIC FRACTURE	2	15NOV2020	60/24	3	No	O	NA/TC	R (08DEC2020)	Y/N	
>55/ C4591001 1039 10391075	NEOPL	Malignant melanoma/ melanoma, left ankle	2	13NOV2020	52/41	3	No	O	NA/TCN	R (23DEC2020)	Y/N	
>55/ C4591001 1042 10421023	CARD	Cardiac failure congestive/ exacerbation of congestive heart failure#	3	22JAN2021	17/5	3	No	O	NA/TC	R (26JAN2021)	Y/N	
>55/ C4591001 1042 10421023	NEOPL	Lung adenocarcinoma/ Adenocarcinoma of the lung	2	15JAN2021	145/C	3	No	O	NA	N	Y/N	
>55/ C4591001 1042 10421166	NERV	Subarachnoid haemorrhage/ SUBARACHNOID HEMORRAGE	1	03SEP2020	9/6	3	No	O	NA/TC	R (08SEP2020)	Y/N	
>55/ C4591001 1044 10441093	INJ&P	Overdose/ Heroin Overdose	2	23OCT2020	26/2	4	No	O	NA/TC	R (24OCT2020)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1044 10441111	NERV	Cerebrovascular accident/ stroke#	3	01MAR2021	14/2	2	No	O	NA/TC	R (02MAR2021)	Y/N	
>55/ C4591001 1044 10441194	GENRL	Fatigue/ Severe Fatigue#	3	07FEB2021	3/1	4	No	O	NA/TC	R (07FEB2021)	Y/N	
>55/ C4591001 1046 10461009	GASTR	Hiatus hernia/ Hiatal Hernia	2	13DEC2020	104/6	3	No	O	NA/TCN	R (18DEC2020)	Y/N	
>55/ C4591001 1047 10471012	NERV	Syncope/ Syncope episodes	2	19JAN2021	134/34	2	No	O	NA	R (21FEB2021)	Y/N	
>55/ C4591001 1047 10471114	NERV	Cerebrovascular accident/ multi focal Cerebral Vascular Accidents	2	18OCT2020	26/C	3	No	O	NA	RG	Y/N	
>55/ C4591001 1047 10471194	RESP	Chronic obstructive pulmonary disease/ Dyspnea with exacerbation of COPD#	2	04FEB2021	109/4	3	No	O	NA/TC	R (07FEB2021)	Y/N	
>55/ C4591001 1047 10471252	CARD	Acute coronary syndrome/ acute coronary syndrome	1	25SEP2020	5/3	2	No	O	NA/TC/TCN	R (27SEP2020)	Y/N	
>55/ C4591001	GASTR	Abdominal hernia/ Abdominal hernia	2	07DEC2020	56/8	3	No	O	NA/TCN	R (14DEC2020)	Y/N	



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1047 10471290		Intestinal strangulation/ Small bowel strangulation	2	07DEC2020	56/8	3	No	O	NA/TCN	R (14DEC2020)	Y/N	
	INFEC	Post procedural infection/ Intra abdominal infection post cholecystectomy#	2	22FEB2021	133/C	3	No	O	NA/TC	N	Y/N	
>55/ C4591001 1054 10541168	INJ&P	Lumbar vertebral fracture/ closed fracture, transverse process of lumbar vertebra	2	03DEC2020	57/C	3	No	O	NA/TC/TCN	RG	Y/N	
>55/ C4591001 1054 10541173	CARD	Aortic valve incompetence/ acute aortic insufficiency	2	28OCT2020	20/49	4	No	O	NA/TC/TCN	R (15DEC2020)	Y/N	
	INFEC	Subacute endocarditis/ subacute bacterial endocarditis	2	28OCT2020	20/49	4	No	O	NA/TC/TCN	R (15DEC2020)	Y/N	
	NERV	Subarachnoid haemorrhage/ subarachnoid hemorrhage	2	05NOV2020	28/1	3	No	O	NA/TC/TCN	R (05NOV2020)	Y/N	
>55/ C4591001 1055 10551153	INFEC	Appendicitis perforated/ Perforated appendicitis	1	31AUG2020	1/17	3	No	O	NA/TC/TCN	R (16SEP2020)	Y/N	
>55/ C4591001 1055 10551182	NEOPL	Malignant melanoma/ Melanoma	2	16NOV2020	53/C	2	No	O	NA/TC/TCN	N	Y/N	
>55/ C4591001	INFEC	Pneumonia/ PNEUMONIA	2	20SEP2020	12/15	2	No	O	NA/TC	R (04OCT2020)	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1057 10571052 >55/ C4591001 1057 10571327	INFEC	Peritonsillar abscess/ LEFT PERITONSILLAR ABSCESS	1	22OCT2020	7/33	3	No	O	NA/TC/TCN	R (23NOV2020)	Y/N	
>55/ C4591001 1066 10661350	CARD	Myocardial infarction/ myocardial infarction	1	03NOV2020	16/1	4	No	O	P/W	F (03NOV2020)	Y/N	
>55/ C4591001 1068 10681079	INFEC	Meningitis bacterial/ Suspected bacterial meningitis#	2	06FEB2021	139/15	3	No	O	NA/TC	R (20FEB2021)	Y/N	
>55/ C4591001 1068 10681091	INJ&P	Hip fracture/ Left Hip Fracture	2	20JAN2021	120/C	4	No	O	NA/TCN	RG	Y/N	
>55/ C4591001 1071 10711023	CARD	Coronary artery disease/ WORSENING coronary artery disease	1	23AUG2020	12/9	2	No	O	P/TCN/W	R (31AUG2020)	Y/N	
>55/ C4591001 1071 10711169	INJ&P	Alcohol poisoning/ ACUTE ALCOHOL INTOXICATION	1	02OCT2020	18/14	2	No	O	P/W	R (15OCT2020)	Y/N	
>55/ C4591001 1071 10711172	VASC	Hypertension/ HYPERTENSION#	4	27FEB2021	8/2	3	No	O	NA/TC	RS (28FEB2021)	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1072 10721007	NERV	Transient ischaemic attack/ Transient Ischaemic Attack	1	04SEP2020	19/6	2	No	O	NA/TC/TCN	R (09SEP2020)	Y/N	
>55/ C4591001 1072 10721064	CARD	Myocardial infarction/ myocardial infarction#	3	06MAR2021	16/4	3	No	O	NA/TC/TCN	RS (09MAR2021)	Y/N	
>55/ C4591001 1077 10771194	CARD	Acute myocardial infarction/ ST ELEVATION MYOCARDIAL INFARCTION (STEMI)	2	28JAN2021	126/3	4	No	O	NA/TC	R (30JAN2021)	Y/N	
>55/ C4591001 1077 10771226	RENAL	Nephrolithiasis/ BILATERAL KIDNEY STONES	2	29NOV2020	59/C	2	No	O	NA/TCN	N	Y/N	
>55/ C4591001 1079 10791044	MUSC	Osteoarthritis/ Worsening of Osteoarthritis Bilateral Knee	2	05OCT2020	42/64	2	No	O	NA/TC/TCN	R (07DEC2020)	Y/N	
>55/ C4591001 1079 10791076	NEOPL	Uterine cancer/ Uterine Cancer#	2	25JAN2021	151/C	4	No	O	NA/TC/TCN	RG	Y/N	
>55/ C4591001 1079 10791183	NERV	Cerebrovascular accident/ Cerebrovascular event#	3	06MAR2021	10/C	1	No	O	NA/TC	RG	Y/N	
>55/ C4591001	EYE	Retinal artery occlusion/ Central Retinal Artery Occlusion	2	29SEP2020	1/C	1	No	O	NA	N	Y/N	

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1079 10791228 >55/ C4591001 1079 10791246	NERV	Cerebrovascular accident/ CVA	2	22OCT2020	28/5	2	No	O	NA	R (26OCT2020)	Y/N	
>55/ C4591001 1080 10801006	GENRL	Drug withdrawal syndrome/ Withdraw from valium#	4	08MAR2021	21/C	3	No	CD	NA/TC/TCN	N	Y/N	
>55/ C4591001 1080 10801013	MUSC	Osteoarthritis/ Osteoarthritis of the knee	2	26OCT2020	56/1	3	No	O	NA/TC/TCN	R (26OCT2020)	Y/N	
	GASTR	Colitis ischaemic/ Ischemic colitis	2	31OCT2020	61/C	3	No	O	NA/TC/TCN	RG	Y/N	
		Constipation/ Constipation	2	31OCT2020	61/C	3	No	O	NA/TC/TCN	RG	Y/N	
		Large intestine perforation/ Perforated Colon	2	31OCT2020	61/C	3	No	O	NA/TC/TCN	RG	Y/N	
>55/ C4591001 1080 10801035	NEOPL	Breast cancer in situ/ Stage 0 Breast Cancer Right Breast	2	30OCT2020	57/35	3	No	O	NA/TCN	R (03DEC2020)	Y/N	
>55/ C4591001 1080 10801152	METAB	Fluid retention/ Worsening of WATER RETENTION in lower extremities	1	16SEP2020	13/3	3	No	O	NA/TC	R (18SEP2020)	Y/N	
	VASC	Hypertension/ Worsening of HYPERTENSION	1	16SEP2020	13/3	3	No	O	NA/TC	R (18SEP2020)	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1081 10811026	NEOPL	Borderline serous tumour of ovary/ Serous borderline tumor of left ovary	2	11OCT2020	40/19	3	No	O	NA/TC/TCN	R (29OCT2020)	Y/N	
>55/ C4591001 1081 10811030	NEOPL	Prostate cancer/ Prostate Cancer	2	10SEP2020	10/C	3	No	O	NA/TCN	RG	Y/N	
>55/ C4591001 1081 10811045	CARD	Atrial fibrillation/ Atrial Fibrillation with Rapid Ventricular Response	2	17NOV2020	70/15	2	No	O	NA/TC	R (01DEC2020)	Y/N	
>55/ C4591001 1081 10811048	INJ&P	Fall/ Fall on stairs at home#	2	12JAN2021	126/1	3	No	O	NA/TC/TCN	R (12JAN2021)	Y/N	
		Hip fracture/ Hip Fracture, right#	2	12JAN2021	126/11	3	No	O	NA/TC/TCN	R (22JAN2021)	Y/N	
>55/ C4591001 1081 10811090	CARD	Myocardial infarction/ Myocardial Infarction	2	15NOV2020	63/4	4	No	O	NA/TC/TCN	R (18NOV2020)	Y/N	
	PSYCH	Suicide attempt/ Suicide attempt	2	15JAN2021	124/4	3	No	O	NA/TC/TCN	R (18JAN2021)	Y/N	
>55/ C4591001 1081 10811102	CARD	Angina pectoris/ Angina	2	10JAN2021	118/C	2	No	O	NA/TC/TCN	RG	Y/N	
>55/ C4591001	INFEC	Empyema/ loculated empyema	2	11OCT2020	26/39	3	No	O	NA/TC	R (18NOV2020)	Y/N	

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1081 10811110		Pneumonia/ Right lower lobe pneumonia	2	11OCT2020	26/39	3	No	O	NA/TC	R (18NOV2020)	Y/N
>55/ C4591001 1081 10811170	NEOPL	Prostate cancer/ Malignant Neoplasm of Prostate	2	04NOV2020	43/C	3	No	O	NA/TCN	N	Y/N
>55/ C4591001 1081 10811179	NEOPL	Breast cancer stage II/ Stage II Breast Cancer (Left)#	4	23FEB2021	6/C	3	No	CD	NA/TC	N	Y/N
>55/ C4591001 1082 10821076	HEPAT	Cholelithiasis/ cholelithiasis	1	13AUG2020	7/3	3	No	O	NA/TCN	R (15AUG2020)	Y/N
>55/ C4591001 1082 10821094	METAB	Type 2 diabetes mellitus/ New onset type 2 diabetes	2	05NOV2020	66/C	1	No	O	NA/TC	N	Y/N
>55/ C4591001 1083 10831050	GASTR	Acute abdomen/ Acute Abdomen#	2	04MAR2021	183/C	2	No	O	NA/TC/TCN	RG	Y/N
>55/ C4591001 1083 10831173	NEOPL	Prostate cancer/ Prostate Cancer	1	02NOV2020	68/C	3	No	O	NA/TC/TCN	RG	Y/N
>55/ C4591001	REPRO	Ovarian cyst/ Left ovarian cyst, benign tumor	1	24AUG2020	8/27	2	No	O	NA/TC/TCN	R (19SEP2020)	Y/N

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1084 10841219		Uterine prolapse/ Prolapsed uterus	1	24AUG2020	8/27	2	No	O	NA/TC/TCN	R (19SEP2020)	Y/N	
>55/ C4591001 1084 10841266	INFEC	Emphysematous cholecystitis/ Acute Emphysematous Cholecystitis	2	03NOV2020	51/71	4	No	O	NA/TC/TCN/W	F (12JAN2021)	Y/N	
		Sepsis/ Sepsis	2	03NOV2020	51/71	4	No	O	NA/TC/TCN/W	F (12JAN2021)	Y/N	
>55/ C4591001 1084 10841470	GENRL	Multiple organ dysfunction syndrome/ Mutli-system organ failure	2	31DEC2020	72/12	4	No	O	NA/TC/TCN	F (11JAN2021)	Y/N	
	INFEC	COVID-19/ COVID-19 Infection	2	31DEC2020	72/12	4	No	O	NA/TC/TCN/W	F (11JAN2021)	Y/N	
>55/ C4591001 1085 10851116	CARD	Acute myocardial infarction/ ACUTE NON ST ELEVATION MYOCARDIAL INFARCTION (MI) - NSTEMI	2	26DEC2020	108/4	4	No	O	NA/TC/TCN	R (29DEC2020)	Y/N	
		Cardiac failure congestive/ ACUTE DIASTOLIC CONGESTIVE HEART FAILURE (CHF)	2	26DEC2020	108/4	3	No	O	NA/TC/TCN	RS (29DEC2020)	Y/N	
	RENAL	Acute kidney injury/ Acute Kidney Injury	2	26DEC2020	108/4	3	No	O	NA	R (29DEC2020)	Y/N	
>55/ C4591001 1085 10851216	INJ&P	Lower limb fracture/ Left leg fracture of tibia/fibula	2	17OCT2020	25/2	1	No	O	NA/TC/TCN	R (18OCT2020)	Y/N	

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>55/ C4591001 1087 10871029	NERV	Toxic encephalopathy/ Acute Toxic Metabolic Encephalopathy	2	28OCT2020	64/9	3	No	CD	NA/TC	R (05NOV2020)	Y/N	
>55/ C4591001 1087 10871070	CARD	Acute coronary syndrome/ ACUTE CORONARY SYNDROME	2	08SEP2020	8/3	3	No	O	NA/TC/TCN	R (10SEP2020)	Y/N	
>55/ C4591001 1087 10871121	GASTR	Gastrointestinal haemorrhage/ GI Bleed	1	07SEP2020	20/3	3	No	O	P/TC/TCN/W	R (09SEP2020)	Y/N	
>55/ C4591001 1087 10871150	INFEC	Peritonsillar abscess/ Tonsillar Abscess - Right	1	01SEP2020	12/5	3	No	O	NA/TC	R (05SEP2020)	Y/N	
>55/ C4591001 1087 10871228	CARD	Cardiac failure congestive/ Worsening of Chronic Congestive Heart Failure	1	03SEP2020	9/6	3	No	O	P/TC/W	R (08SEP2020)	Y/N	
>55/ C4591001 1087 10871266	NEOPL	Gallbladder cancer stage II/ Gallbladder Cancer - Stage 2	2	20NOV2020	61/C	4	No	O	NA/TC/TCN	RG	Y/N	
>55/ C4591001 1087 10871286	GASTR	Gastrointestinal haemorrhage/ Gastrointestinal Bleed	2	04NOV2020	44/3	3	No	O	NA/TC/TCN	R (06NOV2020)	Y/N	
>55/ C4591001	INFEC	Device related infection/ Worsening of Chronic Recurrent	2	16NOV2020	56/9	3	No	O	NA/TC/TCN	R (24NOV2020)	Y/N	



## 16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age

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1087 10871289 >55/ C4591001 1088 10881126	INFEC	Infection of Right Total Knee Replacement COVID-19/ COVID-19	2	29NOV2020	68/C	4	No	O	NA	UNK	Y/N
	CARD	Cardiac arrest/ cardiac arrest	2	01DEC2020	70/1	4	No	O	NA/W	F (01DEC2020)	Y/N
		Coronary artery disease/ Coronary Artery Disease	2	01DEC2020	70/1	4	No	O	NA	UNK (01DEC2020)	Y/N
>55/ C4591001 1088 10881139	NEOPL	Metastases to lung/ Metastases to the lungs#	2	24FEB2021	133/11	4	No	O	NA/W	F (06MAR2021)	Y/N
		Pancreatic carcinoma metastatic/ Metastatic pancreatic cancer#	2	24FEB2021	133/C	4	No	O	NA	N	Y/N
>55/ C4591001 1089 10891073	RESP	Chronic obstructive pulmonary disease/ Worsening of COPD	2	12NOV2020	70/1	4	No	O	NA/W	F (12NOV2020)	Y/N
>55/ C4591001 1089 10891088	NERV	Dementia Alzheimer's type/ Worsening of Dementia (Alzheimer's).	2	20DEC2020	115/11	4	No	O	NA/W	F (30DEC2020)	Y/N
>55/ C4591001 1089 10891150	CARD	Atrial fibrillation/ Chronic atrial fibrillation with RVR'	2	04OCT2020	26/2	3	No	O	NA/TC/TCN	R (05OCT2020)	Y/N
>55/ C4591001	INJ&P	Concussion/ concussion	2	07NOV2020	65/8	2	No	O	NA/TC/TCN	R (14NOV2020)	Y/N

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1090 10901175		Road traffic accident/ bike accident	2	07NOV2020	65/1	3	No	O	NA/TC	R (07NOV2020)	Y/N	
	NERV	Intraventricular haemorrhage/ intraventricular hemorrhage, left occipital horn	2	07NOV2020	65/8	2	No	O	NA/TC	RS (14NOV2020)	Y/N	
>55/ C4591001 1090 10901300	IMMUN	Anaphylactic shock/ anaphylactic shock	2	09OCT2020	19/1	4	No	O	NA/TC	R (09OCT2020)	Y/N	
>55/ C4591001 1090 10901486	GASTR	Duodenal obstruction/ duodenal obstruction	2	13JAN2021	80/4	4	No	O	NA/TC/TCN	R (16JAN2021)	Y/N	
>55/ C4591001 1091 10911213	CARD	Myocardial infarction/ Myocardial Infarction	2	06NOV2020	47/1	4	No	O	NA/TC/TCN	R (06NOV2020)	Y/N	
>55/ C4591001 1092 10921010	GASTR	Abdominal pain upper/ Worsening Intermittent Stomach Pain#	2	02FEB2021	147/C	2	No	O	NA/TC	N	Y/N	
>55/ C4591001 1092 10921015	CARD	Atrial fibrillation/ Arrhythmia atrial fibrillation	1	26AUG2020	8/2	2	No	O	NA/TC	R (27AUG2020)	Y/N	
>55/ C4591001	CARD	Atrial fibrillation/ Atrial Fibrillation	2	23NOV2020	71/3	2	No	O	NA/TC	R (25NOV2020)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1092 10921048 >55/ C4591001 1092 10921120	EAR	Vertigo/ Vertigo	2	16JAN2021	117/3	3	No	O	NA/TC	R (18JAN2021)	Y/N	
	NERV	Transient ischaemic attack/ Transient Ischemic Attack (TIA)	2	16JAN2021	117/1	3	No	O	NA/TC	R (16JAN2021)	Y/N	
>55/ C4591001 1092 10921123	GASTR	Abdominal pain upper/ Epigastric Pain	1	07OCT2020	37/2	3	No	O	NA/TC	R (08OCT2020)	Y/N	
>55/ C4591001 1092 10921187	CARD	Cardiac failure congestive/ Congestive heart failure	1	01OCT2020	17/3	2	No	O	NA/TC	R (03OCT2020)	Y/N	
>55/ C4591001 1093 10931141	INFEC	Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	2	26DEC2020	74/3	1	No	O	NA/TC	R (28DEC2020)	Y/N	
		Urinary tract infection/ URINARY TRACT INFECTION	2	26DEC2020	74/3	1	No	O	NA/TC	R (28DEC2020)	Y/N	
>55/ C4591001 1094 10941112	INFEC	COVID-19/ COVID-19 Infection	2	26NOV2020	59/23	4	No	O	NA/TC	F (18DEC2020)	Y/N	
		Pneumonia/ Pneumonia	2	26NOV2020	59/23	4	No	O	NA/TC/TCN	F (18DEC2020)	Y/N	
	RESP	Acute respiratory failure/ Acute hypoxemic respiratory failure	2	28NOV2020	61/21	4	No	O	NA/TC/TCN/W	F (18DEC2020)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1095 10951080	NEOPL	Lobular breast carcinoma in situ/ Left Lobular Breast Cancer, Stage I, Grade I	2	12DEC2020	108/C	2	No	O	NA/TCN	N	Y/N	
>55/ C4591001 1095 10951101	RESP	Pulmonary embolism/ Pulmonary Embolism	2	30OCT2020	64/9	3	No	O	NA/TC	R (07NOV2020)	Y/N	
>55/ C4591001 1095 10951107	NERV	Dizziness/ Dizziness, secondary to Clonidine reaction	2	31AUG2020	5/3	2	No	O	NA	R (02SEP2020)	Y/N	
	CARD	Tachyarrhythmia/ Suspected tachy-arrythmia	2	08SEP2020	13/15	3	No	O	NA/TC	R (22SEP2020)	Y/N	
>55/ C4591001 1095 10951125	EYE	Diplopia/ Diplopia#	3	08JAN2021	12/13	1	No	O	NA	R (20JAN2021)	Y/N	
>55/ C4591001 1095 10951134	CARD	Cardiac arrest/ Cardiac Arrest	2	16OCT2020	32/32	4	No	O	NA/TC/TCN	R (16NOV2020)	Y/N	
	INJ&P	Craniocerebral injury/ Traumatic Brain Injury	2	16OCT2020	32/C	4	No	O	NA/TC/TCN	RG	Y/N	
		Road traffic accident/ Bicycle Accident	2	16OCT2020	32/57	4	No	O	NA/TCN	R (11DEC2020)	Y/N	
>55/ C4591001 1095 10951180	NERV	Dizziness/ Dizziness	2	05NOV2020	45/2	1	No	O	NA	R (06NOV2020)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1095 10951204	NEOPL	Bladder cancer/ STAGE I Bladder Cancer	2	02NOV2020	43/3	3	No	O	NA/TCN	R (04NOV2020)	Y/N	
>55/ C4591001 1095 10951206	EYE	Eye haemorrhage/ ruptured blood vessel behind Left eye	2	17NOV2020	55/2	2	No	O	NA/TC/TCN	R (18NOV2020)	Y/N	
>55/ C4591001 1095 10951228	INFEC	Pneumonia/ Pneumonia	2	13NOV2020	51/29	2	No	O	NA/TC	R (11DEC2020)	Y/N	
>55/ C4591001 1095 10951256	NEOPL	Prostate cancer metastatic/ Prostate Cancer with mets	2	26OCT2020	8/C	3	No	O	NA/TC	N	Y/N	
>55/ C4591001 1096 10961017	INJ&P	Head injury/ Head Injury	2	29NOV2020	90/19	3	No	O	NA/TC	R (17DEC2020)	Y/N	
>55/ C4591001 1096 10961044	INV	Hepatic enzyme increased/ Elevated Liver Enzymes	2	21SEP2020	12/22	3	No	O	NA	R (12OCT2020)	Y/N	
>55/ C4591001 1096 10961056	NERV	Cerebrovascular accident/ Cerebrovascular accident#	4	22FEB2021	28/5	2	No	O	NA/TC	RS (26FEB2021)	Y/N	
>55/ C4591001	RESP	Acute respiratory failure/ Acute Hypoxic Respiratory Failure#	4	23FEB2021	23/5	2	No	O	NA	R (27FEB2021)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1096 10961181	CARD	Acute myocardial infarction/ Non-St-Elevation Myocardial Infarction#	4	26FEB2021	26/1	2	No	O	NA/TCN	R (26FEB2021)	Y/N	
	CARD	Arteriospasm coronary/ Coronary Spasm#	4	08MAR2021	36/4	3	No	O	NA	R (11MAR2021)	Y/N	
		Cardiovascular disorder/ Coronary Blood Stasis#	4	08MAR2021	36/5	3	No	O	NA/TC	R (12MAR2021)	Y/N	
>55/ C4591001 1096 10961355	INJ&P	Lower limb fracture/ Multiple lower extremity fractures	2	31JAN2021	116/C	3	No	O	NA/TC	N	Y/N	
>55/ C4591001 1097 10971011	INFEC	Pneumonia/ Pneumonia	2	20SEP2020	12/16	3	No	O	NA/TC	R (05OCT2020)	Y/N	
>55/ C4591001 1097 10971017	GASTR	Retroperitoneal haematoma/ non traumatic retroperitoneal hematoma	2	13NOV2020	60/3	3	No	O	NA	R (15NOV2020)	Y/N	
>55/ C4591001 1097 10971023	INFEC	Septic shock/ Septic Shock	2	16DEC2020	93/6	4	No	O	NA/TC/TCN/W	F (21DEC2020)	Y/N	
>55/ C4591001 1097 10971025	CARD	Acute myocardial infarction/ Non-STEMI	2	15SEP2020	2/1	3	No	O	NA/TC/TCN	R (15SEP2020)	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1097 10971026	NERV	Cerebrovascular accident/ CEREBROVASCULAR ACCIDENT#	4	24FEB2021	17/C	3	No	O	NA	N	Y/N	
>55/ C4591001 1097 10971031	MUSC	Arthralgia/ Worsening Chronic right hip pain	2	03NOV2020	50/15	3	No	O	NA/TCN	R (17NOV2020)	Y/N	
>55/ C4591001 1097 10971061	NERV	Uraemic encephalopathy/ Uremic encephalopathy	2	22OCT2020	36/4	3	No	O	NA/TC	RS (25OCT2020)	Y/N	
	RENAL	Acute kidney injury/ Acute kidney injury	2	22OCT2020	36/4	3	No	CD	NA/TC	RS (25OCT2020)	Y/N	
>55/ C4591001 1097 10971064	CARD	Atrial fibrillation/ NEW ONSET ATRIAL FIB	2	04JAN2021	103/3	3	No	O	NA/TC	R (06JAN2021)	Y/N	
	CARD	Atrial fibrillation/ Persistent Atrial Fibrillation#	2	21JAN2021	120/C	3	No	O	NA/TC/TCN	RG	Y/N	
>55/ C4591001 1097 10971084	INFEC	Bacterial sepsis/ Sepsis Bacteremia	2	29SEP2020	7/13	3	No	O	NA/TC	R (11OCT2020)	Y/N	
		Urinary tract infection/ Urinary Tract Infection	2	29SEP2020	7/13	3	No	O	NA/TC/TCN	R (11OCT2020)	Y/N	
	INJ&P	Fall/ fall#	2	13FEB2021	144/1	1	No	O	NA	R (13FEB2021)	Y/N	
	NERV	Dizziness/ dizziness#	2	13FEB2021	144/3	2	No	O	NA/TC	R (15FEB2021)	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1097 10971087	INFEC	Tooth infection/ Dental Infection	2	19NOV2020	57/19	3	No	O	NA/TC	R (07DEC2020)	Y/N	
>55/ C4591001 1098 10981024	GENRL	Chest pain/ ChestPain	2	07OCT2020	14/3	1	No	O	NA/TC/TCN	R (09OCT2020)	Y/N	
	INFEC	Pneumonia/ Community Acquired Pneumonia	2	07OCT2020	14/3	1	No	O	NA	R (09OCT2020)	Y/N	
>55/ C4591001 1107 11071044	HEPAT	Cholelithiasis/ CHOLELITHIASIS	2	11SEP2020	17/5	3	No	O	NA/TC/TCN	R (15SEP2020)	Y/N	
>55/ C4591001 1107 11071116	RENAL	Nephrolithiasis/ RIGHT KIDNEY STONE#	2	25FEB2021	171/C	3	No	O	NA/TC/TCN	N	Y/N	
>55/ C4591001 1107 11071191	NEOPL	Papillary serous endometrial carcinoma/ UTERINE PAPILLARY SEROUS CARCINOMA	2	NOV2020	39/	3	No	O	NA/TC/TCN	R (30DEC2020)	Y/N	
>55/ C4591001 1107 11071196	INFEC	Diverticulitis/ DIVERTICULITIS	2	DEC2020	70/	3	No	O	NA/TC/TCN	R (22FEB2021)	Y/N	
>55/ C4591001 1109 11091074	INFEC	COVID-19 pneumonia/ Pneumonia COVID-19 illness	2	04DEC2020	107/18	4	No	O	NA/TC	R (21DEC2020)	Y/N	



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>55/ C4591001 1109 11091084	NEOPL	Malignant melanoma/ REGIONALLY ADVANCED MELANOMA OF THE RIGHT INGUINAL AREA	2	26NOV2020	98/C	4	No	O	NA/TC/TCN	N	Y/N	
>55/ C4591001 1109 11091111	INFEC	Diverticulitis/ Diverticulitis flair-up	2	08NOV2020	78/6	4	No	O	NA/TC	R (13NOV2020)	Y/N	
>55/ C4591001 1109 11091164	VASC	Deep vein thrombosis/ Deep Vein Thrombosis	2	07SEP2020	15/C	4	No	O	NA/TC	RG	Y/N	
>55/ C4591001 1109 11091269	NERV	Cerebrovascular accident/ CVA	2	17NOV2020	69/50	3	No	O	NA/TC	RS (05JAN2021)	Y/N	
>55/ C4591001 1109 11091276	INFEC	Complicated appendicitis/ Acute appendicitis with necrosis	2	30SEP2020	22/3	4	No	O	NA/TC/TCN	R (02OCT2020)	Y/N	
>55/ C4591001 1109 11091284	RENAL	Hydronephrosis/ Acute Left Hydro Nephrosis	2	16NOV2020	63/38	3	No	O	NA/TC/TCN	R (23DEC2020)	Y/N	
>55/ C4591001 1109 11091387	MUSC	Osteoarthritis/ Worsening osteoarthritis of the right knee	2	14OCT2020	23/2	4	No	O	NA/TC/TCN	R (15OCT2020)	Y/N	
>55/ C4591001	RESP	Chronic obstructive pulmonary disease/ EXACERBATION OF COPD	2	06NOV2020	14/15	3	No	O	NA/TC	R (20NOV2020)	Y/N	

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1109 11091558	RESP	Chronic obstructive pulmonary disease/ RE-EXACERBATION OF COPD	2	30NOV2020	38/24	3	No	O	NA/TC	R (23DEC2020)	Y/N	
>55/ C4591001 1110 11101031	METAB	Diabetes mellitus inadequate control/ Uncontrolled Diabetes Mellitus Type 2	2	10NOV2020	78/4	3	No	O	NA/TC/TCN	R (13NOV2020)	Y/N	
>55/ C4591001 1110 11101160	GENRL	Chest pain/ Chest Pain	2	15DEC2020	86/2	3	No	O	NA/TC	R (16DEC2020)	Y/N	
>55/ C4591001 1110 11101176	NERV	Transient ischaemic attack/ Transient Ischemic Attack	2	03NOV2020	44/4	3	No	O	NA/TC	R (06NOV2020)	Y/N	
>55/ C4591001 1110 11101302	NEOPL	Tonsil cancer/ tonsil cancer	2	15FEB2021	124/C	1	No	O	NA	N	Y/N	
>55/ C4591001 1110 11101367	INJ&P	Procedural pain/ post op pain#	2	22FEB2021	131/15	3	No	O	NA/TC	R (08MAR2021)	Y/N	
>55/ C4591001 1110 11101367	INV	Blood glucose abnormal/ uncontrolled blood sugar (glucose)	2	20NOV2020	2/4	3	No	O	NA/TC	R (23NOV2020)	Y/N	
>55/ C4591001 1111 11111010	INFEC	Urosepsis/ Urosepsis#	3	11JAN2021	7/5	3	No	O	NA/TC	R (15JAN2021)	Y/N	

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	RESP	Acute respiratory failure/ Acute hypoxic respiratory failure#	3	11JAN2021	7/5	3	No	O	NA/TCN	R (15JAN2021)	Y/N	
	NEOPL	Non-small cell lung cancer stage III/ Nonsmall cell lung carcinoma stage 3#	4	25FEB2021	31/C	3	No	O	NA/TC	N	Y/N	
	INFEC	Clostridium difficile infection/ clostridium difficile infection#	4	13MAR2021	47/C	2	No	O	NA/TC	N	Y/N	
>55/ C4591001 1111 11111016	RESP	Pulmonary embolism/ Pulmonary emboli#	3	07JAN2021	3/2	3	No	O	NA/TC	R (08JAN2021)	Y/N	
	VASC	Thrombosis/ Occlusive thrombus in the right calf#	3	07JAN2021	3/2	3	No	O	NA/TC	R (08JAN2021)	Y/N	
>55/ C4591001 1111 11111095	PSYCH	Mental disorder/ Undiagnosed Mental Disorder (not otherwise specified)	2	25SEP2020	25/C	2	No	O	NA	N	Y/N	
>55/ C4591001 1111 11111103	RESP	Dyspnoea exertional/ Dyspnea on exertion#	2	FEB2021	155/	3	No	O	NA/TC	R (27FEB2021)	Y/N	
	INFEC	Bacteraemia/ Bacteremia#	2	16FEB2021	170/12	3	No	O	NA/TC	R (27FEB2021)	Y/N	
		Endocarditis/ Endocarditis#	2	16FEB2021	170/12	2	No	O	NA/TC	R (27FEB2021)	Y/N	
>55/ C4591001 1111 11111109	INFEC	Pyelonephritis/ Pyelonephritis	2	28SEP2020	25/5	2	No	O	NA/TC	R (02OCT2020)	Y/N	
>55/ C4591001	GASTR	Pancreatitis acute/ Acute Pancreatitis	1	19OCT2020	5/3	3	No	O	NA/TC	R (21OCT2020)	Y/N	

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1111 11111193 >55/ C4591001 1114 11141006	CARD	Ventricular tachycardia/ Ventricular Tachycardia	2	11DEC2020	102/5	4	No	O	NA/TC/TCN	RS (15DEC2020)	Y/N	
>55/ C4591001 1114 11141050	GENRL	Sudden cardiac death/ Sudden cardiac death	2	19OCT2020	42/1	4	No	O	NA/W	F (19OCT2020)	Y/N	
>55/ C4591001 1114 11141080	INFEC	Staphylococcal infection/ MRSA infection Right Stump	1	12SEP2020	20/27	2	No	O	NA/TC	R (08OCT2020)	Y/N	
>55/ C4591001 1116 11161045	BLOOD	Thrombocytopenia/ Thrombocytopenia	2	27OCT2020	40/16	1	No	O	NA	R (11NOV2020)	Y/N	
>55/ C4591001 1116 11161198	INJ&P	Delayed recovery from anaesthesia/ slow to recover from anesthesia	2	02DEC2020	65/2	2	No	O	NA	R (03DEC2020)	Y/N	
	RESP	Pulmonary embolism/ PULMONARY EMBOLISM/ BLOOD CLOTS IN UPPER RIGHT LOBE	2	22DEC2020	85/1	3	No	O	NA/TC	RG (22DEC2020)	Y/N	
>55/ C4591001 1117 11171079	CARD	Myocardial infarction/ MYOCARDIAL INFARCTION#	2	28JAN2021	136/2	3	No	O	NA/TC/TCN	R (29JAN2021)	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1117 11171086	CARD	Cardiac failure congestive/ CARDIAC FAILURE, CONGESTIVE#	2	14FEB2021	146/6	3	No	O	NA/TC	R (19FEB2021)	Y/N	
>55/ C4591001 1117 11171088	GENRL	Non-cardiac chest pain/ NON CARDIAC CHEST PAIN	2	14NOV2020	53/3	3	No	O	NA/TC/TCN	R (16NOV2020)	Y/N	
>55/ C4591001 1117 11171141	GASTR	Small intestinal obstruction/ SMALL BOWEL OBSTRUCTION	2	27NOV2020	46/4	4	No	O	NA	R (30NOV2020)	Y/N	
	GASTR	Small intestinal obstruction/ SMALL BOWEL OBSTRUCTION	2	27DEC2020	76/4	3	No	O	NA/TC	R (30DEC2020)	Y/N	
>55/ C4591001 1117 11171146	RESP	Pulmonary embolism/ PULMONARY EMBOLI#	3	21JAN2021	3/3	1	No	O	NA/TC	R (23JAN2021)	Y/N	
	VASC	Deep vein thrombosis/ DEEP VEIN THROMBOSIS, LOWER EXTREMITY, RIGHT#	3	21JAN2021	3/3	2	No	O	NA/TC	R (23JAN2021)	Y/N	
>55/ C4591001 1117 11171167	EAR	Vertigo/ VERTIGO	2	06NOV2020	24/4	3	No	O	NA/TC	R (09NOV2020)	Y/N	
>55/ C4591001 1118 11181013	VASC	Hypertension/ WORSENING OF HYPERTENSION	2	19JAN2021	141/C	3	No	O	NA/TC/TCN	RG	Y/N	
>55/ C4591001	CARD	Angina pectoris/ cardiac chest pain	2	24NOV2020	82/3	2	No	O	NA/TC	R (26NOV2020)	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1118 11181031 >55/ C4591001 1118 11181044	RESP	Pulmonary embolism/ bilateral pulmonary embolism	2	11NOV2020	65/C	3	No	O	NA/TC	RG	Y/N	
>55/ C4591001 1118 11181057	INFEC	Diverticulitis/ Sigmoid diverticulitis	1	04SEP2020	18/15	3	No	O	NA/TC	R (18SEP2020)	Y/N	
>55/ C4591001 1118 11181074	CARD	Bradycardia/ BRADYCARDIA	2	14SEP2020	4/51	2	No	O	NA/TC/TCN	RS (03NOV2020)	Y/N	
>55/ C4591001 1118 11181123	GASTR	Pancreatitis acute/ IDIOPATHIC ACUTE PANCREATITIS#	3	06FEB2021	18/7	3	No	O	NA	R (12FEB2021)	Y/N	
>55/ C4591001 1120 11201002	NEOPL	Uterine leiomyoma/ fibroids	2	27DEC2020	131/31	2	No	O	NA/TC/TCN	R (26JAN2021)	Y/N	
>55/ C4591001 1120 11201050	CARD	Cardiac arrest/ Cardiac arrest	2	07NOV2020	73/1	4	No	O	NA/W	F (07NOV2020)	Y/N	
>55/ C4591001 1120 11201059	NEOPL	Breast cancer/ breast cancer	2	05NOV2020	72/28	3	No	O	NA/TC	R (02DEC2020)	Y/N	

## 16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1120 11201350	INFEC	Postoperative wound infection/ Postoperative wound infection to left upper chest	1	23NOV2020	35/43	1	No	O	NA/TC	R (04JAN2021)	Y/N
>55/ C4591001 1120 11201432	NEOPL	Pancreatic carcinoma/ Pancreatic cancer	2	04DEC2020	15/C	4	No	O	NA	N	Y/N
>55/ C4591001 1125 11251154	INFEC	COVID-19/ Covid-19	2	20JAN2021	121/26	3	No	O	NA/TC	R (14FEB2021)	Y/N
>55/ C4591001 1127 11271023	NEOPL	Invasive ductal breast carcinoma/ Malignant invasive ductal carcinoma left breast	2	05NOV2020	80/C	3	No	O	NA	N	Y/N
>55/ C4591001 1128 11281009	CARD	Myocardial infarction/ Myocardial Infarction	2	27OCT2020	70/2	4	No	O	NA	R (28OCT2020)	Y/N
	INFEC	Pneumonia/ Pneumonia	2	28OCT2020	71/32	4	No	O	NA/TC/W	F (28NOV2020)	Y/N
>55/ C4591001 1128 11281014	INJ&P	Fall/ Fall	2	28AUG2020	2/24	2	No	O	NA/TCN	R (20SEP2020)	Y/N
>55/ C4591001 1128 11281138	NEOPL	Oropharyngeal cancer recurrent/ Recurrence of Oropharyngeal Cancer, Left side	2	12NOV2020	64/C	3	No	O	NA/TC	N	Y/N

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1128 11281192	MUSC	Osteoarthritis/ worsening of right hip osteoarthritis#	4	23FEB2021	15/C	3	No	O	NA/TCN	RG	Y/N	
>55/ C4591001 1128 11281250	NEOPL	Breast cancer/ Breast Cancer	2	27DEC2020	89/C	3	No	O	NA	RG	Y/N	
>55/ C4591001 1128 11281296	INJ&P	Post-traumatic pain/ post traumatic pain	2	23DEC2020	86/11	2	No	O	NA/TC	R (02JAN2021)	Y/N	
		Road traffic accident/ MOTOR VEHICLE ACCIDENT	2	23DEC2020	86/3	2	No	O	NA/TC/TCN	R (25DEC2020)	Y/N	
>55/ C4591001 1129 11291032	MUSC	Osteoarthritis/ worsened degenerative joint disease left shoulder#	4	16FEB2021	23/2	3	No	O	NA/TC/TCN	R (17FEB2021)	Y/N	
>55/ C4591001 1129 11291037	NEOPL	Squamous cell carcinoma of head and neck/ Metastatic Squamous Cell Carcinoma of head and neck	2	30NOV2020	99/C	3	No	O	NA/TC	RG	Y/N	
>55/ C4591001 1129 11291046	NERV	Intracranial aneurysm/ Aneurysm x3 Mid lateral Cranial Artery#	2	22JAN2021	152/19	3	No	O	NA/TC/TCN	R (09FEB2021)	Y/N	
>55/ C4591001 1129 11291074	EAR	Vertigo/ Worsened Vertigo	1	21AUG2020	12/4	3	No	O	NA	R (24AUG2020)	Y/N	



16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	EYE	Diplopia/ double vision	1	21AUG2020	12/2	3	No	O	NA	R (22AUG2020)	Y/N	
>55/ C4591001 1129 11291095	MUSC	Osteoarthritis/ worsened left knee degenerative joint disease	2	05OCT2020	36/2	3	No	O	NA	R (06OCT2020)	Y/N	
>55/ C4591001 1129 11291127	INFEC	Sepsis/ Sepsis#	2	16JAN2021	131/11	3	No	O	NA/TC/TCN	R (26JAN2021)	Y/N	
	BLOOD	Pancytopenia/ Pancytopenia#	2	20JAN2021	135/C	3	No	O	NA	RG	Y/N	
>55/ C4591001 1129 11291138	INFEC	Osteomyelitis/ osteomyelitis distal phalanx right 3rd toe	1	31AUG2020	7/27	3	No	O	NA/TC	R (26SEP2020)	Y/N	
>55/ C4591001 1129 11291161	CARD	Coronary artery disease/ worsening coronary artery disease	2	01DEC2020	71/49	3	No	O	NA/TC/TCN	R (18JAN2021)	Y/N	
>55/ C4591001 1129 11291166	CARD	Myocardial infarction/ myocardial infarction#	2	03FEB2021	129/1	4	No	O	NA/W	F (03FEB2021)	Y/N	
>55/ C4591001 1129 11291183	RENAL	Urinary tract obstruction/ Urinary Obstruction#	4	09MAR2021	23/2	3	No	O	NA/TCN	R (10MAR2021)	Y/N	
>55/ C4591001	NERV	Transient ischaemic attack/ Transient Ischemic Attack#	4	07MAR2021	27/1	2	No	O	NA/TC	R (07MAR2021)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1130 11301031 >55/ C4591001 1131 11311021	RESP	Pulmonary embolism/ Pulmonary Embolism#	2	02MAR2021	175/C	3	No	O	NA	N	Y/N	
	VASC	Aortic aneurysm/ Aortic Aneurysm#	2	02MAR2021	175/C	3	No	O	NA	N	Y/N	
		Deep vein thrombosis/ Deep Vein Thrombosis#	2	02MAR2021	175/C	3	No	O	NA	N	Y/N	
>55/ C4591001 1131 11311067	VASC	Peripheral artery stenosis/ Right femoral artery stenosis	2	19NOV2020	70/	3	No	O	NA/TCN	R	Y/N	
>55/ C4591001 1131 11311140	NEOPL	Breast cancer/ Breast Cancer, Right Breast	2	08DEC2020	76/C	2	No	O	NA/TCN	N	Y/N	
>55/ C4591001 1131 11311145	NERV	Syncope/ Syncope	1	08OCT2020	31/6	3	No	O	NA/TC	R (13OCT2020)	Y/N	
	VASC	Orthostatic hypotension/ Hypotension, orthostatic	1	18OCT2020	41/8	3	No	O	NA/TC	R (25OCT2020)	Y/N	
>55/ C4591001 1131 11311151	CARD	Atrioventricular block complete/ complete heart block	2	08DEC2020	71/12	4	No	O	NA/TC/TCN	RS (19DEC2020)	Y/N	
>55/ C4591001	VASC	Aortic stenosis/ Worsening Aortic Stenosis#	3	05FEB2021	16/9	3	No	O	NA	R (13FEB2021)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1131 11311204	CARD	Cardio-respiratory arrest/ Cardiopulmonary Arrest#	3	15FEB2021	26/1	4	No	O	NA/W	F (15FEB2021)	Y/N	
>55/ C4591001 1131 11311216	INJ&P	Post procedural haematoma/ Post-op Hematoma	2	30DEC2020	77/2	3	No	O	NA	R (31DEC2020)	Y/N	
>55/ C4591001 1131 11311222	CONG	Heart disease congenital/ congenital heart anomaly	2	02NOV2020	18/14	4	No	O	NA/TC/TCN	R (15NOV2020)	Y/N	
>55/ C4591001 1133 11331006	PSYCH	Bipolar disorder/ Worsening Bipolar Disorder	2	24AUG2020	4/12	3	No	O	NA/TC/TCN	R (04SEP2020)	Y/N	
>55/ C4591001 1133 11331147	INFEC	Urinary tract infection/ Urinary tract infection	2	05OCT2020	46/10	3	No	O	NA	R (14OCT2020)	Y/N	
>55/ C4591001 1133 11331147	GASTR	Pancreatitis acute/ Acute Pancreatitis#	3	21JAN2021	18/2	2	No	O	NA/TC	R (22JAN2021)	Y/N	
>55/ C4591001 1134 11341058	GASTR	Intestinal obstruction/ Intestinal Obstruction	1	20AUG2020	9/15	3	No	O	NA/TCN	R (03SEP2020)	Y/N	
>55/ C4591001 1134 11341085	MUSC	Intervertebral disc compression/ COMPRESSED CERVICAL DISC	2	15DEC2020	99/17	3	No	O	NA/TC	R (31DEC2020)	Y/N	

## 16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1134 11341250	NEOPL	Adrenal gland cancer/ ADRENAL ADENOCARCINOMA	2	20OCT2020	27/C	4	No	O	NA/TC	N	Y/N
>55/ C4591001 1134 11341432	INJ&P	Overdose/ HEROINE OVERDOSE	2	26NOV2020	16/3	4	No	O	NA	R (28NOV2020)	Y/N
>55/ C4591001 1135 11351033	PSYCH	Completed suicide/ Suicide#	3	29JAN2021	5/1	4	No	O	NA/W	F (29JAN2021)	Y/N
>55/ C4591001 1135 11351143	HEPAT	Cholecystitis acute/ acute cholecystitis	2	14OCT2020	36/4	3	No	O	NA/TC/TCN	R (17OCT2020)	Y/N
	CARD	Myocardial infarction/ myocardial infarction	2	18NOV2020	71/3	2	No	O	NA/TC/TCN	R (20NOV2020)	Y/N
>55/ C4591001 1135 11351257	NEOPL	Non-small cell lung cancer stage IV/ stage IV non-small cell lung cancer	2	16NOV2020	55/C	3	No	O	NA	RG	Y/N
	CARD	Atrial fibrillation/ Atrial fibrillation	2	10DEC2020	79/5	2	No	O	NA/TCN	R (14DEC2020)	Y/N
	CARD	Atrial fibrillation/ Atrial fibrillation	2	03JAN2021	103/2	2	No	O	NA/TCN	R (04JAN2021)	Y/N
>55/ C4591001 1136 11361102	CARD	Cardiac arrest/ cardiac arrest	2	19DEC2020	31/1	4	No	O	NA/TC/TCN/W	F (19DEC2020)	Y/N

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1139 11391024	NEOPL	Hormone receptor positive breast cancer/ Malignant neoplasm of upper-outer quadrant of right breast in female, estrogen receptor positive#	2	02FEB2021	168/C	3	No	O	NA	N	Y/N	
>55/ C4591001 1140 11401002	CARD	Coronary artery dissection/ Spontaneous coronary artery dissection	2	28AUG2020	12/1	4	No	O	NA	R (28AUG2020)	Y/N	
>55/ C4591001 1140 11401066	NEOPL	Thyroid cancer/ Thyroid Cancer	2	18SEP2020	25/C	3	No	O	NA	N	Y/N	
>55/ C4591001 1140 11401078	HEPAT	Cholecystitis acute/ Acute Cholecystitis	2	16SEP2020	20/15	3	No	O	NA/TC	R (30SEP2020)	Y/N	
>55/ C4591001 1140 11401117	CARD	Cardiac arrest/ Cardiac Arrest	2	29DEC2020	117/1	4	No	O	NA/W	F (29DEC2020)	Y/N	
>55/ C4591001 1140 11401156	CARD	Aortic valve incompetence/ Aortic Valve Dysfunction	2	01OCT2020	23/C	2	No	O	NA	RG	Y/N	
>55/ C4591001 1140 11401181	NEOPL	Brain neoplasm/ Brain Tumor#	4	07FEB2021	5/C	4	No	O	NA	N	Y/N	
>55/ C4591001	GASTR	Small intestinal obstruction/ Small Bowel Obstruction	1	08SEP2020	7/13	3	No	O	NA	R (20SEP2020)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1140 11401244 >55/ C4591001 1141 11411143	INJ&P	Procedural dizziness/ Post Anesthesia Dizziness#	2	03MAR2021	167/2	3	No	O	NA	R (04MAR2021)	Y/N	
>55/ C4591001 1142 11421032	VASC	Orthostatic hypotension/ Possible postural hypotension	2	31AUG2020	4/1	3	No	O	NA/TC	R (31AUG2020)	Y/N	
>55/ C4591001 1142 11421044	GASTR	Colitis/ Colitis	2	05SEP2020	8/C	3	No	CD	NA/TC	RG	Y/N	
>55/ C4591001 1142 11421073	VASC	Aortic aneurysm/ Ascending Aortic Aneurysm#	2	04JAN2021	126/C	4	No	O	NA/TCN	RG	Y/N	
>55/ C4591001 1142 11421215	MUSC	Spondylolisthesis/ Worsening of spondylolisthesis	2	01JAN2021	92/C	3	No	O	NA	N	Y/N	
>55/ C4591001 1142 11421247	CARD	Ventricular arrhythmia/ Ventricular arrhythmias	2	14OCT2020	1/8	3	Yes		NA/TC	R (21OCT2020)	Y/N	
>55/ C4591001 1145 11451055	CARD	Atrial fibrillation/ atrial fibrillation	2	12DEC2020	87/2	3	No	O	NA/TC	R (13DEC2020)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1145 11451056	CARD	Tachycardia/ tachycardia	2	07OCT2020	21/2	3	No	O	NA	R (08OCT2020)	Y/N	
>55/ C4591001 1146 11461015	NERV	Transient ischaemic attack/ Transient Ischemic Attack#	3	11JAN2021	6/2	2	No	O	NA	R (12JAN2021)	Y/N	
>55/ C4591001 1146 11461109	CARD	Coronary artery occlusion/ Mid Left Anterior Descending Coronary Artery Occlusion#	2	20JAN2021	128/1	2	No	CND	NA/TCN	R (20JAN2021)	Y/N	
>55/ C4591001 1146 11461152	RESP	Chronic obstructive pulmonary disease/ Chronic Obstructive Pulmonary Disease with acute exacerbation#	2	06FEB2021	144/7	3	No	O	NA/TC/TCN	R (12FEB2021)	Y/N	
>55/ C4591001 1146 11461161	RESP	Interstitial lung disease/ Interstitial Pneumonitis	1	09SEP2020	10/1	2	No	O	NA	R (09SEP2020)	Y/N	
>55/ C4591001 1146 11461181	METAB	Hyperglycaemia/ Hyperglycemia	2	11JAN2021	113/3	3	No	O	NA	R (13JAN2021)	Y/N	
>55/ C4591001 1146 11461191	INFEC	Pneumonia/ Pneumonia#	4	17FEB2021	3/5	3	No	O	NA	R (21FEB2021)	Y/N	
>55/ C4591001	RESP	Pulmonary embolism/ Pulmonary Emboli	2	08NOV2020	26/8	2	No	O	NA/TC	R (15NOV2020)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1146 11461264 >55/ C4591001 1147 11471230	INFEC	COVID-19/ COVID-19	2	29JAN2021	120/9	4	No	O	NA/TC/TCN	R (06FEB2021)	Y/N	
	RESP	Acute respiratory failure/ Acute hypoxemic respiratory failure	2	29JAN2021	120/9	4	No	O	NA/TC/TCN	R (06FEB2021)	Y/N	
>55/ C4591001 1147 11471239	REPRO	Ovarian mass/ Ovarian Mass	1	21SEP2020	12/C	2	No	O	NA/TCN	RG	Y/N	
>55/ C4591001 1149 11491239	GENRL	Chest pain/ Chest pain (cocaine induce)	1	15JAN2021	123/2	1	No	O	NA	R (16JAN2021)	Y/N	
	GENRL	Drug withdrawal syndrome/ Opioid dependence withdrawal	1	21JAN2021	129/6	4	No	O	NA	R (26JAN2021)	Y/N	
>55/ C4591001 1149 11491313	INJ&P	Head injury/ Acute Trauma Head Injury	2	30OCT2020	16/5	3	No	O	NA	R (03NOV2020)	Y/N	
	NERV	Cervicogenic headache/ Cervicogenic headache	2	30OCT2020	16/5	3	No	O	NA	R (03NOV2020)	Y/N	
>55/ C4591001 1152 11521095	PSYCH	Bipolar disorder/ worsening of bipolar disorder	2	29OCT2020	50/9	3	No	O	NA/TC	R (06NOV2020)	Y/N	
	PSYCH	Bipolar disorder/ Worsening of Bipolar Disorder#	4	13MAR2021	16/C	3	No	O	NA	RG	Y/N	



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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1152 11521260	NEOPL	Malignant melanoma/ malignant melanoma	1	04SEP2020	5/35	3	No	O	NA/TC/TCN	R (08OCT2020)	Y/N	
>55/ C4591001 1152 11521411	CARD	Myocardial infarction/ Myocardial Infarction	2	04FEB2021	129/C	4	No	O	NA/TC/TCN	RG	Y/N	
>55/ C4591001 1152 11521497	INFEC	Shigella sepsis/ sepsis related to Shigella infection	1	26OCT2020	20/17	4	No	O	NA/TC/TCN/W	F (11NOV2020)	Y/N	
>55/ C4591001 1156 11561001	INJ&P	Facial bones fracture/ FRACTURE OF ROOF OF RIGHT ORBITAL (GRADE 3)	2	06OCT2020	29/70	3	No	O	NA/TC	R (14DEC2020)	Y/N	
		Traumatic intracranial haemorrhage/ TRAUMATIC INTRACRANIAL HEMORRHAGE	2	06OCT2020	29/150	3	No	O	NA/TC	R (04MAR2021)	Y/N	
	NERV	Subarachnoid haemorrhage/ SUBARACHNOID HEMORRHAGE	2	06OCT2020	29/12	4	No	O	NA/TC	R (17OCT2020)	Y/N	
>55/ C4591001 1156 11561160†	INJ&P	Road traffic accident/ MOTOR VEHICLE ACCIDENT	2	24DEC2020	74/1	4	No	O	NA/W	F (24DEC2020)	Y/N	
>55/ C4591001 1157 11571134	NERV	Transient ischaemic attack/ Suspected Transient Ischemic Attack	2	27OCT2020	34/2	3	No	O	NA/TC	R (28OCT2020)	Y/N	
>55/ C4591001	INFEC	Pneumonia/ pneumonia	2	03SEP2020	2/11	3	No	O	NA/TC	R (13SEP2020)	Y/N	

## 16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1162 11621059 >55/ C4591001	CARD	Myocardial infarction/ myocardial infarction	2	10NOV2020	47/3	2	No	O	NA/TC/TCN	R (12NOV2020)	Y/N
1162 11621276 >55/ C4591001	VASC	Arteriosclerosis/ Atherosclerotic Disease	1	13SEP2020	4/1	4	No	O	NA/W	F (13SEP2020)	Y/N
1162 11621327 >55/ C4591001	CONG	Hypertrophic cardiomyopathy/ Hypertrophic cardiomyopathy#	4	08MAR2021	42/C	2	No	O	NA/TC	N	Y/N
1167 11671069 >55/ C4591001	INJ&P	Brain contusion/ contusion of the frontal lobe	2	28NOV2020	75/26	2	No	O	NA/TC	R (23DEC2020)	Y/N
1167 11671077 >55/ C4591001	CARD	Angina unstable/ Unstable Angina Pectoris	2	20OCT2020	34/1	2	No	O	NA/TC/TCN	R (20OCT2020)	Y/N
1167 11671085 >55/ C4591001	VASC	Aortic rupture/ Aortic Rupture	2	18NOV2020	65/1	4	No	O	NA/W	F (18NOV2020)	Y/N
1168 11681083 >55/ C4591001	CARD	Coronary artery disease/ Newly Diagnosed Coronary Artery Disease	2	01OCT2020	16/78	3	No	O	NA/TC/TCN	R (17DEC2020)	Y/N
1170 11701090											

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1170 11701217	BLOOD	Neutropenia/ Neutropenia	2	01OCT2020	3/32	3	No	O	NA/TC	R (01NOV2020)	Y/N	
		Thrombocytopenia/ Thrombocytopenia	2	01OCT2020	3/32	2	No	O	NA	R (01NOV2020)	Y/N	
	INFEC	Cellulitis/ Cellulitis of left lower leg	2	01OCT2020	3/32	3	No	O	NA/TC/TCN	R (01NOV2020)	Y/N	
>55/ C4591001 1171 11711045	GASTR	Intestinal ulcer perforation/ Perforated Intestinal marginated Ulcer#	3	31JAN2021	13/1	3	No	O	NA/TCN	R (31JAN2021)	Y/N	
>55/ C4591001 1174 11741042	RENAL	Nephrolithiasis/ nephrolithiasis	1	02OCT2020	17/5	3	No	O	NA/TC/TCN	R (06OCT2020)	Y/N	
>55/ C4591001 1177 11771204	NEOPL	Bladder cancer/ Bladder Cancer	2	24OCT2020	34/C	3	No	O	NA/TC/TCN	RG	Y/N	
>55/ C4591001 1177 11771317	NEOPL	Breast cancer stage I/ Breast Cancer, Stage 1	2	30NOV2020	62/C	2	No	O	NA/TCN	RG	Y/N	
>55/ C4591001 1178 11781012	MUSC	Osteoarthritis/ worsening of osteoarthritis, right hip	1	08SEP2020	16/108	3	No	O	NA/TCN	R (24DEC2020)	Y/N	
>55/ C4591001	NERV	Transient global amnesia/ transient global amnesia	2	10OCT2020	26/1	3	No	O	NA	R (10OCT2020)	Y/N	

## 16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1178 11781015 >55/ C4591001 1178 11781025	RENAL	Nephrolithiasis/ kidney stones	2	19SEP2020	4/5	3	No	O	NA/TC	R (23SEP2020)	Y/N
1178 11781025 >55/ C4591001 1178 11781048	INFEC	Pyelonephritis/ Pyelonephritis	2	03OCT2020	18/28	2	No	O	NA/TC	R (30OCT2020)	Y/N
1178 11781048 >55/ C4591001 1178 11781122	GASTR	Salivary gland calculus/ Sialolithiasis	1	20SEP2020	21/54	2	No	O	NA/TC	R (12NOV2020)	Y/N
1178 11781122 >55/ C4591001 1178 11781138	INFEC	Post procedural infection/ Post operative infection (sialolithiasis removal)	2	18NOV2020	59/12	3	No	O	NA/TC	R (29NOV2020)	Y/N
1178 11781122 >55/ C4591001 1178 11781167	CARD	Atrial fibrillation/ worsening of paroxysmal atrial fibrillation	2	14JAN2021	109/22	2	No	O	NA/TCN	R (04FEB2021)	Y/N
1178 11781138 >55/ C4591001 1178 11781167	GASTR	Intestinal obstruction/ intestinal obstruction#	3	09FEB2021	22/11	3	No	O	NA	R (19FEB2021)	Y/N
1178 11781138 >55/ C4591001 1178 11781167	CARD	Myocardial infarction/ Myocardial infarction	2	08OCT2020	10/12	3	No	O	NA	R (19OCT2020)	Y/N
1178 11781167 >55/ C4591001 1178 11781167	HEPAT	Cholecystitis/ cholecystitis	2	09OCT2020	5/4	3	No	O	NA/TC/TCN	R (12OCT2020)	Y/N

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1178 11781287	RENAL	Nephrolithiasis/ Nephrolithiasis#	2	28FEB2021	125/3	2	No	O	NA	R (02MAR2021)	Y/N	
>55/ C4591001 1178 11781293	GASTR	Small intestinal obstruction/ small bowel obstruction	2	14DEC2020	48/4	3	No	O	NA	R (17DEC2020)	Y/N	
>55/ C4591001 1195 11951006	NEOPL	Adenocarcinoma pancreas/ Adenocarcinoma Pancreas	2	11DEC2020	39/C	2	No	O	NA	RG	Y/N	
	GENRL	Impaired healing/ post operative wound healing disturbance#	2	11FEB2021	101/6	2	No	O	NA	R (16FEB2021)	Y/N	
>55/ C4591001 1195 11951014	MUSC	Osteoarthritis/ rhisarthrosis thumb right	2	17NOV2020	13/90	2	No	O	NA	R (14FEB2021)	Y/N	
>55/ C4591001 1195 11951059	CARD	Arrhythmia/ absolute arrhythmia#	4	25FEB2021	8/C	2	No	O	NA	RG	Y/N	
>55/ C4591001 1195 11951131	GASTR	Umbilical hernia/ umbilical hernia	2	24NOV2020	18/10	1	No	O	NA	R (03DEC2020)	Y/N	
>55/ C4591001 1195 11951132	NEOPL	Lymphoma/ Lymphoma	2	30DEC2020	54/63	2	No	O	NA	R (02MAR2021)	Y/N	

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>55/ C4591001 1197 11971097	CARD	Acute myocardial infarction/ Acute Posterior Myocardial Infarction	2	03JAN2021	58/6	4	No	O	NA/TC/TCN	R (08JAN2021)	Y/N	
>55/ C4591001 1207 12071055	INFEC	Pneumonia bacterial/ Bacterial Pneumonia#	2	05FEB2021	72/5	4	No	O	NA/W	F (09FEB2021)	Y/N	
>55/ C4591001 1209 12091014	INFEC	COVID-19/ COVID-19 Illness	2	18DEC2020	25/6	1	No	O	NA/TC	R (23DEC2020)	Y/N	
>55/ C4591001 1213 12131049	VASC	Hypertensive crisis/ Hypertensive crisis	1	24NOV2020	19/2	3	No	O	NA/TC	R (25NOV2020)	Y/N	
>55/ C4591001 1223 12231058	RESP	Dyspnoea/ Shortness of breath	2	03FEB2021	134/10	2	No	O	NA/TC/TCN	RS (12FEB2021)	Y/N	
>55/ C4591001 1223 12231159	NEOPL	Adenocarcinoma pancreas/ Pancreatic Adenocarcinoma	2	05NOV2020	36/C	3	No	O	NA/TC/TCN	N	Y/N	
	GASTR	Enterocolitis/ Enterocolitis	2	15JAN2021	107/C	3	No	CD	NA/TC	N	Y/N	
>55/ C4591001 1223 12231182	INFEC	Diverticulitis/ progression of diverticulitis	1	29SEP2020	14/C	3	No	O	NA/TC	RG	Y/N	

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	INFEC	Abscess intestinal/ Pericolonic Abscess	2	13OCT2020	5/C	4	No	O	NA/TC/TCN	N	Y/N	
>55/ C4591001 1226 12261477	INFEC	Appendicitis/ Appendicitis	2	12JAN2021	116/10	4	No	O	NA/TC/TCN	R (21JAN2021)	Y/N	
>55/ C4591001 1226 12262004	GASTR	Rectal haemorrhage/ Anorectal hemorrhage#	2	20FEB2021	122/7	4	No	O	NA/TC/TCN	R (26FEB2021)	Y/N	
>55/ C4591001 1226 12262240	INJ&P	Femur fracture/ Fracture of the right femur	1	24OCT2020	9/6	3	No	O	NA/TCN	R (29OCT2020)	Y/N	
>55/ C4591001 1226 12262253	RENAL	Nephrolithiasis/ Nephrolithiasis	2	01JAN2021	59/3	4	No	O	NA/TCN	R (03JAN2021)	Y/N	
>55/ C4591001 1230 12301025	NEOPL	Penile neoplasm/ Penile Intra Epithelial Neoplasia	2	06NOV2020	22/C	3	No	O	NA	N	Y/N	
>55/ C4591001 1231 12311182	NERV	Ischaemic stroke/ Ischemic Stroke	2	07DEC2020	95/35	3	No	O	NA/TC/TCN	RS (10JAN2021)	Y/N	
>55/ C4591001 1231 12311379	NEOPL	Prostate cancer/ Prostate adenocarcinoma.	2	20NOV2020	75/C	2	No	O	NA/TC/TCN	N	Y/N	

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>55/ C4591001 1231 12311510	NEOPL	Carcinoid tumour of the stomach/ Well-differentiated multifocal neuroendocrine tumor of the stomach	2	02JAN2021	118/C	3	No	O	NA/TC/TCN	N	Y/N	
	HEPAT	Portosplenomesenteric venous thrombosis/ Portosplenomesenteric venous thrombosis#	2	03MAR2021	178/C	3	No	O	NA/TC	N	Y/N	
>55/ C4591001 1231 12311579	GASTR	Gastritis/ Acute gastritis	2	17OCT2020	41/18	3	No	O	NA/TC/TCN	R (03NOV2020)	Y/N	
>55/ C4591001 1231 12311946	NERV	Syncope/ Syncope	2	11SEP2020	4/2	3	No	O	NA/TC	R (12SEP2020)	Y/N	
>55/ C4591001 1231 12312073	SURG	Finger amputation/ Right index finger partial distal phalanx amputation	2	05DEC2020	88/75	3	No	O	NA/TC/TCN	RS (17FEB2021)	Y/N	
>55/ C4591001 1231 12312162	INJ&P	Humerus fracture/ Right humerus fracture	2	26SEP2020	20/111	3	No	O	NA/TC/TCN	RS (14JAN2021)	Y/N	
>55/ C4591001 1231 12312722	CARD	Acute myocardial infarction/ acute myocardial infarction with ST elevation	2	25NOV2020	79/6	4	No	O	NA/TC/TCN	R (30NOV2020)	Y/N	
>55/ C4591001	INJ&P	Humerus fracture/ Right humerus fracture#	2	20JAN2021	130/38	2	No	O	NA/TC/TCN	R (26FEB2021)	Y/N	



## 16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12312749 >55/ C4591001	INJ&P	Wrist fracture/ Right wrist fracture	2	02FEB2021	145/26	2	No	O	NA/TCN	R (27FEB2021)	Y/N
1231 12312885 >55/ C4591001	NEOPL	Polycythaemia vera/ Polycythemia vera	2	15DEC2020	96/C	2	No	O	NA/TC	N	Y/N
1231 12312893 >55/ C4591001	CARD	Atrial flutter/ Atrial Flutter#	2	19FEB2021	162/C	2	No	O	NA/TC	N	Y/N
1231 12313610 >55/ C4591001	RESP	Pulmonary mass/ Right pulmonary nodule	2	24SEP2020	10/C	3	No	O	NA/TCN	UNK	Y/N
1231 12313621 >55/ C4591001	RESP	Pneumonitis/ Non-specific Pneumonitis	2	29SEP2020	17/12	2	No	O	NA	R (10OCT2020)	Y/N
1231 12313674 >55/ C4591001	INFEC	Extradural abscess/ Epidural abscess	2	01DEC2020	77/51	2	No	O	NA/TC/TCN	R (20JAN2021)	Y/N
1231 12313730		Staphylococcal sepsis/ Oxacillin sensitive Staphylococcus aureus sepsis	2	01DEC2020	77/51	3	No	O	NA/TC/TCN	R (20JAN2021)	Y/N

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>55/ C4591001 1231 12313753	CARD	Atrial fibrillation/ Atrial fibrillation#	3	25FEB2021	7/C	2	No	O	NA/TC	RG	Y/N	
>55/ C4591001 1231 12313783	MUSC	Intervertebral disc protrusion/ Worsening lumbar disc herniation	1	10SEP2020	18/64	3	No	O	NA/TC/TCN	R (12NOV2020)	Y/N	
>55/ C4591001 1231 12313894	CONG	Congenital bladder neck obstruction/ primary bladder neck obstruction	2	15OCT2020	31/148	2	No	O	NA/TC/TCN	R (11MAR2021)	Y/N	
>55/ C4591001 1231 12313972	NERV	Haemorrhagic stroke/ Hemorrhagic stroke	2	27SEP2020	15/2	4	No	O	NA/TC/W	F (28SEP2020)	Y/N	
>55/ C4591001 1231 12314001	CARD	Angina unstable/ Unstable angina	2	08NOV2020	55/5	3	No	O	NA/TC/TCN	R (12NOV2020)	Y/N	
>55/ C4591001 1231 12314035	CARD	Angina pectoris/ Angina Pectoris	2	20SEP2020	7/5	3	No	O	NA/TC/TCN	R (24SEP2020)	Y/N	
>55/ C4591001 1231 12314041	EYE	Retinal tear/ Right eye retinal tear#	2	03MAR2021	172/C	2	No	O	NA/TC/TCN	RG	Y/N	
>55/ C4591001	INFEC	Appendicitis/ Accute appendictis	2	06JAN2021	115/18	3	No	O	NA/TC/TCN	R (23JAN2021)	Y/N	

## 16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12314091 >55/ C4591001	MUSC	Osteoarthritis/ Worsening of left hip osteoarthritis	2	23JAN2021	132/C	3	No	O	NA/TC/TCN	N	Y/N
1231 12314197 >55/ C4591001	INFEC	Appendicitis/ Acute Appendicitis	1	05SEP2020	11/5	3	No	O	NA/TC/TCN	R (09SEP2020)	Y/N
1231 12314216 >55/ C4591001	NEOPL	Non-Hodgkin's lymphoma recurrent/ Recurrence of Non-Hodgkin Lymphoma	2	20NOV2020	68/C	2	No	O	NA	N	Y/N
1231 12314233 >55/ C4591001	CARD	Coronary artery disease/ Coronary Cardiopathy	2	04DEC2020	81/57	2	No	O	NA/TC/TCN	R (29JAN2021)	Y/N
1231 12314411 >55/ C4591001	INFEC	Pneumonia/ Community-acquired pneumonia	2	12NOV2020	57/6	3	No	O	NA/TC	R (17NOV2020)	Y/N
1231 12314414 >55/ C4591001	INFEC	Penile infection/ Penile infection	2	22JAN2021	130/C	3	No	O	NA/TC/TCN	RG	Y/N
1231 12314465 >55/ C4591001	NEOPL	Gastric cancer/ Signetringcellgastriccarcinoma(SRCGC)	2	29JAN2021	136/C	3	No	O	NA	N	Y/N
1231 12314690											

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>55/ C4591001 1231 12314759	NERV	Amyotrophic lateral sclerosis/ potential amyotrophic lateral sclerosis	2	10OCT2020	25/C	2	No	O	NA/TC/TCN	N	Y/N	
>55/ C4591001 1231 12314898	INFEC	Pneumonia/ community acquired pneumonia	2	03OCT2020	18/13	4	No	O	NA/TC/TCN	R (15OCT2020)	Y/N	
>55/ C4591001 1231 12315081	INFEC	Pyelonephritis/ left pyelonephritis	2	04DEC2020	79/19	2	No	O	NA/TC	R (22DEC2020)	Y/N	
>55/ C4591001 1231 12315126	NEOPL	Squamous cell carcinoma/ In situ squamous cell carcinoma	2	15JAN2021	121/C	2	No	O	NA	N	Y/N	
>55/ C4591001 1231 12315193	CARD	Arteriosclerosis coronary artery/ Worsening of Coronary atherosclerosis	2	02DEC2020	77/43	2	No	O	NA/TCN	R (13JAN2021)	Y/N	
>55/ C4591001 1231 12315301	METAB	Hyperglycaemia/ Hyperglycemia	2	27NOV2020	72/9	2	No	O	NA/TC/TCN	R (05DEC2020)	Y/N	
>55/ C4591001 1231 12315324	INFEC	COVID-19/ Severe Covid-19 illness	2	25DEC2020	99/38	4	No	O	NA/TC/TCN	F (31JAN2021)	Y/N	
		Septic shock/ Septic shock	2	25DEC2020	99/38	4	No	O	NA/TC/TCN/W	F (31JAN2021)	Y/N	

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>55/ C4591001 1231 12315404	NEOPL	Transitional cell carcinoma/ High grade infiltrating urothelial carcinoma	2	29DEC2020	83/C	3	No	O	NA/TC	N	Y/N	
>55/ C4591001 1231 12315520	EYE	Ophthalmic vein thrombosis/ Venous thrombosis of the right eye	2	05NOV2020	48/C	3	No	O	NA/TC	RG	Y/N	
>55/ C4591001 1231 12315579	INJ&P	Patella fracture/ Left Patella fracture	2	30JAN2021	134/C	3	No	O	NA/TC/TCN	N	Y/N	
>55/ C4591001 1231 12315632	CARD	Pericarditis/ Pericarditis	2	17OCT2020	29/C	2	No	O	NA/TC/TCN	N	Y/N	
>55/ C4591001 1231 12315653	NERV	Ischaemic stroke/ Ischemic stroke	2	12OCT2020	24/5	2	No	O	NA/TC	R (16OCT2020)	Y/N	
>55/ C4591001 1231 12315671	NEOPL	Transitional cell carcinoma/ High-grade urothelial carcinoma	2	11NOV2020	54/C	3	No	O	NA/TC/TCN	N	Y/N	
>55/ C4591001 1235 12351205	NEOPL	Oropharyngeal squamous cell carcinoma/ squamous cell carcinoma of oropharynx	1	23OCT2020	4/C	3	No	O	NA/TC/TCN	N	Y/N	
>55/ C4591001	GASTR	Diverticulum intestinal/ Diverticular disease of the colon	2	16DEC2020	106/C	4	No	O	NA/TC/TCN	RG	Y/N	

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1241 12411067	GASTR	Intestinal mass/ Mass in sigmoid#	2	08FEB2021	160/2	4	No	O	NA/TCN	RS (09FEB2021)	Y/N	
>55/ C4591001 1241 12411643	HEPAT	Cholecystitis acute/ Acute cholecystitis	2	24OCT2020	31/5	3	No	O	NA/TC	R (28OCT2020)	Y/N	
		Cholelithiasis/ Cholelithiasis	2	24OCT2020	31/5	3	No	O	NA/TC	R (28OCT2020)	Y/N	
>55/ C4591001 1241 12411825	INFEC	Pyelonephritis acute/ ACUTE PYELONEPHRITIS	2	02NOV2020	26/15	2	No	O	NA/TC	R (16NOV2020)	Y/N	
>55/ C4591001 1241 12411829	GASTR	Gastrointestinal haemorrhage/ High digestive bleeding#	4	12MAR2021	22/C	4	No	O	NA/W	N	Y/N	
>55/ C4591001 1241 12412191	PSYCH	Disorientation/ Disorientation to clarify	2	09NOV2020	4/4	3	No	O	NA/TC	R (12NOV2020)	Y/N	
>55/ C4591001 1241 12412263	INFEC	Respiratory tract infection viral/ Respiratory Tract Viral infection	2	10DEC2020	36/9	2	No	O	NA/TC	R (18DEC2020)	Y/N	
>55/ C4591001 1246 12461035	GENRL	Non-cardiac chest pain/ REFERRED NON-CARDIAC CHEST PAIN	2	10NOV2020	22/3	3	No	O	NA/TCN	R (12NOV2020)	Y/N	

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>55/ C4591001 1247 12471135	NERV	Cerebral infarction/ Left Middle Cerebral Artery Infarct	1	21OCT2020	22/C	3	No	O	P/TC/TCN	N	Y/N	
>55/ C4591001 1248 12481120	CARD	Cardiac failure acute/ Acute Heart Failure	1	23SEP2020	13/C	3	No	O	NA	RG	Y/N	
>55/ C4591001 1248 12481163	INFEC	Brain abscess/ Brain abscess	2	10OCT2020	6/C	4	No	O	NA/TCN	RG	Y/N	
>55/ C4591001 1251 12511029	INJ&P	Ankle fracture/ Shattered Ankle/Tibia#	2	24FEB2021	154/2	3	No	O	NA/TC/TCN	RS (25FEB2021)	Y/N	
>55/ C4591001 1251 12511050	VASC	Hypertension/ exacerbation of hypertension	1	04SEP2020	11/C	3	No	O	NA	RG	Y/N	
>55/ C4591001 1251 12511072	NEOPL	Uterine cancer/ Uterine Cancer	2	28JAN2021	134/1	4	No	O	NA/TC/TCN	R (28JAN2021)	Y/N	
>55/ C4591001 1251 12511145	INJ&P	Spinal fracture/ Broken Vertebrae#	3	08MAR2021	13/3	3	No	O	NA/TCN	R (10MAR2021)	Y/N	
>55/ C4591001	MUSC	Arthralgia/ increased pain with activities-right knee	2	02DEC2020	22/C	4	No	O	NA/TC/TCN	RG	Y/N	

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1251 12511250 >55/ C4591001 1252 12521010	INFEC	COVID-19 pneumonia/ Pneumonia due to COVID-19	2	25DEC2020	109/2	4	No	O	NA/TC/W	F (26DEC2020)	Y/N	
>55/ C4591001 1252 12521011	RESP	Chronic obstructive pulmonary disease/ COPD exacerbation	2	06JAN2021	120/5	3	No	O	NA/TC	R (10JAN2021)	Y/N	
>55/ C4591001 1254 12541014	INFEC	Clostridium difficile colitis/ Clostridium Difficile Colitis#	2	21JAN2021	126/12	4	No	O	NA/TC	R (01FEB2021)	Y/N	
>55/ C4591001 1260 12601035	INJ&P	Traumatic intracranial haemorrhage/ traumatic subarachnoid hemorrhage#	3	31JAN2021	19/3	3	No	O	NA/TC	R (02FEB2021)	Y/N	
>55/ C4591001 1260 12601037	GASTR	Small intestinal obstruction/ small bowel obstruction	2	29OCT2020	38/8	3	No	O	NA/TC/TCN	R (05NOV2020)	Y/N	
>55/ C4591001 1260 12601069	INFEC	Appendicitis/ acute appendicitis	2	05OCT2020	12/3	2	No	O	NA/TC/TCN	R (07OCT2020)	Y/N	
>55/ C4591001 1264 12641133	CARD	Myocardial infarction/ Myocardial Infarction#	2	20FEB2021	146/9	4	No	O	NA/TC	RG (28FEB2021)	Y/N	



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>55/ C4591001 1264 12641229	RESP	Pulmonary embolism/ Pulmonary embolism	2	07DEC2020	22/C	4	No	O	NA/TC	RG	Y/N	
>55/ C4591001 1270 12701057	RESP	Pulmonary embolism/ Pulmonary embolism	1	23SEP2020	21/C	3	No	O	P/TC	RG	Y/N	
>55/ C4591001 4444 44441145	INFEC	Complicated appendicitis/ Acute gangrenous appendicitis	2	12DEC2020	61/24	3	No	O	NA/TC/TCN	R (04JAN2021)	Y/N	
>55/ C4591001 4444 44441161	CARD	Coronary artery disease/ Coronary heart disease	1	01OCT2020	11/140	2	No	O	NA/TC/TCN	R (17FEB2021)	Y/N	
>55/ C4591001 4444 44441371	INFEC	COVID-19/ Covid-19 Illness	2	15JAN2021	95/20	3	No	O	NA/TC	R (03FEB2021)	Y/N	
>55/ C4591001 4444 44441385	VASC	Aortic stenosis/ Severe Aortic Stenosis	2	27JAN2021	107/42	3	No	O	NA/TC/TCN	R (09MAR2021)	Y/N	
	CARD	Ischaemic cardiomyopathy/ Ischemic cardiomyopathy worsening#	3	05FEB2021	3/33	3	No	O	NA/TC/TCN	R (09MAR2021)	Y/N	
>55/ C4591001 4444 44441422	NEOPL	Adenocarcinoma of colon/ Poorly differentiated colon adenocarcinoma	2	20JAN2021	101/C	3	No	O	NA/TC/TCN	N	Y/N	

## 16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 4444 44441470	INFEC	Pneumonia/ Community-acquired pneumonia	2	29JAN2021	109/33	3	No	O	NA/TC	R (02MAR2021)	Y/N
>55/ C4591001 4444 44441473	HEPAT	Cholelithiasis/ Worsening of biliary lithiasis	2	02NOV2020	21/122	3	No	O	NA/TC/TCN	R (03MAR2021)	Y/N
>55/ C4591001 4444 44441595	VASC	Hypertensive emergency/ Hypertensive emergency	2	28JAN2021	107/8	3	No	O	NA/TC	R (04FEB2021)	Y/N
	METAB	Hyponatraemia/ Hyponatremia	2	31JAN2021	110/5	2	No	O	NA/TCN	R (04FEB2021)	Y/N
>55/ C4591001 4444 44441665	GENRL	Pelvic mass/ Pelvic mass#	3	06FEB2021	2/C	2	No	O	NA/TC/TCN	N	Y/N
>55/ C4591001 4444 44441873	HEPAT	Cholelithiasis/ Gallstones (gallbladder stones)	2	13DEC2020	60/26	4	No	O	NA/TCN	R (07JAN2021)	Y/N
	GASTR	Pancreatitis acute/ Acute pancreatitis	2	16DEC2020	63/23	3	No	O	NA/TC/TCN	R (07JAN2021)	Y/N

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v23.1) coding dictionary applied.

Note: ^ = Phase 1 subjects, † = human immunodeficiency virus (HIV)-positive subject, # = AE occurring on or after unblinding.

a. Relative day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

c. Vaccine related (Vax Rel): relationship to investigational vaccine as assessed by the investigator.

### 16.2.7.5 Listing of Serious Adverse Events – All Subjects $\geq$ 16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Cause of Vax Rel <sup>c</sup>	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
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PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (01:37)  
 (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adae\_l002\_sae\_all\_all

16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1012 10121163	GENRL	Injection site dermatitis/ LEFT UPPER ARM DERMATITIS AT INJECTION SITE	1	11SEP2020	3/C	2	Yes		P/W	RG	N/N
16-55/ C4591001 1015 10151134	EAR	Vertigo/ Worsening and continuing episode of Vertigo	1	28AUG2020	2/116	2	Yes		P	R (21DEC2020)	N/N
16-55/ C4591001 1016 10161087	GENRL	Injection site swelling/ injection site swelling	1	10AUG2020	1/10	3	Yes		P/TC	R (19AUG2020)	N/N
16-55/ C4591001 1021 10211127	CARD	Cardiac failure congestive/ Acute on Chronic Combined Systolic and Diastolic Congestive Heart Failure	2	30NOV2020	69/20	4	No	O	NA/TC/W	F (19DEC2020)	Y/N
16-55/ C4591001 1027 10271105	IMMUN	Drug hypersensitivity/ Allergic Reaction to investigational product	1	29AUG2020	2/14	2	Yes		P/TC	R (11SEP2020)	N/N
16-55/ C4591001 1028 10281003	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	29NOV2020	87/C		Yes		NA/W	N	N/N
16-55/ C4591001 1044 10441163	GENRL	Injection site pain/ Injection site pain#	3	04MAR2021	1/1	1	Yes		NA/TC/W	R (04MAR2021)	N/N
16-55/ C4591001	GASTR	Dysphagia/ Dysphagia	1	AUG2020	1/C	1	No	O	P	N	N/N

16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1055 10551145 16-55/ C4591001 1079 10791004	NEOPL	Adenocarcinoma gastric/ INFILTRATING, POORLY DIFFERENTIATED ADENOCARCINOMA - STOMACH	1	20AUG2020	23/C	3	No	O	P/W	N	Y/N	
16-55/ C4591001 1081 10811194	CARD	Myocardial infarction/ Myocardial Infarction	2	04NOV2020	37/1	4	No	O	NA/W	F (04NOV2020)	Y/N	
16-55/ C4591001 1082 10821149	NEOPL	Malignant melanoma/ Malignant Melanoma (etiology unknown)	2	24NOV2020	63/C	3	No	O	NA/W	N	Y/N	
16-55/ C4591001 1083 10831029	CARD	Atrial fibrillation/ Paroxysmal Atrial fibrillation with rapid ventricular response	1	23AUG2020	20/17	3	No	O	P/TC/TCN	R (08SEP2020)	Y/N	
16-55/ C4591001 1083 10831060	GASTR	Diverticular perforation/ Ruptured diverticulum	1	14AUG2020	9/11	4	No	O	P/TC/TCN	R (24AUG2020)	Y/N	
16-55/ C4591001 1085 10851129	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	23DEC2020	105/C		No	O	NA/W	N	N/N	
16-55/ C4591001 1087 10871354	MUSC	Myalgia/ Myalgia	1	11SEP2020	4/C	1	Yes		P/W	N	N/N	

16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1087 10871557	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	24OCT2020	11/C		No	O	P	UNK	N/N
16-55/ C4591001 1089 10891289	HEPAT	Acute hepatic failure/ Acute Liver Failure#	2	19DEC2020	79/C	4	No	O	NA/W	N	Y/N
16-55/ C4591001 1090 10901140	GENRL	Injection site pain/ Injection site pain-right arm#	4	18FEB2021	1/3	2	Yes		NA/TC/W	R (20FEB2021)	N/N
16-55/ C4591001 1090 10901507	SKIN	Urticaria/ Hives, upper chest	1	19OCT2020	4/4	2	Yes		P/TC	R (22OCT2020)	N/N
16-55/ C4591001 1091 10911297	GENRL	Fatigue/ fatigue#	3	22FEB2021	1/5	2	Yes		NA/W	R (26FEB2021)	N/N
16-55/ C4591001 1093 10931058	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY*		25AUG2020	1/C		No	O	P	UNK	N/N
16-55/ C4591001 1095 10951141	SKIN	Diabetic foot/ Diabetic Foot Ulcer R Foot	1	14SEP2020	20/C	1	No	O	P/TCN/W	N	N/N
16-55/ C4591001	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	14AUG2020	1/40		No	O	P	R (22SEP2020)	N/N

16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1096 10961031 16-55/ C4591001 1096 10961036	PSYCH	Depression suicidal/ worsening of depression with suicidal ideation	2	OCT2020	23/	3	No	O	P/TC	RS (14NOV2020)	Y/N	
16-55/ C4591001 1117 11171186	PSYCH	Suicide attempt/ SUICIDAL IDEATION WITH ATTEMPT	1	19OCT2020	14/8	3	No	O	P/TC/TCN	R (26OCT2020)	Y/N	
16-55/ C4591001 1120 11201266	NEOPL	Lung cancer metastatic/ Metastatic Lung cancer	2	04DEC2020	67/47	4	No	O	NA/TC/W	F (19JAN2021)	Y/N	
16-55/ C4591001 1122 11221026	GASTR	Vomiting/ vomiting*		11SEP2020	/1	1	No	O	NA/W	R (11SEP2020)	N/N	
	NERV	Presyncope/ pre-syncope*		11SEP2020	/1	1	No	O	NA/W	R (11SEP2020)	N/N	
16-55/ C4591001 1125 11251243	GENRL	Injection site pain/ Grade 3 Pain at Injection site	1	09DEC2020	2/1	3	Yes		P	R (09DEC2020)	N/N	
	NERV	Headache/ Grade 3 Headache	1	09DEC2020	2/1	3	Yes		P/TC	R (09DEC2020)	N/N	
16-55/ C4591001 1126 11261017	IMMUN	Allergy to vaccine/ VACCINE ALLERGIC REACTION#	3	07JAN2021	1/2	2	Yes		P/TC/TCN	R (08JAN2021)	N/Y	

16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1127 11271112	CARD	Cardio-respiratory arrest/ Cardiopulmonary arrest	2	04DEC2020	86/1	4	No	O	NA/W	F (04DEC2020)	Y/N	
16-55/ C4591001 1128 11281241	NEOPL	Breast cancer/ Breast Cancer	2	NOV2020	42/C	3	No	O	NA/TC/W	RG	N/N	
16-55/ C4591001 1129 11291260	IMMUN	Anaphylactoid reaction/ Anaphylactoid Reaction#	3	27JAN2021	3/1	4	Yes		P/TC	R (27JAN2021)	Y/N	
16-55/ C4591001 1134 11341153	EYE	Eye pain/ right eye pain	1	25AUG2020	2/28	2	Yes		P	R (21SEP2020)	N/N	
16-55/ C4591001 1134 11341174	NERV	Headache/ WORSENING HEADACHE	1	27AUG2020	2/8	2	Yes		P/TC	R (03SEP2020)	N/N	
16-55/ C4591001 1140 11401306	EYE	Visual impairment/ Change in Visual Perception	1	07NOV2020	17/3	3	No	O	P/W	R (09NOV2020)	Y/N	
	NERV	Amnesia/ short term memory loss	1	07NOV2020	17/4	1	No	O	P/TC/TCN	R (10NOV2020)	Y/N	
		Paraparesis/ Worsening of Chronic Spastic Paraparesis	1	07NOV2020	17/C	3	No	O	P/TC/TCN	N	N/N	



16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1152 11521085	GENRL	Death/ UNDETERMINED CAUSE OF DEATH	1	26AUG2020	8/1	4	No	O	P/W	F (26AUG2020)	Y/N	
16-55/ C4591001 1156 11561015	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY*		21AUG2020	1/C		No	O	P	UNK	N/N	
16-55/ C4591001 1156 11561124	INJ&P	Overdose/ MULTIPLE DRUG OVERDOSE	2	02NOV2020	32/1	4	No	O	NA/W	F (02NOV2020)	Y/N	
	RESP	Respiratory arrest/ RESPIRATORY ARREST	2	02NOV2020	32/1	4	No	O	NA/W	F (02NOV2020)	Y/N	
16-55/ C4591001 1163 11631059	IMMUN	Drug hypersensitivity/ Allergic Reaction to study investigational product	1	08AUG2020	2/18	2	Yes		P/TC	R (25AUG2020)	N/N	
16-55/ C4591001 1166 11661047	NERV	Dizziness/ Dizziness	1	31AUG2020	1/1	1	Yes		P	R (31AUG2020)	N/N	
16-55/ C4591001 1170 11701013	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	NOV2020	55/C		No	O	NA/W		N/N	
16-55/ C4591001 1171 11711023	SKIN	Urticaria/ Urticaria on forehead, posterior neck, bilateral posterior hands and bilateral plantar areas#	3	10FEB2021	2/7	2	Yes		P/TC	R (16FEB2021)	N/N	

16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	SKIN	Angioedema/ Angioedema - Forehead#	3	11FEB2021	3/6	1	Yes		P/TC	R (16FEB2021)	N/N
16-55/ C4591001 1178 11781107	BLOOD	Lymphadenopathy/ right axilla lymphadenopathy	1	16SEP2020	13/66	2	Yes		P/TC	R (20NOV2020)	Y/N
16-55/ C4591001 1205 12051028	INV	Blood pressure increased/ Increasing of systolic and diastolic blood pressure*		30OCT2020	/1	2	No	O	NA/W	R (30OCT2020)	N/N
16-55/ C4591001 1217 12171031	INJ&P	Exposure during pregnancy/ exposure during pregnancy	1	30OCT2020	1/C		No	O	P	UNK	N/N
16-55/ C4591001 1224 12241065	INV	Heart rate irregular/ Irregular Heart Rate	1	24AUG2020	1/18	2	Yes		P	R (10SEP2020)	N/N
16-55/ C4591001 1226 12261072	MUSC	Myalgia/ Muscle pain (shoulders and neck, on the right body side)	1	18AUG2020	8/C	2	Yes		P/TC/W	N	N/N
16-55/ C4591001 1229 12291083†	INFEC	COVID-19 pneumonia/ Covid 19 Pneumonia	2	01JAN2021	72/5	4	No	O	NA/W	F (05JAN2021)	Y/N
16-55/ C4591001 1230 12301045†	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	1	20OCT2020	22/C		No	O	P	UNK	N/N

16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311409	GASTR	Vomiting/ vomits*		15AUG2020	/1	1	No	O	P/TCN/W	R (15AUG2020)	N/N	
	NERV	Syncope/ Syncope*		15AUG2020	/1	2	No	O	P/TCN/W	R (15AUG2020)	N/N	
16-55/ C4591001 1231 12311926	NERV	Syncope/ Syncope*		18AUG2020	/1	2	No	O	NA/W	R (18AUG2020)	N/N	
16-55/ C4591001 1231 12312577	NEOPL	Metastases to central nervous system/ Brain metastasis	1	28AUG2020	9/C	2	No	O	P/TC	N	Y/N	
16-55/ C4591001 1231 12314987	CARD	Cardio-respiratory arrest/ Non-traumatic cardiorespiratory arrest	2	05DEC2020	81/2	4	No	O	NA/W	F (06DEC2020)	Y/N	
16-55/ C4591001 1231 12315429	GENRL	Injection site pain/ pain at injection site	1	30AUG2020	1/18	2	Yes		P/TC/W	R (16SEP2020)	N/Y	
16-55/ C4591001 1231 12315441	PSYCH	Depression/ Depressive syndrome	1	10SEP2020	12/137	3	No	O	P/TC	RS (24JAN2021)	N/N	
16-55/ C4591001 1232 12321175	VASC	Hypertension/ high blood pressure	1	25SEP2020	23/29	2	No	O	P	R (23OCT2020)	N/N	

16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1232 12321213	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	01OCT2020	23/C		No	O	P	UNK	N/N
16-55/ C4591001 1232 12321293	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	1	22OCT2020	22/C		No	O	P	RG	N/N
16-55/ C4591001 1232 12321299	VASC	Hypertension/ Hypertension*		06OCT2020	1/C	2	No	O	NA/W	UNK	N/N
16-55/ C4591001 1241 12411208	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy#	3	10FEB2021	6/C		No	O	P	UNK	N/N
16-55/ C4591001 1241 12411279	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	10SEP2020	23/35		No	O	P	R (14OCT2020)	N/N
16-55/ C4591001 1241 12411514	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy#	3	05FEB2021	10/C		No	O	P	UNK	N/N
16-55/ C4591001 1241 12411766	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy	1	17SEP2020	2/C		No	O	P	UNK	N/N
16-55/ C4591001	INJ&P	Maternal exposure during pregnancy/	2	21JAN2021	72/C		No	O	P	UNK	N/N

16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412369		Maternal exposure during pregnancy									
16-55/ C4591001	INJ&P	Maternal exposure during pregnancy/	3	12FEB2021	5/C		No	O	P	UNK	N/N
1241 12412411		Maternal exposure during pregnancy#									
16-55/ C4591001	SKIN	Urticaria/ Intermittent urticaria generalised.	1	07OCT2020	10/27	2	Yes		P/TC	R (02NOV2020)	N/N
1246 12461025											
16-55/ C4591001	NERV	Syncope/ vasovagal syncope*		20SEP2020	/1	2	No	O	NA/W	R (20SEP2020)	N/N
1248 12481218											
16-55/ C4591001	INJ&P	Maternal exposure during pregnancy/	1	12SEP2020	1/C		No	O	P	UNK	N/N
1254 12541142		Maternal Exposure During Pregnancy									
16-55/ C4591001	NERV	Headache/ headache#	4	18FEB2021	2/2	2	Yes		NA/TC/W	R (19FEB2021)	N/N
1254 12541189											
16-55/ C4591001	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	25SEP2020	1/C		No	O	P	UNK	N/N
4444 44441979											
16-55/ C4591001	PSYCH	Panic attack/ Worsening of panic attacks	1	15OCT2020	19/C	3	No	O	P/W	N	N/N
4444 44442319											

16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1005 10051214	GENRL	Facial pain/ FACIAL TENDERNESS	1	06SEP2020	4/11	2	No	O	P/TC	R (16SEP2020)	N/N	
		Swelling face/ FACIAL SWELLING	1	06SEP2020	4/11	2	No	O	P/TC	R (16SEP2020)	N/N	
>55/ C4591001 1006 10061020	CARD	Coronary artery occlusion/ CORONARY ARTERY OCCLUSION	1	25AUG2020	14/3	4	No	O	P/TC/TCN/W	R (27AUG2020)	Y/N	
>55/ C4591001 1007 10071101	CARD	Cardiac arrest/ Cardiac Arrest	2	18OCT2020	60/4	4	No	O	NA/W	F (21OCT2020)	Y/N	
>55/ C4591001 1007 10071347	CARD	Atrial fibrillation/ atrial fibrillation	1	25OCT2020	11/2	3	No	O	P/TC	R (26OCT2020)	Y/N	
>55/ C4591001 1008 10081667	NEOPL	Hepatic cancer/ liver cancer#	4	25FEB2021	23/C	3	No	O	NA/W	N	Y/N	
>55/ C4591001 1011 10111181	GASTR	Paraesthesia oral/ Tingling around the mouth	1	08OCT2020	1/1	1	Yes		P	R (08OCT2020)	N/N	
>55/ C4591001 1019 10191146	NEOPL	Biliary cancer metastatic/ Biliary Cancer Metastatic	2	27OCT2020	36/52	4	No	O	NA/W	F (17DEC2020)	Y/N	

16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1022 10221053	GENRL	Metastases to liver/ Metastases to Liver	2	27OCT2020	36/52	4	No	O	NA/W	F (17DEC2020)	Y/N	
		Chills/ Moderate Chills#	3	01FEB2021	1/3	2	Yes		P	R (03FEB2021)	N/N	
		Injection site pain/ Injection Site Pain#	3	01FEB2021	1/4	3	Yes		P	R (04FEB2021)	N/N	
		Myalgia/ Generalized Myalgias#	3	01FEB2021	1/3	2	Yes		P	R (03FEB2021)	N/N	
		Headache/ Moderate Headache#	3	01FEB2021	1/3	2	Yes		P	R (03FEB2021)	N/N	
>55/ C4591001 1027 10271191	INFEC	Diarrhoea/ Moderate Diarrhea#	3	04FEB2021	4/4	2	Yes		P	R (07FEB2021)	N/N	
		COVID-19/ COVID-19#	2	12JAN2021	103/33	4	No	O	NA/TC/TCN/W	F (13FEB2021)	Y/N	
		Acute respiratory failure/ Acute Hypoxic Respiratory Failure#	2	12JAN2021	103/33	4	No	O	NA/TC/TCN/W	F (13FEB2021)	Y/N	
>55/ C4591001 1036 10361140	INJ&P	Injury/ Traumatic Injuries#	2	10FEB2021	91/1	4	No	O	NA/W	F (10FEB2021)	Y/N	
		Road traffic accident/ Motor Vehicle Accident#	2	10FEB2021	91/1	4	No	CND	NA/W	F (10FEB2021)	Y/N	
>55/ C4591001	CARD	Hypertensive heart disease/ hypertensive cardiovascular disease	2	18NOV2020	71/1	4	No	O	NA/W	F (18NOV2020)	Y/N	

16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1039 10391010	VASC	Arteriosclerosis/ arthroscloratic cardiovascular disease	2	18NOV2020	71/1	4	No	O	NA/W	F (18NOV2020)	Y/N	
>55/ C4591001 1054 10541186	GASTR	Nausea/ nausea	1	23SEP2020	1/1	1	Yes		P	R (23SEP2020)	N/Y	
	NERV	Dizziness/ lightheadedness	1	23SEP2020	1/1	1	Yes		P	R (23SEP2020)	N/Y	
>55/ C4591001 1066 10661350	CARD	Myocardial infarction/ myocardial infarction	1	03NOV2020	16/1	4	No	O	P/W	F (03NOV2020)	Y/N	
>55/ C4591001 1071 10711023	CARD	Coronary artery disease/ WORSENING coronary artery disease	1	23AUG2020	12/9	2	No	O	P/TCN/W	R (31AUG2020)	Y/N	
>55/ C4591001 1071 10711169	INJ&P	Alcohol poisoning/ ACUTE ALCOHOL INTOXICATION	1	02OCT2020	18/14	2	No	O	P/W	R (15OCT2020)	Y/N	
>55/ C4591001 1084 10841266	INFEC	Emphysematous cholecystitis/ Acute Emphysematous Cholecystitis	2	03NOV2020	51/71	4	No	O	NA/TC/TCN/W	F (12JAN2021)	Y/N	
		Sepsis/ Sepsis	2	03NOV2020	51/71	4	No	O	NA/TC/TCN/W	F (12JAN2021)	Y/N	



16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1084 10841470	INFEC	COVID-19/ COVID-19 Infection	2	31DEC2020	72/12	4	No	O	NA/TC/TCN/W	F (11JAN2021)	Y/N
>55/ C4591001 1087 10871121	GASTR	Gastrointestinal haemorrhage/ GI Bleed	1	07SEP2020	20/3	3	No	O	P/TC/TCN/W	R (09SEP2020)	Y/N
>55/ C4591001 1087 10871228	CARD	Cardiac failure congestive/ Worsening of Chronic Congestive Heart Failure	1	03SEP2020	9/6	3	No	O	P/TC/W	R (08SEP2020)	Y/N
>55/ C4591001 1088 10881126	CARD	Cardiac arrest/ cardiac arrest	2	01DEC2020	70/1	4	No	O	NA/W	F (01DEC2020)	Y/N
>55/ C4591001 1088 10881139	NEOPL	Metastases to lung/ Metastases to the lungs#	2	24FEB2021	133/11	4	No	O	NA/W	F (06MAR2021)	Y/N
>55/ C4591001 1089 10891073	RESP	Chronic obstructive pulmonary disease/ Worsening of COPD	2	12NOV2020	70/1	4	No	O	NA/W	F (12NOV2020)	Y/N
>55/ C4591001 1089 10891088	NERV	Dementia Alzheimer's type/ Worsening of Dementia (Alzheimer's).	2	20DEC2020	115/11	4	No	O	NA/W	F (30DEC2020)	Y/N
>55/ C4591001	VASC	Hypertension/ hypertension	1	09OCT2020	23/C	2	No	O	P/TC	N	N/N

16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1090 10901415 >55/ C4591001	GENRL	Fatigue/ Fatigue#	4	23FEB2021	2/2	1	Yes		NA/W	R (24FEB2021)	N/N
1090 10901492 >55/ C4591001	SKIN	Dermatitis/ Dermatitis of unknown origin on chest and bilateral arms	2	JAN2021	102/C	1	No	O	NA/TC/W	RG	N/N
1091 10911247 >55/ C4591001	GENRL	Pain/ Body aches#	4	23FEB2021	1/2	2	Yes		NA/TC/W	R (24FEB2021)	N/N
1092 10921021 >55/ C4591001	VASC	Hypertension/ WORSENING HYPERTENSION	1	30SEP2020	20/22	1	No	O	P/TC	R (21OCT2020)	N/N
1093 10931128 >55/ C4591001	RESP	Acute respiratory failure/ Acute hypoxemic respiratory failure	2	28NOV2020	61/21	4	No	O	NA/TC/TCN/W	F (18DEC2020)	Y/N
1094 10941112 >55/ C4591001	INFEC	Septic shock/ Septic Shock	2	16DEC2020	93/6	4	No	O	NA/TC/TCN/W	F (21DEC2020)	Y/N
1097 10971023 >55/ C4591001	GASTR	Abdominal pain upper/ ABDOMINAL PAIN RUQ	1	SEP2020	1/	3	No	O	P	R (30SEP2020)	N/N
1109 11091503											

16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1112 11121118	CARD	Tachycardia/ Tachycardia	1	12AUG2020	2/1	3	Yes		P/TC	R (12AUG2020)	N/N
>55/ C4591001 1112 11121255	GENRL	Chills/ Chills	1	06OCT2020	1/2	2	Yes		P/TC	R (07OCT2020)	N/N
		Pyrexia/ Fever	1	06OCT2020	1/2	2	Yes		P/TC	R (07OCT2020)	N/N
	NERV	Headache/ Headaches	1	06OCT2020	1/2	3	Yes		P/TC	R (07OCT2020)	N/N
>55/ C4591001 1112 11121337	GASTR	Diarrhoea/ Diarrhea	1	22OCT2020	2/4	3	Yes		NA/TC/W	R (25OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	22OCT2020	2/7	2	Yes		P	R (28OCT2020)	N/N
>55/ C4591001 1114 11141050	GENRL	Sudden cardiac death/ Sudden cardiac death	2	19OCT2020	42/1	4	No	O	NA/W	F (19OCT2020)	Y/N
>55/ C4591001 1120 11201050	CARD	Cardiac arrest/ Cardiac arrest	2	07NOV2020	73/1	4	No	O	NA/W	F (07NOV2020)	Y/N
>55/ C4591001 1120 11201127	GASTR	Diarrhoea/ Diarrhea	1	12AUG2020	2/3	3	Yes		P/TC/W	R (14AUG2020)	N/N

16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
>55/ C4591001 1128 11281009	INFEC	Pneumonia/ Pneumonia	2	28OCT2020	71/32	4	No	O	NA/TC/W	F (28NOV2020)	Y/N	
>55/ C4591001 1129 11291166	CARD	Myocardial infarction/ myocardial infarction#	2	03FEB2021	129/1	4	No	O	NA/W	F (03FEB2021)	Y/N	
>55/ C4591001 1131 11311204	CARD	Cardio-respiratory arrest/ Cardiopulmonary Arrest#	3	15FEB2021	26/1	4	No	O	NA/W	F (15FEB2021)	Y/N	
>55/ C4591001 1134 11341019	CARD	Angina pectoris/ CHEST PAIN (CARDIC)#	3	02FEB2021	1/C	2	Yes		P	N	N/N	
>55/ C4591001 1135 11351033	PSYCH	Completed suicide/ Suicide#	3	29JAN2021	5/1	4	No	O	NA/W	F (29JAN2021)	Y/N	
>55/ C4591001 1136 11361102	CARD	Cardiac arrest/ cardiac arrest	2	19DEC2020	31/1	4	No	O	NA/TC/TCN/W	F (19DEC2020)	Y/N	
>55/ C4591001 1140 11401035	SKIN	Urticaria/ urticaria	1	13AUG2020	10/1	2	No	O	P/TC/W	R (13AUG2020)	N/N	
>55/ C4591001	CARD	Cardiac arrest/ Cardiac Arrest	2	29DEC2020	117/1	4	No	O	NA/W	F (29DEC2020)	Y/N	

16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1140 11401117 >55/ C4591001 1145 11451076	NERV	Parkinsonism/ parkinsonism	1	18SEP2020	15/C	1	No	O	P	N	N/N	
>55/ C4591001 1152 11521476	EAR	Deafness unilateral/ hearing loss right ear	1	14OCT2020	20/10	3	Yes		P/TC	R (23OCT2020)	N/N	
>55/ C4591001 1152 11521497	INFEC	Shigella sepsis/ sepsis related to Shigella infection	1	26OCT2020	20/17	4	No	O	NA/TC/TCN/W	F (11NOV2020)	Y/N	
>55/ C4591001 1156 11561160†	INJ&P	Road traffic accident/ MOTOR VEHICLE ACCIDENT	2	24DEC2020	74/1	4	No	O	NA/W	F (24DEC2020)	Y/N	
>55/ C4591001 1162 11621327	VASC	Arteriosclerosis/ Atherosclerotic Disease	1	13SEP2020	4/1	4	No	O	NA/W	F (13SEP2020)	Y/N	
>55/ C4591001 1168 11681083	VASC	Aortic rupture/ Aortic Rupture	2	18NOV2020	65/1	4	No	O	NA/W	F (18NOV2020)	Y/N	
>55/ C4591001 1207 12071055	INFEC	Pneumonia bacterial/ Bacterial Pneumonia#	2	05FEB2021	72/5	4	No	O	NA/W	F (09FEB2021)	Y/N	

16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
>55/ C4591001 1231 12311815	NEOPL	Lymphoproliferative disorder/ REACTIVE LYMPHOID PROLIFERATION SUPRACLAVICULAR	1	06SEP2020	21/C	1	No	O	P	N	N/N
>55/ C4591001 1231 12313972	NERV	Haemorrhagic stroke/ Hemorrhagic stroke	2	27SEP2020	15/2	4	No	O	NA/TC/W	F (28SEP2020)	Y/N
>55/ C4591001 1231 12315324	INFEC	Septic shock/ Septic shock	2	25DEC2020	99/38	4	No	O	NA/TC/TCN/W	F (31JAN2021)	Y/N
>55/ C4591001 1241 12411829	GASTR	Gastrointestinal haemorrhage/ High digestive bleeding#	4	12MAR2021	22/C	4	No	O	NA/W	N	Y/N
>55/ C4591001 1247 12471135	NERV	Cerebral infarction/ Left Middle Cerebral Artery Infarct	1	21OCT2020	22/C	3	No	O	P/TC/TCN	N	Y/N
>55/ C4591001 1252 12521010	INFEC	COVID-19 pneumonia/ Pneumonia due to COVID-19	2	25DEC2020	109/2	4	No	O	NA/TC/W	F (26DEC2020)	Y/N
>55/ C4591001 1254 12541006	GENRL	Chills/ Chills#	4	17FEB2021	2/2	1	Yes		NA/W	R (18FEB2021)	N/N
>55/ C4591001	GASTR	Dry mouth/ Dry mouth	1	07OCT2020	16/C	2	Yes		P	N	N/N

## 16.2.7.6 Listing of Adverse Events Leading to Discontinuation – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1264 12641195	SKIN	Eczema/ Worsening eczema	1	07OCT2020	16/C	2	Yes		P	N	N/N
		Pruritus/ Pruritus, abdomen	1	07OCT2020	16/C	2	Yes		P/TCN	N	N/N
		Rash maculo-papular/ Rash maculo-papular, abdomen	1	07OCT2020	16/C	1	Yes		P/TCN	N	N/N
>55/ C4591001 1270 12701057	RESP	Pulmonary embolism/ Pulmonary embolism	1	23SEP2020	21/C	3	No	O	P/TC	RG	Y/N

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v23.1) coding dictionary applied.

Note: \* = prevaccination AE, † = human immunodeficiency virus (HIV)-positive subject, # = AE occurring on or after unblinding.

a. Relative day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

c. Vaccine related (Vax Rel): relationship to investigational vaccine as assessed by the investigator.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (01:37)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adae\_1002\_disc\_all\_all

## 16.2.7.7 Listing of Deaths – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Sex	Date of Death	Age at Death (Years)	Primary Cause of Death	Secondary Cause(s) of Death
16-55	C4591001 1021 10211127∞	2	88	M	19DEC2020	54	Cardiac failure congestive	
	C4591001 1081 10811194	2	37	F	04NOV2020	51	Myocardial infarction	
	C4591001 1120 11201266∞	2	113	M	19JAN2021	51	Lung cancer metastatic	
	C4591001 1127 11271112∞	2	86	M	04DEC2020	53	Cardio-respiratory arrest	
	C4591001 1152 11521085	1	8	F	26AUG2020	42	Death	
	C4591001 1156 11561124	2	32	M	02NOV2020	53	Overdose	
	C4591001 1229 12291083†	2	76	F	05JAN2021	56	COVID-19 pneumonia	
	C4591001 1231 12314987	2	82	M	06DEC2020	47	Cardio-respiratory arrest	
>55	C4591001 1007 10071101∞	2	63	F	21OCT2020	56	Cardiac arrest	
	C4591001 1019 10191146	2	87	M	17DEC2020	67	Metastases to liver	Biliary cancer metastatic
	C4591001 1027 10271191#	2	135	F	13FEB2021	68	Respiratory failure	COVID-19
	C4591001 1036 10361140∞#	2	91	M	10FEB2021	64	Road traffic accident	
	C4591001 1039 10391010∞	2	71	M	18NOV2020	85	Arteriosclerosis	Hypertensive heart disease
	C4591001 1066 10661350	1	16	M	03NOV2020	58	Myocardial infarction	
	C4591001 1084 10841266∞	2	121	M	12JAN2021	77	Sepsis	Emphysematous cholecystitis



## 16.2.7.7 Listing of Deaths – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Sex	Date of Death	Age at Death (Years)	Primary Cause of Death	Secondary Cause(s) of Death
	C4591001 1084 10841470	2	83	M	11JAN2021	65	Multiple organ dysfunction syndrome	COVID-19
	C4591001 1088 10881126	2	70	M	01DEC2020	66	Cardiac arrest	
	C4591001 1088 10881139∞#	2	143	M	06MAR2021	83	Metastases to lung	Pancreatic carcinoma metastatic
	C4591001 1089 10891073∞	2	70	F	12NOV2020	63	Chronic obstructive pulmonary disease	
	C4591001 1089 10891088	2	125	F	30DEC2020	82	Dementia	
	C4591001 1094 10941112	2	81	F	18DEC2020	57	Acute respiratory failure	COVID-19
	C4591001 1094 10941112	2	81	F	18DEC2020	57	Acute respiratory failure	Pneumonia
	C4591001 1097 10971023∞	2	98	F	21DEC2020	87	Septic shock	
	C4591001 1114 11141050∞	2	42	F	19OCT2020	64	Unevaluable event	
	C4591001 1120 11201050∞	2	73	F	07NOV2020	58	Cardiac arrest	
	C4591001 1128 11281009	2	102	M	28NOV2020	66	Pneumonia	
	C4591001 1129 11291166∞#	2	129	F	03FEB2021	79	Myocardial infarction	
	C4591001 1131 11311204*#	3	26	M	15FEB2021	84	Cardio-respiratory arrest	Cerebrovascular accident
	C4591001 1135 11351033*#	3	5	M	29JAN2021	67		
	C4591001 1136 11361102∞	2	31	M	19DEC2020	76	Cardiac arrest	

## 16.2.7.7 Listing of Deaths – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Sex	Date of Death	Age at Death (Years)	Primary Cause of Death	Secondary Cause(s) of Death
	C4591001 1140 11401117∞	2	117	M	29DEC2020	59	Cardiac arrest	
	C4591001 1152 11521497∞	1	36	M	11NOV2020	72	Shigella sepsis	
	C4591001 1156 11561160†∞	2	74	F	24DEC2020	62	Road traffic accident	
	C4591001 1162 11621327∞	1	4	M	13SEP2020	60	Arteriosclerosis	
	C4591001 1168 11681083	2	65	M	18NOV2020	65	Aortic rupture	
	C4591001 1207 12071055#	2	76	M	09FEB2021	65	Pneumonia bacterial	
	C4591001 1231 12313972	2	16	F	28SEP2020	61	Haemorrhagic stroke	
	C4591001 1231 12315324	2	136	F	31JAN2021	59	Multiple organ dysfunction syndrome	
	C4591001 1252 12521010∞	2	110	M	26DEC2020	81	COVID-19 pneumonia	

Note: MedDRA (v23.1) coding dictionary applied.

Note: † = Human immunodeficiency virus (HIV)-positive subject, # = death occurring on or after unblinding, \* = subjects who originally received placebo and then received BNT162b2 after unblinding, ∞ = subjects who originally received BNT162b2.

a. Relative day (Rel Day) = date of death - date of last vaccination + 1.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adsl Table Generation: 27MAR2021 (06:44)  
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/cdl\_dth\_all\_all

### 16.2.7.8 Listing of Subjects Reporting Pregnancy After Dose 1 – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Race	Dose No.	Rel Day <sup>a</sup>	Date of Pregnancy	Age at Pregnancy (Years)
16-55	C4591001 1006 10061040*	White	4	32	08FEB2021	26
	C4591001 1006 10061094#	White	2	59	15NOV2020	35
	C4591001 1008 10081337#	White	2	79	23DEC2020	39
	C4591001 1015 10151071*	White	3	18	07JAN2021	32
	C4591001 1015 10151101#	White	2	130	22JAN2021	33
	C4591001 1016 10161103*	White	4	22	03FEB2021	29
	C4591001 1016 10161265#	White	2	63	29NOV2020	27
	C4591001 1019 10191002#	White	2	27	26SEP2020	31
	C4591001 1037 10371214*	White	4	29	08FEB2021	25
	C4591001 1042 10421129#	Black or African American	1	1	19AUG2020	29
	C4591001 1042 10421217*	White	3	3	20JAN2021	30
	C4591001 1046 10461118#	White	2	114	09JAN2021	24
	C4591001 1048 10481088#	White	1	17	20SEP2020	24
	C4591001 1055 10551084#	Asian	2	150	04FEB2021	31
	C4591001 1055 10551092#	White	2	142	03FEB2021	48
	C4591001 1083 10831162#	White	2	80	04DEC2020	30
	C4591001 1087 10871557#	Asian	1	11	24OCT2020	34
	C4591001 1089 10891181#	Black or African American	2	102	25DEC2020	22
	C4591001 1089 10891273#	Black or African American	2	85	25DEC2020	19
	C4591001 1092 10921208#	White	2	81	16JAN2021	36
	C4591001 1110 11101164#	White	2	161	25FEB2021	35
	C4591001 1116 11161059#	Black or African American	2	49	09NOV2020	20
	C4591001 1122 11221051#	White	2	29	25NOV2020	26
	C4591001 1123 11231204#	White	2	38	22OCT2020	22
	C4591001 1136 11361082#	White	2	13	01DEC2020	31
	C4591001 1150 11501069#	White	2	55	11NOV2020	31

### 16.2.7.8 Listing of Subjects Reporting Pregnancy After Dose 1 – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Race	Dose No.	Rel Day <sup>a</sup>	Date of Pregnancy	Age at Pregnancy (Years)
	C4591001 1152 11521053#	White	2	168	15FEB2021	30
	C4591001 1152 11521450#	White	2	79	26DEC2020	28
	C4591001 1162 11621128#	Black or African American	2	1	09SEP2020	37
	C4591001 1177 11771222#	White	2	94	23DEC2020	36
	C4591001 1178 11781061#	White	1	32	02OCT2020	38
	C4591001 1220 12201020#	American Indian or Alaska Native	1	8	23OCT2020	26
	C4591001 1226 12261210#	White	2	94	10DEC2020	30
	C4591001 1230 12301045#	Black or African American	1	22	20OCT2020	27
	C4591001 1231 12311635#	White	2	78	20NOV2020	42
	C4591001 1231 12312205#	White	2	23	29SEP2020	40
	C4591001 1231 12312378#	White	2	108	24DEC2020	45
	C4591001 1231 12314395#	White	2	59	12NOV2020	29
	C4591001 1231 12315677#	White	2	85	12DEC2020	38
	C4591001 1232 12321159#	White	2	97	28DEC2020	22
	C4591001 1232 12321293#	Black or African American	1	22	22OCT2020	32
	C4591001 1241 12411208*	Black or African American	3	6	10FEB2021	35
	C4591001 1241 12411343#	Black or African American	2	50	30OCT2020	34
	C4591001 1241 12411514*	Multiracial	3	10	05FEB2021	33
	C4591001 1241 12411766#	White	1	2	17SEP2020	34
	C4591001 1241 12411915#	Black or African American	2	68	15DEC2020	38
	C4591001 1241 12412411*	Multiracial	3	5	12FEB2021	33
	C4591001 1251 12511060#	Black or African American	2	108	01JAN2021	33
	C4591001 1254 12541142#	White	1	1	12SEP2020	21
>55	C4591001 1037 10371141#	Black or African American	2	139	08FEB2021	62

### 16.2.7.8 Listing of Subjects Reporting Pregnancy After Dose 1 – All Subjects $\geq$ 16 Years of Age

Age Group (Years)	Subject	Race	Dose No.	Rel Day <sup>a</sup>	Date of Pregnancy	Age at Pregnancy (Years)
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Note: MedDRA (v23.1) coding dictionary applied.

Note: \* = subjects who originally received placebo and then received BNT162b2 after unblinding, # = subjects who originally received BNT162b2.

a. Relative day (Rel Day) = date of pregnancy - date of last vaccination before pregnancy + 1.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (01:53)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adae\_1002\_preg\_all