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16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
Concomitant medications	Dosing/administration error, subject did not receive correct dose of vaccine	1	C4591001 1231 12313428
	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	259	C4591001 1003 10031166
			C4591001 1006 10061078 (2)
			C4591001 1006 10061109 (2)
			C4591001 1007 10071082 (2)
			C4591001 1007 10071110
			C4591001 1007 10071186
			C4591001 1007 10071212
			C4591001 1007 10071218
			C4591001 1007 10071225
			C4591001 1007 10071243
			C4591001 1007 10071250
			C4591001 1007 10071266
			C4591001 1007 10071269

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1007 10071276
			C4591001 1007 10071286
			C4591001 1007 10071295
			C4591001 1007 10071339
			C4591001 1007 10071380
			C4591001 1007 10071387
			C4591001 1007 10071402
			C4591001 1007 10071556
			C4591001 1009 10091133
			C4591001 1009 10091185
			C4591001 1012 10121083
			C4591001 1012 10121110
			C4591001 1015 10151116
			C4591001 1016 10161087

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1016 10161280
			C4591001 1018 10181009
			C4591001 1018 10181027
			C4591001 1018 10181039
			C4591001 1018 10181058
			C4591001 1018 10181105
			C4591001 1018 10181111
			C4591001 1018 10181113
			C4591001 1018 10181127
			C4591001 1018 10181141
			C4591001 1018 10181164
			C4591001 1018 10181170
			C4591001 1018 10181191
			C4591001 1018 10181204

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1018 10181214
			C4591001 1018 10181223
			C4591001 1018 10181302
			C4591001 1018 10181306
			C4591001 1018 10181319
			C4591001 1019 10191063
			C4591001 1028 10281162 (2)
			C4591001 1037 10371219
			C4591001 1039 10391124
			C4591001 1039 10391153
			C4591001 1042 10421028
			C4591001 1042 10421262
			C4591001 1044 10441056
			C4591001 1048 10481027

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1048 10481070
			C4591001 1048 10481085
			C4591001 1052 10521121
			C4591001 1054 10541110
			C4591001 1054 10541161
			C4591001 1055 10551145
			C4591001 1055 10551152
			C4591001 1056 10561009 (2)
			C4591001 1056 10561197 (2)
			C4591001 1056 10561477 (2)
			C4591001 1057 10571050
			C4591001 1057 10571198
			C4591001 1057 10571201
			C4591001 1057 10571222

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1057 10571236 (2)
			C4591001 1066 10661121
			C4591001 1071 10711234
			C4591001 1072 10721012
			C4591001 1072 10721029
			C4591001 1072 10721058
			C4591001 1072 10721077
			C4591001 1072 10721084
			C4591001 1079 10791177 (2)
			C4591001 1080 10801019
			C4591001 1080 10801055
			C4591001 1081 10811094
			C4591001 1081 10811114
			C4591001 1081 10811186

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1083 10831154
			C4591001 1083 10831162
			C4591001 1083 10831242
			C4591001 1083 10831252
			C4591001 1083 10831284
			C4591001 1084 10841017
			C4591001 1084 10841061
			C4591001 1084 10841137
			C4591001 1084 10841156
			C4591001 1084 10841241
			C4591001 1084 10841358
			C4591001 1084 10841439 (2)
			C4591001 1084 10841456
			C4591001 1084 10841480

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 108510851064
			C4591001 108510851069
			C4591001 108510851136
			C4591001 108510851137
			C4591001 108510851237
			C4591001 108510851244
			C4591001 108510851286 (2)
			C4591001 108510851287
			C4591001 108710871066
			C4591001 108910891103 (2)
			C4591001 109110911091
			C4591001 109110911122
			C4591001 109110911215
			C4591001 109310931216

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1094 10941167
			C4591001 1094 10941169
			C4591001 1095 10951031
			C4591001 1096 10961026
			C4591001 1096 10961109
			C4591001 1096 10961216
			C4591001 1096 10961256
			C4591001 1096 10961318
			C4591001 1098 10981224
			C4591001 1107 11071013
			C4591001 1109 11091275
			C4591001 1109 11091352
			C4591001 1110 11101053
			C4591001 1110 11101177

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1110 11101234
			C4591001 1110 11101244
			C4591001 1111 11111051
			C4591001 1112 11121062
			C4591001 1112 11121083
			C4591001 1112 11121135
			C4591001 1112 11121243
			C4591001 1114 11141015
			C4591001 1114 11141054
			C4591001 1116 11161008
			C4591001 1116 11161012 (2)
			C4591001 1120 11201096
			C4591001 1121 11211029 (2)
			C4591001 1121 11211057 (2)

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1121 11211059
			C4591001 1121 11211067
			C4591001 1121 11211087
			C4591001 1122 11221003
			C4591001 1122 11221038
			C4591001 1123 11231104
			C4591001 1123 11231145
			C4591001 1123 11231249
			C4591001 1124 11241025
			C4591001 1124 11241052
			C4591001 1124 11241103
			C4591001 1124 11241120 (2)
			C4591001 1125 11251043
			C4591001 1126 11261045

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1126 11261080
			C4591001 1126 11261135
			C4591001 1126 11261151
			C4591001 1128 11281026
			C4591001 1128 11281083
			C4591001 1128 11281112
			C4591001 1128 11281132
			C4591001 1128 11281177
			C4591001 1128 11281227
			C4591001 1128 11281265
			C4591001 1129 11291064
			C4591001 1129 11291072
			C4591001 1130 11301028
			C4591001 1130 11301094 (2)

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1133 11331130
			C4591001 1133 11331406
			C4591001 1133 11331438 (2)
			C4591001 1133 11331555
			C4591001 1135 11351241 (2)
			C4591001 1135 11351555
			C4591001 1139 11391042
			C4591001 1140 11401176
			C4591001 1142 11421112
			C4591001 1147 11471001
			C4591001 1147 11471007 (3)
			C4591001 1147 11471047
			C4591001 1149 11491025 (2)
			C4591001 1149 11491040

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1149 11491307
			C4591001 1152 11521137
			C4591001 1152 11521192 (2)
			C4591001 1152 11521347 (2)
			C4591001 1167 11671071 (2)
			C4591001 1167 11671132
			C4591001 1169 11691014
			C4591001 1169 11691023
			C4591001 1169 11691034
			C4591001 1169 11691057
			C4591001 1169 11691069
			C4591001 1170 11701026
			C4591001 1170 11701045
			C4591001 1170 11701081

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 117011701110
			C4591001 11701171
			C4591001 117011701209
			C4591001 117011701231 (2)
			C4591001 117011701296
			C4591001 117011701413
			C4591001 1171117111071
			C4591001 1171117111181
			C4591001 1171117111183
			C4591001 1171117111186
			C4591001 117111711247
			C4591001 117111711250
			C4591001 117111711261
			C4591001 117711771076

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1177 11771157
			C4591001 1177 11771369
			C4591001 1178 11781065
			C4591001 1204 12041094
			C4591001 1204 12041176†
			C4591001 1204 12041280
			C4591001 1207 12071045
			C4591001 1208 12081012
			C4591001 1226 12261080
			C4591001 1226 12261085
			C4591001 1226 12261455
			C4591001 1226 12262132
			C4591001 1226 12262138
			C4591001 1231 12311081

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1231 12311145
			C4591001 1231 12311230
			C4591001 1231 12311237
			C4591001 1231 12311647
			C4591001 1231 12311975 (2)
			C4591001 1231 12312528
			C4591001 1231 12312856
			C4591001 1231 12313059
			C4591001 1231 12314046
			C4591001 1231 12314324
			C4591001 1231 12314974
			C4591001 1231 12315286
			C4591001 1231 12315386
			C4591001 1231 12315578

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1232 12321054
			C4591001 1232 12321202
			C4591001 1241 12411211
			C4591001 1241 12411449
			C4591001 1241 12411465 (2)
			C4591001 1241 12411569 (2)
			C4591001 1241 12412120
			C4591001 1254 12541007
			C4591001 1254 12541167
			C4591001 1264 12641159
			C4591001 1265 12651153 (2)
			C4591001 1269 12691014
			C4591001 1269 12691026
			C4591001 1269 12691047

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1269 12691088
			C4591001 1270 12701003
			C4591001 1270 12701008
			C4591001 1270 12701069
			C4591001 1270 12701118
			C4591001 1270 12701137
			C4591001 4444 44441327
			C4591001 4444 44442088
	Receipt of blood/plasma products or immunoglobulins within 60 days before enrollment through conclusion of the study.	8	C4591001 1091 10911241
			C4591001 1096 10961012
			C4591001 1096 10961305
			C4591001 1107 11071065
			C4591001 1170 11701482
			C4591001 1218 12181027

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
Subject received chronic systemic treatment with known immunosuppressant medication, or radiotherapy, within 60 days before enrollment through conclusion of the study.		6	C4591001 1231 12313697
			C4591001 1231 12313895
			C4591001 1028 10281059
			C4591001 1046 10461261
			C4591001 1128 11281241
			C4591001 1140 11401020 (2)
			C4591001 1226 12262078
			C4591001 1254 12541144
			C4591001 1003 10031101
			C4591001 1007 10071276
Subject received systemic corticosteroids (≥ 20 mg/day of prednisone or equivalent) for ≥ 14 days is prohibited from 28 days prior to enrollment to specified visits/cohorts per protocol.		7	C4591001 1028 10281026
			C4591001 1220 12201029
			C4591001 1221 12211002 (2)
			C4591001 1247 12471244

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
Inclusion/exclusion	Participant failed to meet inclusion criterion #01 (Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study phase).	1	C4591001 126112611054
			C4591001 114211421084
	Participant failed to meet inclusion criterion #02 (Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures).	1	C4591001 122912291135†
	Participant failed to meet inclusion criterion #03 (Healthy participants who are determined by medical history, physical examination and clinical judgement of the investigator to be eligible for inclusion in the study)	9	C4591001 104410441152†
			C4591001 109610961036
			C4591001 111711171036
			C4591001 111711171186
			C4591001 112011201038
			C4591001 116111611023
			C4591001 120312031048
			C4591001 123112311088
			C4591001 1231123113140
	Participant met exclusion criterion #01 (participant having other medical or psychiatric condition)	4	C4591001 100610061246

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 109610961036
			C4591001 111711171036
			C4591001 111711171186
	Participant met exclusion criterion #02 (participant having known infection with HIV, HCV or HBV)	6	C4591001 109810981155
			C4591001 109810981168†
			C4591001 109810981169†
			C4591001 117011701457†
			C4591001 122412241158†
			C4591001 122612262255†
	Participant met exclusion criterion #05 (previous clinical or microbiological diagnosis of COVID-19)	4	C4591001 105410541033
			C4591001 123112311191
			C4591001 123112313211
			C4591001 123512351167
	Participant met exclusion criterion #11 (women who are pregnant or breastfeeding)	23	C4591001 100310031186

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1015 10151071
			C4591001 1047 10471301
			C4591001 1133 11331207
			C4591001 1136 11361082
			C4591001 1152 11521450
			C4591001 1156 11561015
			C4591001 1161 11611016
			C4591001 1162 11621128
			C4591001 1166 11661078
			C4591001 1170 11701365 (2)
			C4591001 1178 11781061
			C4591001 1185 11851055
			C4591001 1204 12041280
			C4591001 1220 12201020

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1226 12261313
			C4591001 1231 12312378
			C4591001 1231 12313998
			C4591001 1241 12411679
			C4591001 1241 12412369
			C4591001 1241 12412411
			C4591001 1254 12541142
			C4591001 1254 12541145
	Participant met exclusion criterion #13 (participant receiving treatment with immunosuppressive therapy as specified in protocol)	1	C4591001 1038 10381061
	Participant met exclusion criterion #16 (Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation)	3	C4591001 1006 10061099
			C4591001 1081 10811114
			C4591001 1081 10811186
	Participant met exclusion criterion #22 (investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members)	6	C4591001 1112 11121058

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
Investigational product	Blind compromised	2	C4591001 116111611002
			C4591001 116111611008
			C4591001 116111611011
			C4591001 116111611014
			C4591001 116111611018
			C4591001 109610961195
	Dosing/administration error, subject did not receive correct dose of vaccine	96	C4591001 109610961197
			C4591001 106810681002
			C4591001 106810681003
			C4591001 106810681006
			C4591001 106810681010
			C4591001 106810681011
			C4591001 106810681012
			C4591001 106810681013

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 106810681016
			C4591001 106810681017
			C4591001 106810681018
			C4591001 106810681021
			C4591001 106810681024
			C4591001 106810681025
			C4591001 106810681026
			C4591001 106810681027
			C4591001 106810681028
			C4591001 106810681031
			C4591001 106810681034
			C4591001 106810681035
			C4591001 106810681036
			C4591001 106810681037

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 106810681038
			C4591001 106810681042
			C4591001 106810681046
			C4591001 106810681047
			C4591001 106810681052
			C4591001 106810681053
			C4591001 106810681058
			C4591001 106810681060
			C4591001 106810681061
			C4591001 106810681064
			C4591001 106810681066
			C4591001 106810681071
			C4591001 106810681072
			C4591001 106810681073

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 106810681074
			C4591001 106810681076
			C4591001 106810681077
			C4591001 106810681080
			C4591001 106810681081
			C4591001 106810681083
			C4591001 109110911005
			C4591001 109110911008
			C4591001 109110911014
			C4591001 109110911015
			C4591001 113611361027
			C4591001 113611361039
			C4591001 113611361083
			C4591001 113611361084

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1136 11361109
			C4591001 1141 11411011
			C4591001 1141 11411014
			C4591001 1141 11411023
			C4591001 1141 11411065
			C4591001 1141 11411068
			C4591001 1141 11411080
			C4591001 1141 11411093
			C4591001 1141 11411139
			C4591001 1169 11691033
			C4591001 1231 12313429
			C4591001 1231 12313449
			C4591001 1231 12313456
			C4591001 1231 12313459

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1231 12313467
			C4591001 1231 12313469 (2)
			C4591001 1231 12313479
			C4591001 1231 12313483
			C4591001 1231 12313486
			C4591001 1231 12313487
			C4591001 1231 12313492
			C4591001 1231 12313497
			C4591001 1231 12313498
			C4591001 1231 12313501
			C4591001 1231 12313505
			C4591001 1231 12313506
			C4591001 1231 12313508
			C4591001 1231 12313509

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1231 12313512
			C4591001 1231 12313514
			C4591001 1231 12313515
			C4591001 1231 12313517
			C4591001 1231 12313518
			C4591001 1231 12313519
			C4591001 1231 12313528
			C4591001 1231 12313533
			C4591001 1231 12313534
			C4591001 1231 12313537
			C4591001 1231 12313541
			C4591001 1231 12313542
			C4591001 1231 12313546
			C4591001 1231 12313551

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
IP administered that was deemed not suitable for use by Almac		68	C4591001 1231 12313553
			C4591001 1231 12313554
			C4591001 1231 12313556
			C4591001 1231 12313564
			C4591001 1231 12313567
			C4591001 1024 10241002
			C4591001 1024 10241004
			C4591001 1024 10241006
			C4591001 1024 10241014
			C4591001 1024 10241023
			C4591001 1024 10241032
			C4591001 1024 10241033
			C4591001 1024 10241039
			C4591001 1024 10241040

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1024 10241042
			C4591001 1024 10241044
			C4591001 1024 10241046
			C4591001 1024 10241054
			C4591001 1024 10241055
			C4591001 1024 10241061
			C4591001 1024 10241066
			C4591001 1024 10241067
			C4591001 1024 10241071
			C4591001 1024 10241072
			C4591001 1024 10241074
			C4591001 1024 10241078
			C4591001 1024 10241084
			C4591001 1024 10241085

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1024 10241091
			C4591001 1024 10241094
			C4591001 1024 10241100
			C4591001 1024 10241102
			C4591001 1024 10241104
			C4591001 1024 10241108
			C4591001 1044 10441001
			C4591001 1044 10441015
			C4591001 1044 10441028
			C4591001 1044 10441029
			C4591001 1044 10441031
			C4591001 1044 10441034
			C4591001 1044 10441037
			C4591001 1044 10441045

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1044 10441048
			C4591001 1044 10441050
			C4591001 1044 10441052
			C4591001 1044 10441054
			C4591001 1044 10441060
			C4591001 1044 10441063
			C4591001 1044 10441068
			C4591001 1044 10441071
			C4591001 1044 10441076
			C4591001 1044 10441079
			C4591001 1044 10441088
			C4591001 1044 10441089
			C4591001 1096 10961011
			C4591001 1096 10961027

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 109610961059
			C4591001 109610961209
			C4591001 109610961245
			C4591001 109610961246
			C4591001 116311631117
			C4591001 116311631121
			C4591001 116311631124
			C4591001 116311631127
			C4591001 116311631136
			C4591001 116311631142
			C4591001 116311631145
			C4591001 123212321354
			C4591001 123212321373
			C4591001 123212321382

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1232 12321385
			C4591001 1232 12321394
			C4591001 1232 12321395
	Incorrect IP assigned to subject due to IRT not being utilized	1	C4591001 1163 11631006 (2)
	Incorrect vaccine allocation/assigned to subject	6	C4591001 1012 10121103
			C4591001 1079 10791130
			C4591001 1088 10881077 (2)
			C4591001 1090 10901334
			C4591001 1116 11161226
			C4591001 1169 11691049
	Other IP deviation	10	C4591001 1096 10961195
			C4591001 1096 10961197
			C4591001 1101 11011024
			C4591001 1126 11261053

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1161 11611015
			C4591001 1163 11631039
			C4591001 1163 11631064
			C4591001 1163 11631096
			C4591001 1213 12131012
			C4591001 1221 12211079
	Subject was vaccinated despite being ineligible	4	C4591001 1092 10921158
			C4591001 1112 11121270†
			C4591001 1170 11701334†
			C4591001 1265 12651164†
	Subject was vaccinated despite meeting temporary delay criterion #4 (receiving short-term (<14 days) systemic corticosteroids, IP administration should be delayed until systemic corticosteroid use has been discontinued for at least 28 days.	4	C4591001 1028 10281241
			C4591001 1028 10281294
			C4591001 1231 12311499

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age				
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)	
Laboratory	Nasal swab can't be analyzed due to incorrect shipping procedure	1	C4591001 1247 12471244	
Other	Efficacy data considered potentially unreliable due to lack of PI oversight identified as significant quality event	19	C4591001 1083 10831154	
			C4591001 1161 11611001	
			C4591001 1161 11611004	
			C4591001 1161 11611007	
			C4591001 1161 11611008	
			C4591001 1161 11611009	
			C4591001 1161 11611010	
			C4591001 1161 11611014	
			C4591001 1161 11611017	
			C4591001 1161 11611020	
			C4591001 1161 11611023	
			C4591001 1161 11611024	
			C4591001 1161 11611026	

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
Safety and efficacy data considered potentially unreliable due to lack of PI oversight identified as significant quality event.		8	C4591001 116111611027
			C4591001 116111611028
			C4591001 116111611032
			C4591001 116111611033
			C4591001 116111611034
			C4591001 116111611040
			C4591001 116111611041
			C4591001 116111611002
			C4591001 116111611005
			C4591001 116111611006
			C4591001 116111611011
			C4591001 116111611015
			C4591001 116111611016
			C4591001 116111611018

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
Procedures/tests	Procedure/Test not done	1	C4591001 1161 11611019
			C4591001 1146 11461010
	Subject had a vaccination diary activated, but was not part of the reactogenicity subset	18	C4591001 1098 10981168† (2)
			C4591001 1098 10981169†
			C4591001 1112 11121174
			C4591001 1133 11331537
			C4591001 1219 12191001
			C4591001 1219 12191002
			C4591001 1219 12191003
			C4591001 1219 12191004
			C4591001 1219 12191013
			C4591001 1219 12191014
			C4591001 1219 12191016
			C4591001 1219 12191017

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1219 12191042
			C4591001 1219 12191044
			C4591001 1219 12191048
			C4591001 1235 12351152
			C4591001 1235 12351153
			C4591001 1235 12351155
Note: † = Human immunodeficiency virus (HIV)-positive subject. PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: addv Table Generation: 30MAR2021 (13:45) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/addv_l001_1655			

16.2.3.2.2 Listing of Subjects Excluded From Safety Population – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)	Subject	Reason for Exclusion
16-55	C4591001 1003 10031140	Subject did not receive study vaccine.
	C4591001 1003 10031143	Subject did not receive study vaccine.
	C4591001 1005 10051381	Subject did not receive study vaccine.
	C4591001 1013 10131017	Subject did not receive study vaccine.
	C4591001 1013 10131740	Subject did not receive study vaccine.
	C4591001 1036 10361050	Subject did not receive study vaccine.
	C4591001 1057 10571031	Subject did not receive study vaccine.
	C4591001 1057 10571211	Subject did not receive study vaccine.
	C4591001 1057 10571212	Subject did not receive study vaccine.
	C4591001 1057 10571215	Subject did not receive study vaccine.
	C4591001 1057 10571268	Subject did not receive study vaccine.
	C4591001 1066 10661335	Subject did not receive study vaccine.
	C4591001 1071 10711162	Subject did not receive study vaccine.
	C4591001 1081 10811105	Subject did not receive study vaccine.
	C4591001 1082 10821013	Subject did not receive study vaccine.
	C4591001 1089 10891346	Subject did not receive study vaccine.
	C4591001 1089 10891351	Subject did not receive study vaccine.
	C4591001 1092 10921128	Subject did not receive study vaccine.
	C4591001 1093 10931055	Subject did not receive study vaccine.
	C4591001 1109 11091349	Subject did not receive study vaccine.
	C4591001 1112 11121229	Subject did not receive study vaccine.
	C4591001 1116 11161015	Subject did not receive study vaccine.
	C4591001 1120 11201038	Subject did not receive study vaccine.
	C4591001 1120 11201252	Subject did not receive study vaccine.
	C4591001 1122 11221006	Subject did not receive study vaccine.
	C4591001 1122 11221026	Subject did not receive study vaccine.
	C4591001 1123 11231027	Subject did not receive study vaccine.

16.2.3.2.2 Listing of Subjects Excluded From Safety Population – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)	Subject	Reason for Exclusion
	C4591001 1123 11231301	Subject did not receive study vaccine.
	C4591001 1126 11261074	Subject did not receive study vaccine.
	C4591001 1129 11291048	Subject did not receive study vaccine.
	C4591001 1133 11331162	Subject did not receive study vaccine.
	C4591001 1135 11351389	Subject did not receive study vaccine.
	C4591001 1149 11491108	Subject did not receive study vaccine.
	C4591001 1161 11611002	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611005	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611006	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611011	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611015	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611016	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611018	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611019	Unreliable data due to lack of PI oversight.
	C4591001 1162 11621024	Subject did not receive study vaccine.
	C4591001 1162 11621477	Subject did not receive study vaccine.
	C4591001 1167 11671003	Subject did not receive study vaccine.
	C4591001 1168 11681030	Subject did not receive study vaccine.
	C4591001 1205 12051028	Subject did not receive study vaccine.
	C4591001 1212 12121023	Subject did not receive study vaccine.
	C4591001 1223 12231200	Subject did not receive study vaccine.
	C4591001 1223 12231234	Subject did not receive study vaccine.
	C4591001 1224 12241170	Subject did not receive study vaccine.
	C4591001 1231 12311409	Subject did not receive study vaccine.
	C4591001 1231 12311516	Subject did not receive study vaccine.
	C4591001 1231 12311926	Subject did not receive study vaccine.
	C4591001 1231 12312176	Subject did not receive study vaccine.

16.2.3.2.2 Listing of Subjects Excluded From Safety Population – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)	Subject	Reason for Exclusion
	C4591001 1231 12312483	Subject did not receive study vaccine.
	C4591001 1231 12313443	Subject did not receive study vaccine.
	C4591001 1231 12313527	Subject did not receive study vaccine.
	C4591001 1231 12313869	Subject did not receive study vaccine.
	C4591001 1231 12314738	Subject did not receive study vaccine.
	C4591001 1231 12315308	Subject did not receive study vaccine.
	C4591001 1232 12321037	Subject did not receive study vaccine.
	C4591001 1235 12351167	Subject did not receive study vaccine.
	C4591001 1248 12481018	Subject did not receive study vaccine.
	C4591001 1248 12481025	Subject did not receive study vaccine.
	C4591001 1248 12481060	Subject did not receive study vaccine.
	C4591001 1248 12481218	Subject did not receive study vaccine.
	C4591001 1251 12511204	Subject did not receive study vaccine.
	C4591001 1260 12601049	Subject did not receive study vaccine.
	C4591001 1260 12601070	Subject did not receive study vaccine.
	C4591001 1264 12641018	Subject did not receive study vaccine.
	C4591001 4444 44441135	Subject did not receive study vaccine.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 30MAR2021 (13:27) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001 EUA 1655/adsl l001 excl saf 1655		

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
16-55	C4591001101110111215	1	19OCT2020	Product administration error	DOSE NOT CHANGED	N	N	19OCT2020	N	N
	C4591001101210121103	2	22SEP2020	Product administration error	DOSE NOT CHANGED	N	N	22SEP2020	Y	N
	C4591001102410241002	2	01SEP2020	Product storage error	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001102410241004	2	02SEP2020	Product storage error	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001102410241006	2	02SEP2020	Product storage error	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001102410241014	2	01SEP2020	Product storage error	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001102410241023	2	02SEP2020	Product storage error	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001102410241032	1	17AUG2020	Product storage error	DOSE NOT CHANGED	N	N	17AUG2020	N	N
	C4591001102410241033	1	18AUG2020	Product storage error	DOSE NOT CHANGED	N	N	18AUG2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001 1024 10241039	1	18AUG2020	Product storage error	DOSE NOT CHANGED	N	N	18AUG2020	N	N
	C4591001 1024 10241040	1	18AUG2020	Product storage error	DOSE NOT CHANGED	N	N	18AUG2020	N	N
	C4591001 1024 10241042	1	19AUG2020	Product storage error	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1024 10241044	1	19AUG2020	Product storage error	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1024 10241046	1	19AUG2020	Product storage error	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1024 10241054	1	20AUG2020	Product storage error	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1024 10241055	1	20AUG2020	Product storage error	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1024 10241061	1	21AUG2020	Product storage error	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1024 10241066	1	24AUG2020	Product storage error	DOSE NOT CHANGED	N	N	24AUG2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001 1024 10241067	1	24AUG2020	Product storage error	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1024 10241071	1	24AUG2020	Product storage error	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1024 10241072	1	25AUG2020	Product storage error	DOSE NOT CHANGED	N	N	25AUG2020	N	N
	C4591001 1024 10241074	1	25AUG2020	Product storage error	DOSE NOT CHANGED	N	N	25AUG2020	N	N
	C4591001 1024 10241078	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1024 10241084	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1024 10241085	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1024 10241091	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1024 10241094	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001 1024 10241100	1	31AUG2020	Product storage error	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1024 10241102	1	31AUG2020	Product storage error	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1024 10241104	1	01SEP2020	Product storage error	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1024 10241108	1	02SEP2020	Product storage error	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001 1044 10441001	2	02SEP2020	Product temperature excursion issue	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001 1044 10441015	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1044 10441028		24AUG2020	Product storage error	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1044 10441029	1	25AUG2020	Product storage error	DOSE NOT CHANGED	N	N	25AUG2020	N	N
	C4591001 1044 10441031	1	25AUG2020	Product storage error	DOSE NOT CHANGED	N	N	25AUG2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001 1044 10441034	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1044 10441037	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1044 10441045	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1044 10441048		27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1044 10441050	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1044 10441052	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1044 10441054	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1044 10441060	1	31AUG2020	Product storage error	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1044 10441063	1	01SEP2020	Product storage error	DOSE NOT CHANGED	N	N	01SEP2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001 1044 10441068	1	01SEP2020	Product storage error	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1044 10441071	1	02SEP2020	Product storage error	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001 1044 10441076	1	03SEP2020	Product storage error	DOSE NOT CHANGED	N	N	03SEP2020	N	N
	C4591001 1044 10441079	1	04SEP2020	Product storage error	DOSE NOT CHANGED	N	N	04SEP2020	N	N
	C4591001 1044 10441088	1	06SEP2020	Product storage error	DOSE NOT CHANGED	N	N	06SEP2020	N	N
	C4591001 1044 10441089	1	06SEP2020	Product storage error	DOSE NOT CHANGED	N	N	06SEP2020	N	N
	C4591001 1068 10681002	1	18AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	18AUG2020	N	N
	C4591001 1068 10681003	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1068 10681006	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001 1068 10681010	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1068 10681011	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1068 10681012	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1068 10681013	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1068 10681016	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1068 10681017	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
		4	08JAN2021	Product administration error	DOSE NOT CHANGED	N	N	08JAN2021	N	N
	C4591001 1068 10681018	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1068 10681021	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001 1068 10681024	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1068 10681025	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1068 10681026	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1068 10681027	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1068 10681028	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681031	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681034	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681035	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681036	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
		4	08JAN2021	Product administration error	DOSE NOT CHANGED	N	N	08JAN2021	N	N
	C4591001 1068 10681037	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681038	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681042	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681046	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681047	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681052	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1068 10681053	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1068 10681058	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001 1068 10681060	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681061	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681064	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681066	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681071	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681072	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681073	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681074	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681076	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001 1068 10681077	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681080	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681081	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681083	1	01SEP2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1079 10791039	1	03AUG2020	Product administration error	DOSE NOT CHANGED	N	N	03AUG2020	N	N
	C4591001 1079 10791130	1	17AUG2020	Wrong product administered	DRUG WITHDRAWN	N	N	17AUG2020	N	N
	C4591001 1079 10791170	3	25FEB2021	Product administration error	DOSE NOT CHANGED	N	N	25FEB2021	N	N
	C4591001 1079 10791206	1	28AUG2020	Product administration error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1088 10881077	2	11SEP2020	Wrong product administered	DOSE NOT CHANGED	N	N	11SEP2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001109010901334	1	03SEP2020	Wrong product administered	DOSE NOT CHANGED	N	N	03SEP2020	N	N
	C4591001109110911005	1	30JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	30JUL2020	N	N
	C4591001109110911008	1	31JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001109110911014	1	31JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001109110911015	1	31JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001109610961011	3	26FEB2021	Product storage error	DOSE NOT CHANGED	N	N	26FEB2021	N	N
	C4591001109610961027	3	26FEB2021	Product storage error	DOSE NOT CHANGED	N	N	26FEB2021	N	N
	C4591001109610961059	4	26FEB2021	Product storage error	DOSE NOT CHANGED	N	N	26FEB2021	N	N
	C4591001109610961195	2	21SEP2020	Product administration error	DOSE NOT CHANGED	N	N	21SEP2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001109610961197	2	21SEP2020	Product administration error	DOSE NOT CHANGED	N	N	21SEP2020	N	N
	C4591001109610961209	4	26FEB2021	Product storage error	DOSE NOT CHANGED	N	N	26FEB2021	N	N
	C4591001109610961245	4	26FEB2021	Product storage error	DOSE NOT CHANGED	N	N	26FEB2021	N	N
	C4591001109610961246	4	26FEB2021	Product storage error	DOSE NOT CHANGED	N	N	26FEB2021	N	N
	C4591001110111011024	3	28DEC2020	Expired product administered	DOSE NOT CHANGED	N	N	28DEC2020	N	N
	C4591001111611161226	1	11SEP2020	Wrong product administered	DOSE NOT CHANGED	N	N	11SEP2020	N	N
	C4591001112611261053	1	20AUG2020	Expired product administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001112911291129	2	08SEP2020	Product administration error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001113611361027	4	25FEB2021	Incorrect dose administered	DOSE NOT CHANGED	N	N	25FEB2021	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001 1136 11361039	4	24FEB2021	Incorrect dose administered	DOSE NOT CHANGED	N	N	24FEB2021	N	N
	C4591001 1136 11361083	4	24FEB2021	Incorrect dose administered	DOSE NOT CHANGED	N	N	24FEB2021	N	N
	C4591001 1136 11361084	4	25FEB2021	Incorrect dose administered	DOSE NOT CHANGED	N	N	25FEB2021	N	N
	C4591001 1136 11361109	4	24FEB2021	Incorrect dose administered	DOSE NOT CHANGED	N	N	24FEB2021	N	N
	C4591001 1141 11411011	2	21AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1141 11411014	1	03AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	03AUG2020	N	N
	C4591001 1141 11411023	2	25AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	25AUG2020	N	N
	C4591001 1141 11411065	1	12AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	12AUG2020	N	N
	C4591001 1141 11411068	1	12AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	12AUG2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001 1141 11411080	1	14AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	14AUG2020	N	N
	C4591001 1141 11411093	1	18AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	18AUG2020	N	N
	C4591001 1141 11411139	1	27AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1146 11461196	1	03SEP2020	Product administration error	DOSE NOT CHANGED	N	N	03SEP2020	N	N
	C4591001 1146 11461338	2	13NOV2020	Product administration error	DOSE NOT CHANGED	N	N	13NOV2020	N	N
	C4591001 1161 11611010	1	31JUL2020	Product administration error	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001 1161 11611015	1	01AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	01AUG2020	N	N
	C4591001 1163 11631006	1	31JUL2020	Product administration error	DRUG WITHDRAWN	N	N	31JUL2020	N	N
	C4591001 1163 11631039	1	06AUG2020	Expired product administered	DOSE NOT CHANGED	N	N	06AUG2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001 1163 11631064	1	07AUG2020	Expired product administered	DOSE NOT CHANGED	N	N	07AUG2020	N	N
	C4591001 1163 11631096	1	12AUG2020	Product administration error	DOSE NOT CHANGED	N	N	12AUG2020	N	N
	C4591001 1163 11631117	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1163 11631121	2	09SEP2020	Product storage error	DOSE NOT CHANGED	N	N	09SEP2020	N	N
	C4591001 1163 11631124	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1163 11631127	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1163 11631136	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1163 11631142	2	09SEP2020	Product storage error	DOSE NOT CHANGED	N	N	09SEP2020	N	N
	C4591001 1163 11631145	2	09SEP2020	Product storage error	DOSE NOT CHANGED	N	N	09SEP2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001 1169 11691033	3	07JAN2021	Underdose	DOSE NOT CHANGED	N	N	07JAN2021	N	N
	C4591001 1169 11691049	2	05OCT2020	Product administration error	DOSE NOT CHANGED	N	N	05OCT2020	N	N
	C4591001 1185 11851017	2	16NOV2020	Product administration error	DOSE NOT CHANGED	N	N	16NOV2020	N	N
	C4591001 1185 11851037	2	16NOV2020	Product administration error	DOSE NOT CHANGED	N	N	16NOV2020	N	N
	C4591001 1212 12121005	3	25JAN2021	Product preparation error	DOSE NOT CHANGED	N	N	25JAN2021	N	N
	C4591001 1212 12121008	3	25JAN2021	Product preparation error	DOSE NOT CHANGED	N	N	25JAN2021	N	N
	C4591001 1212 12121013	3	25JAN2021	Product preparation error	DOSE NOT CHANGED	N	N	25JAN2021	N	N
	C4591001 1212 12121022	3	25JAN2021	Product preparation error	DOSE NOT CHANGED	N	N	25JAN2021	N	N
	C4591001 1212 12121031	3	25JAN2021	Product preparation error	DOSE NOT CHANGED	N	N	25JAN2021	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001 1221 12211079	1	02DEC2020	Expired product administered	DOSE NOT CHANGED	N	N	02DEC2020	N	N
	C4591001 1230 12301157	2	28OCT2020	Product administration error	DOSE NOT CHANGED	N	N	28OCT2020	N	N
	C4591001 1231 12313428	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313429	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313449	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313456	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313459	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313467	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313469	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001 1231 12313479	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313483	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313486	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313487	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313492	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313497	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313498	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313501	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313505	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001 1231 12313506	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313508	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313509	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313512	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313514	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313515	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313517	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313518	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313519	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001 1231 12313528	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313533	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313534	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313537	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313541	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313542	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313546	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313551	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313553	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001 1231 12313554	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313556	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313564	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313567	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1232 12321354	2	13NOV2020	Product storage error	DOSE NOT CHANGED	N	N	13NOV2020	N	N
	C4591001 1232 12321373	2	13NOV2020	Product storage error	DOSE NOT CHANGED	N	N	13NOV2020	N	N
	C4591001 1232 12321382	2	12NOV2020	Product storage error	DOSE NOT CHANGED	N	N	12NOV2020	N	N
	C4591001 1232 12321385	2	13NOV2020	Product storage error	DOSE NOT CHANGED	N	N	13NOV2020	N	N
	C4591001 1232 12321394	2	12NOV2020	Product storage error	DOSE NOT CHANGED	N	N	12NOV2020	N	N

16.2.5.2.2 Listing of Medication Errors – Phase 2/3 Subjects 16-55 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error– Associated AE (Yes/No)
	C4591001 1232 12321395	2	12NOV2020	Product storage error	DOSE NOT CHANGED	N	N	12NOV2020	N	N
	C4591001 1269 12691004	1	17AUG2020	Product administration error	DOSE NOT CHANGED	N	N	17AUG2020	N	N
	C4591001 1269 12691011	1	20AUG2020	Product administration error	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1269 12691016	1	20AUG2020	Product administration error	DOSE NOT CHANGED	N	N	20AUG2020	N	N
a. Dose No. = the vaccination visit at which the medication error occurred. PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 30MAR2021 (13:33) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adae_l002_me_1655										

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

16.2.7.1 Adverse Events Legend Page

Category	Abbreviation	Text
	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
	SOCCL	Social circumstances
	SURG	Surgical and medical procedures
	VASC	Vascular disorders
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 28MAR2021 (23:09) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001 EUA 1655/ae legend		

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
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	
16-55/ C4591001 1006 10061176	RESP	Asthma/ Acute Asthma Exacerbation#	2	03FEB2021	77/8	3	No	O	NA/TC	R (10FEB2021)	Y/N	
16-55/ C4591001	NEOPL	Chronic myeloid leukaemia/ chronic myelogenous leukemia	2	24SEP2020	8/C	4	No	O	NA/TC	RG	Y/N	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)		
1007 10071276 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 1013 10131255	PREG	Abortion spontaneous/ MISCARRIAGE	2	OCT2020	22/	3	No	O	NA	R	Y/N	
16-55/ C4591001	VASC	Deep vein thrombosis/ RIGHT LOWER EXTREMITY DEEP VEIN THROMBOSIS	2	15NOV2020	20/C	3	No	O	NA/TC	RG	Y/N	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)		
1016 10161289												
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	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1019 10191226 16-55/ C4591001 1019 10191254 16-55/ C4591001 1021 10211127 16-55/ C4591001 1022 10221164 16-55/ C4591001 1028 10281033 16-55/ C4591001	PSYCH	Suicide attempt/ Attempted Suicide#	2	09MAR2021	168/2	3	No	CD	NA	RS (10MAR2021)	Y/N	
	INFEC	COVID-19/ COVID-19 Illness	2	28DEC2020	76/27	3	No	O	NA	R (23JAN2021)	Y/N	
	INFEC	Urinary tract infection/ Urinary Tract Infection	1	15OCT2020	11/10	3	No	O	NA/TC	R (24OCT2020)	Y/N	
	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	
	NEOPL	Plasma cell myeloma/ IGA Kappa Multiple Myeloma	2	27NOV2020	51/C	2	No	O	NA	N	Y/N	
	SOCCI	Miscarriage of partner/ miscarriage for pregnant partner	2	22DEC2020	103/1	2	No	O	NA	R (22DEC2020)	Y/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	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1048 10481032		Impaired gastric emptying/ Worsening of gastroparesis	2	14FEB2021	153/4	3	No	O	NA/TC	R (17FEB2021)	Y/N
16-55/ C4591001 1052 10521172	NERV	Seizure/ Seizure#	4	05FEB2021	11/1	1	No	O	NA/TC	R (05FEB2021)	Y/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 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

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
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	
16-55/ 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	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)		
16-55/ C4591001 1081 10811194 16-55/ C4591001 1082 10821083 16-55/ C4591001 1082 10821149 16-55/ C4591001 1083 10831029 16-55/ C4591001 1083 10831060 16-55/ C4591001 1083 10831162 16-55/ C4591001	METAB	Type 2 diabetes mellitus/ Type II Diabetes Mellitus	2	27OCT2020	36/C	3	No	O	NA/TC	RG	Y/N	
	CARD	Myocardial infarction/ Myocardial Infarction	2	04NOV2020	37/1	4	No	O	NA/W	F (04NOV2020)	Y/N	
	CARD	Myocardial infarction/ myocardial infarction	2	28OCT2020	62/8	4	No	O	NA	R (04NOV2020)	Y/N	
	NEOPL	Malignant melanoma/ Malignant Melanoma (etiology unknown)	2	24NOV2020	63/C	3	No	O	NA/W	N	Y/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	
	GASTR	Diverticular perforation/ Ruptured diverticulum	1	14AUG2020	9/11	4	No	O	P/TC/TCN	R (24AUG2020)	Y/N	
	PREG	Abortion spontaneous/ Miscarriage	2	04DEC2020	80/2	2	No	O	NA	R (05DEC2020)	Y/N	
	CARD	Atrial fibrillation/ New Onset Atrial Fibrillation with rapid ventricular response	2	26OCT2020	34/C	2	No	O	NA/TC	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 ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)		
1083 10831194 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 1084 10841480	CARD	Acute myocardial infarction/ ST-segment elevated MYOCARDIAL INFARCTION	1	26OCT2020	13/1	2	No	O	NA/TC	R (26OCT2020)	Y/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	
		Endometriosis/ Endometriosis#	2	09FEB2021	172/3	3	No	O	NA/TCN	R (11FEB2021)	Y/N	
16-55/ C4591001 1088 10881220	NEOPL	Meningioma/ right frontal meningioma	1	23SEP2020	6/C	2	No	O	NA	N	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)		
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	
16-55/ C4591001 1089 10891182	INJ&P	Hip fracture/ Left Hip Closed Fracture	1	09SEP2020	16/17	3	No	O	NA/TC	R (25SEP2020)	Y/N	
	PSYCH	Psychotic disorder/ Psychosis	1	27SEP2020	34/C	3	No	O	NA/TC/TCN	N	Y/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	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	INFEC	Pyelonephritis/ pyelonephritis	2	11FEB2021	91/2	2	No	O	NA/TC	R (12FEB2021)	Y/N	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)		
1090 10901536												
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	
16-55/ 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	CARD	Acute myocardial infarction/ STEMI: ST elevation Myocardial Infarction	1	05SEP2020	8/5	4	No	O	NA/TC/TCN	R (09SEP2020)	Y/N	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1095 10951173											
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
16-55/ 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

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	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 1110 11101236	EYE	Visual impairment/ change in vision	2	06DEC2020	66/2	2	No	O	NA	R (07DEC2020)	Y/N	
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	NEOPL	Uterine leiomyoma/ Worsening INTRAMURAL AND	2	14SEP2020	14/66	3	No	O	NA/TCN	R (18NOV2020)	Y/N	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1112 11121122		SUBSEROUS LEIOMYOMA OF UTERUS									
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/ Choledocholithiasis	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
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

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1121 11211112 16-55/ C4591001 1124 11241106 16-55/ C4591001 1125 11251020 16-55/ C4591001 1127 11271112 16-55/ C4591001 1128 11281103 16-55/ C4591001	NEOPL	Lung cancer metastatic/ Metastatic Lung cancer	2	04DEC2020	67/47	4	No	O	NA/TC/W	F (19JAN2021)	Y/N
	INFEC	COVID-19/ COVID-19	2	24OCT2020	26/C	3	No	O	NA/TC	RS	Y/N
	CARD	Acute myocardial infarction/ ST elevation myocardial infarction	2	27SEP2020	12/17	4	No	O	NA	R (13OCT2020)	Y/N
	INJ&P	Craniocerebral injury/ traumatic brain injury	2	23DEC2020	111/30	3	No	O	NA/TC	R (21JAN2021)	Y/N
	CARD	Cardio-respiratory arrest/ Cardiopulmonary arrest	2	04DEC2020	86/1	4	No	O	NA/W	F (04DEC2020)	Y/N
	INFEC	Escherichia urinary tract infection/ Escherichia coli urinary tract infection	2	03OCT2020	33/20	2	No	O	NA/TC	R (22OCT2020)	Y/N
	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
	INFEC	Appendicitis/ APPENDICITIS#	2	15JAN2021	129/2	3	No	O	NA/TC/TCN	R (16JAN2021)	Y/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1128 11281123											
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 1129 11291260	IMMUN	Anaphylactoid reaction/ Anaphylactoid Reaction#	3	27JAN2021	3/1	4	Yes		P/TC	R (27JAN2021)	Y/N
16-55/ C4591001	PSYCH	Anxiety/ Increased Anxiety#	3	02MAR2021	21/C	3	No	O	NA/TC	N	Y/N

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1131 11311094	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 1135 11351563	GASTR	Pancreatitis acute/ acute pancreatitis	2	21NOV2020	2/4	2	No	O	NA/TC	R (24NOV2020)	Y/N	
16-55/ C4591001	IMMUN	Anaphylactic reaction/ Anaphylaxis Status Post Bee Sting	2	28AUG2020	9/1	4	No	O	NA/TC	R (28AUG2020)	Y/N	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1140 11401009											
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
16-55/ C4591001	INFEC	Appendicitis/ Acute Appendicitis	2	05DEC2020	68/2	3	No	O	NA/TCN	R (06DEC2020)	Y/N

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)		
1142 11421202 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	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)		
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	PREG	Abortion spontaneous incomplete/ INCOMPLETE SPONTANEOUS ABORTION	2	04OCT2020	25/4	3	No	O	NA/TCN	R (07OCT2020)	Y/N	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)		
1156 11561007												
16-55/ C4591001	INJ&P	Overdose/ MULTIPLE DRUG OVERDOSE	2	02NOV2020	32/1	4	No	O	NA/W	F (02NOV2020)	Y/N	
1156 11561124												
	RESP	Respiratory arrest/ RESPIRATORY ARREST	2	02NOV2020	32/1	4	No	O	NA/W	F (02NOV2020)	Y/N	
16-55/ C4591001	HEPAT	Cholecystitis acute/ Acute Cholecystitis	1	21AUG2020	5/2	3	No	O	NA/TC/TCN	R (22AUG2020)	Y/N	
1167 11671009												
	HEPAT	Hepatitis acute/ Acute hepatitis#	4	25FEB2021	53/C	2	No	O	NA/TC	RG	Y/N	
16-55/ C4591001	NERV	Cerebrovascular accident/ Cerebrovascular accident	2	21OCT2020	23/C	3	No	O	NA/TC	RG	Y/N	
1167 11671175												
16-55/ C4591001	INJ&P	Lower limb fracture/ Right Lower Extremity Fracture#	4	22JAN2021	3/C	3	No	O	NA/TCN	RG	Y/N	
1170 11701121												
16-55/ C4591001	PREG	Abortion spontaneous/ Abortion Spontaneous#	2	23DEC2020	94/1		No	O	NA	R (23DEC2020)	Y/N	
1177 11771222												
16-55/ C4591001	BLOOD	Lymphadenopathy/ right axilla lymphadenopathy	1	16SEP2020	13/66	2	Yes		P/TC	R (20NOV2020)	Y/N	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1178 11781107 16-55/ C4591001 1178 11781257	NEOPL	Breast cancer/ left breast carcinoma	2	13JAN2021	90/C	3	No	O	NA	N	Y/N
16-55/ C4591001 1195 11951003	MUSC	Spondylolisthesis/ Spondylolisthasis 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	INFEC	Anal abscess/ Anal Abscess	2	04JAN2021	35/3	2	No	O	NA/TC/TCN	R (06JAN2021)	Y/N

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1205 12051075	NEOPL	Lipoma/ Encapsulated Lipoma	2	11JAN2021	41/10	2	No	O	NA/TC	R (20JAN2021)	Y/N
16-55/ C4591001 1205 12051077		RESP	Nasal septum deviation/ Nasal Septum Deviation	2	11JAN2021	41/10	2	No	O	NA/TC/TCN	R (20JAN2021)
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	PSYCH	Alcohol abuse/ Alcohol abuse	2	09JAN2021	47/C	1	No	O	NA/TCN	RG	Y/N

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
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
16-55/ 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	INJ&P	Forearm fracture/ Right forearm fracture	2	20SEP2020	18/10	3	No	O	NA/TC/TCN	R (29SEP2020)	Y/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12261583 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 1226 12261836	MUSC	Myalgia/ Muscle pain#	3	12FEB2021	21/2	3	No	O	NA/TC	R (13FEB2021)	Y/N
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

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
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 1231 12311118	RENAL	Nephrolithiasis/ worsening of renal lithiasis	2	21NOV2020	79/7	3	No	O	NA/TC	R (27NOV2020)	Y/N
16-55/ C4591001 1231 12311128	NERV	Peripheral nerve lesion/ Right index finger collateral nerve lesion	2	08OCT2020	37/63	3	No	O	NA/TC/TCN	R (09DEC2020)	Y/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	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 ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)		
1231 12311281 16-55/ C4591001 1231 12311294	HEPAT	Cholecystitis acute/ Acute cholecystitis	2	12DEC2020	97/33	3	No	O	NA/TC/TCN	R (13JAN2021)	Y/N	
16-55/ C4591001 1231 12311315	NEOPL	Malignant melanoma/ Pigmented ephiteloid melanoma of the vagina	2	25SEP2020	23/C	2	No	O	NA/TC/TCN	RG	Y/N	
16-55/ C4591001 1231 12311352	GENRL	Influenza like illness/ Flu like syndrome	1	20AUG2020	6/9	3	No	O	NA	R (28AUG2020)	Y/N	
16-55/ C4591001 1231 12311387	INFEC	Urinary tract infection/ Complicated Urinary Tract Infection	2	04JAN2021	123/15	3	No	O	NA/TC	R (18JAN2021)	Y/N	
16-55/ C4591001 1231 12311538	INFEC	Gangrene/ Rightfoot transmetatarsallimited 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	

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
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
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 hipoglycemia	2	16OCT2020	40/1	3	No	O	NA	R (16OCT2020)	Y/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade	Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
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	
16-55/ C4591001 1231 12312390	MUSC	Osteochondritis/ Osteochondritis	1	05SEP2020	18/2	2	No	O	NA	R (06SEP2020)	Y/N	
16-55/ C4591001	INFEC	Appendicitis/ Acute Appendicitis	2	28DEC2020	110/16	3	No	O	NA/TC/TCN	R (12JAN2021)	Y/N	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)		
1231 12312420 16-55/ C4591001 1231 12312476	HEPAT	Bile duct stone/ Choledochal lithiasis	2	23JAN2021	136/C	3	No	O	NA	N	Y/N	
1231 12312476	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	
16-55/ C4591001 1231 12312854	CARD	Arrhythmia supraventricular/ Arrhythmia supraventricular	2	17SEP2020	7/3	4	No	O	NA/TC/TCN	R (19SEP2020)	Y/N	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)		
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 1231 12313193	RENAL	Urinary bladder polyp/ Bladder polyp	2	18SEP2020	9/C	1	No	O	NA/TCN	RG	Y/N	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12313345	NEOPL	Clear cell renal cell carcinoma/ Clear cell renal cell carcinoma	2	12OCT2020	32/C	3	No	O	NA/TCN	N	Y/N	
16-55/ C4591001 1231 12313437	INFEC	Renal abscess/ Right kidney abscess	2	07DEC2020	86/C	2	No	O	NA/TC/TCN	RG	Y/N	
16-55/ C4591001 1231 12313504	HEPAT	Cholelithiasis/ cholelithiasis	2	24DEC2020	103/13	3	No	O	NA/TC/TCN	R (05JAN2021)	Y/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 12313689	HEPAT	Cholecystitis/ Cholecystitis	2	25DEC2020	104/35	2	No	O	NA/TC/TCN	R (28JAN2021)	Y/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 12313785	INFEC	Appendicitis/ Acute appendicitis	2	22OCT2020	39/16	2	No	O	NA/TC/TCN	R (06NOV2020)	Y/N	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)		
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	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)		
16-55/ C4591001 1231 12314583	GASTR	Pancreatitis acute/ acute pancreatitis	2	30NOV2020	77/15	2	No	O	NA/TC	R (14DEC2020)	Y/N	
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	
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	
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 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 12315186	NEOPL	Adenocarcinoma pancreas/ pancreatic ductal adenocarcinoma#	2	17FEB2021	154/C	3	No	O	NA/TC/TCN	RG	Y/N	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
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 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	Gastrooesophageal 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

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		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	
16-55/ 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	PSYCH	Depression/ Worsening of depression	2	25DEC2020	63/22	3	No	O	NA/TC/TCN	R (15JAN2021)	Y/N	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)		
1246 12461070 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 1247 12471121	INJ&P	Flail chest/ Flail Chest	2	30OCT2020	10/C	3	No	O	NA/TC/TCN	N	Y/N	
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	CARD	Myocardial ischaemia/ Myocardial ischemia	2	13NOV2020	12/4	4	No	O	NA/TC	R (16NOV2020)	Y/N	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1251 12511239 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
16-55/ 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	INJ&P	Procedural haemorrhage/ Intraoperative hemorrhage during an	1	03OCT2020	13/5	3	No	O	NA/TC	R (07OCT2020)	Y/N

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)		
4444 44441007	GASTR	elective laparoscopic ovarian cystectomy										
16-55/ C4591001 4444 44441249		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 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 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	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
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
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: 30MAR2021 (12:07) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adae_1002_sae_1655											

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	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 Veritgo	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	

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1055 10551145	GASTR	Dysphagia/ Dysphagia	1	AUG2020	1/C	1	No	O	P	N	N/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	
16-55/ 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	

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1087 10871354	MUSC	Myalgia/ Myalgia	1	11SEP2020	4/C	1	Yes		P/W	N	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 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

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	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 1096 10961031	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	14AUG2020	1/40		No	O	P	R (22SEP2020)	N/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 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	GENRL	Injection site pain/ Grade 3 Pain at Injection site	1	09DEC2020	2/1	3	Yes		P	R (09DEC2020)	N/N

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1125 11251243	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	
16-55/ 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	

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
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	
16-55/ 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	NERV	Dizziness/ Dizziness	1	31AUG2020	1/1	1	Yes		P	R (31AUG2020)	N/N	

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1166 11661047 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	
	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	

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	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 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	
16-55/ 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	CARD	Cardio-respiratory arrest/ Non-traumatic cardiorespiratory arrest	2	05DEC2020	81/2	4	No	O	NA/W	F (06DEC2020)	Y/N	

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)		
1231 12314987 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		
1231 12315441 16-55/ C4591001 1231 12315441	PSYCH	Depression/ Depressive syndrome	1	10SEP2020	12/137	3	No O	P/TC	RS (24JAN2021)	N/N		
1232 12321175 16-55/ C4591001 1232 12321175	VASC	Hypertension/ high blood pressure	1	25SEP2020	23/29	2	No O	P	R (23OCT2020)	N/N		
1232 12321213 16-55/ C4591001 1232 12321213	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	01OCT2020	23/C		No O	P	UNK	N/N		
1232 12321293 16-55/ C4591001 1232 12321293	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	1	22OCT2020	22/C		No O	P	RG	N/N		
1232 12321299 16-55/ C4591001 1232 12321299	VASC	Hypertension/ Hypertension*		06OCT2020	1/C	2	No O	NA/W	UNK	N/N		
16-55/ C4591001	INJ&P	Maternal exposure during pregnancy/	3	10FEB2021	6/C		No O	P	UNK	N/N		

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411208 16-55/ C4591001 1241 12411279	INJ&P	Maternal exposure during pregnancy# 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 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 12412411	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy#	3	12FEB2021	5/C	No	O	P	UNK	N/N	
16-55/ C4591001 1246 12461025	SKIN	Urticaria/ Intermittent urticaria generalised.	1	07OCT2020	10/27	2	Yes	P/TC	R (02NOV2020)	N/N	
16-55/ C4591001	NERV	Syncope/ vasovagal syncope*		20SEP2020	/1	2	No	O	NA/W	R (20SEP2020)	N/N

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1248 12481218 16-55/ C4591001 1254 12541142	INJ&P	Maternal exposure during pregnancy/ Maternal Exposure During Pregnancy	1	12SEP2020	1/C	No	O	P	UNK	N/N
16-55/ C4591001 1254 12541189	NERV	Headache/ headache#	4	18FEB2021	2/2	2	Yes	NA/TC/W	R (19FEB2021)	N/N
16-55/ C4591001 4444 44441979	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	25SEP2020	1/C	No	O	P	UNK	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

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: 30MAR2021 (18:13)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: .nda2_unblinded/C4591001 EUA 1655/adae 1002 disc 1655

16.2.7.7.2 Listing of Deaths – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	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	

Note: MedDRA (v23.1) coding dictionary applied.

Note: † = Human immunodeficiency virus (HIV)-positive subject, ∞ = 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: 31MAR2021 (04:13)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001 EUA 1655/cdl dth 1655