

<b>16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age</b>			
<b>Protocol Deviation Category</b>	<b>Protocol Deviation Subcategory</b>	<b>Number of Subjects</b>	<b>Subject (Number of Deviations if &gt;1)</b>
	Dosing/administration error, subject did not receive correct dose of vaccine	1	C4591001 1231 12313428
Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	462	C4591001 1001 10011005^ (2) C4591001 1001 10011041^ C4591001 1001 10011042^ C4591001 1001 10011044^ C4591001 1001 10011053^ (2) C4591001 1001 10011081 (2) C4591001 1001 10011099 C4591001 1003 10031166 C4591001 1005 10051019 C4591001 1006 10061078 (2) C4591001 1006 10061109 (2) C4591001 1006 10061147 C4591001 1007 10071082 (2) C4591001 1007 10071110

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1007 10071114
			C4591001 1007 10071173 (2)
			C4591001 1007 10071186
			C4591001 1007 10071188
			C4591001 1007 10071212
			C4591001 1007 10071218
			C4591001 1007 10071225
			C4591001 1007 10071237
			C4591001 1007 10071243
			C4591001 1007 10071250
			C4591001 1007 10071266
			C4591001 1007 10071269
			C4591001 1007 10071276
			C4591001 1007 10071286
			C4591001 1007 10071291 (2)

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1007 10071295
			C4591001 1007 10071335
			C4591001 1007 10071339
			C4591001 1007 10071380
			C4591001 1007 10071387
			C4591001 1007 10071402
			C4591001 1007 10071556
			C4591001 1009 10091035
			C4591001 1009 10091064
			C4591001 1009 10091107 (2)
			C4591001 1009 10091133
			C4591001 1009 10091185
			C4591001 1012 10121040 (2)
			C4591001 1012 10121083
			C4591001 1012 10121110

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1013 10131604
			C4591001 1015 10151116
			C4591001 1016 10161087
			C4591001 1016 10161194
			C4591001 1016 10161280
			C4591001 1018 10181009
			C4591001 1018 10181027
			C4591001 1018 10181039
			C4591001 1018 10181058
			C4591001 1018 10181105
			C4591001 1018 10181111
			C4591001 1018 10181112
			C4591001 1018 10181113
			C4591001 1018 10181127
			C4591001 1018 10181141

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1018 10181164
			C4591001 1018 10181170
			C4591001 1018 10181191
			C4591001 1018 10181204
			C4591001 1018 10181214
			C4591001 1018 10181223
			C4591001 1018 10181302
			C4591001 1018 10181306
			C4591001 1018 10181319
			C4591001 1019 10191021
			C4591001 1019 10191063
			C4591001 1019 10191223
			C4591001 1021 10211177
			C4591001 1021 10211233
			C4591001 1028 10281160

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1028 10281162 (2)
			C4591001 1030 10301094
			C4591001 1037 10371219
			C4591001 1039 10391124
			C4591001 1039 10391142
			C4591001 1039 10391153
			C4591001 1042 10421028
			C4591001 1042 10421097
			C4591001 1042 10421119
			C4591001 1042 10421134
			C4591001 1042 10421139
			C4591001 1042 10421156
			C4591001 1042 10421187
			C4591001 1042 10421262
			C4591001 1044 10441056

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1046 10461079 (2)
			C4591001 1046 10461251 (2)
			C4591001 1047 10471280
			C4591001 1047 10471281
			C4591001 1048 10481027
			C4591001 1048 10481070
			C4591001 1048 10481085
			C4591001 1052 10521037
			C4591001 1052 10521121
			C4591001 1052 10521127
			C4591001 1052 10521151
			C4591001 1054 10541059
			C4591001 1054 10541062
			C4591001 1054 10541110
			C4591001 1054 10541161

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1055 10551093
			C4591001 1055 10551145
			C4591001 1055 10551152
			C4591001 1056 10561009 (2)
			C4591001 1056 10561197 (2)
			C4591001 1056 10561477 (2)
			C4591001 1057 10571040 (2)
			C4591001 1057 10571050
			C4591001 1057 10571094
			C4591001 1057 10571114
			C4591001 1057 10571198
			C4591001 1057 10571201
			C4591001 1057 10571222
			C4591001 1057 10571236 (2)
			C4591001 1066 10661032 (2)



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Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1066 10661121
			C4591001 1068 10681107
			C4591001 1071 10711234
			C4591001 1072 10721003
			C4591001 1072 10721012
			C4591001 1072 10721029
			C4591001 1072 10721044
			C4591001 1072 10721058
			C4591001 1072 10721062
			C4591001 1072 10721068
			C4591001 1072 10721077
			C4591001 1072 10721084
			C4591001 1079 10791020
			C4591001 1079 10791177 (2)
			C4591001 1080 10801019

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1080 10801055
			C4591001 1081 10811094
			C4591001 1081 10811114
			C4591001 1081 10811186
			C4591001 1083 10831154
			C4591001 1083 10831162
			C4591001 1083 10831220
			C4591001 1083 10831230
			C4591001 1083 10831239
			C4591001 1083 10831242
			C4591001 1083 10831248
			C4591001 1083 10831252
			C4591001 1083 10831284
			C4591001 1084 10841017
			C4591001 1084 10841061

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1084 10841077
			C4591001 1084 10841078
			C4591001 1084 10841137
			C4591001 1084 10841156
			C4591001 1084 10841158
			C4591001 1084 10841198
			C4591001 1084 10841241
			C4591001 1084 10841245
			C4591001 1084 10841264
			C4591001 1084 10841358
			C4591001 1084 10841439 (2)
			C4591001 1084 10841456
			C4591001 1084 10841470
			C4591001 1084 10841476
			C4591001 1084 10841480

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1084 10841505 (2)
			C4591001 1085 10851064
			C4591001 1085 10851069
			C4591001 1085 10851080
			C4591001 1085 10851136
			C4591001 1085 10851137
			C4591001 1085 10851161
			C4591001 1085 10851218
			C4591001 1085 10851223
			C4591001 1085 10851237
			C4591001 1085 10851244
			C4591001 1085 10851286 (2)
			C4591001 1085 10851287
			C4591001 1085 10851322
			C4591001 1085 10851340

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1087 10871066
			C4591001 1087 10871269
			C4591001 1087 10871270
			C4591001 1089 10891103 (2)
			C4591001 1090 10901404
			C4591001 1091 10911091
			C4591001 1091 10911122
			C4591001 1091 10911215
			C4591001 1091 10911228
			C4591001 1093 10931216
			C4591001 1094 10941027
			C4591001 1094 10941054
			C4591001 1094 10941167
			C4591001 1094 10941169
			C4591001 1095 10951031

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1095 10951077
			C4591001 1095 10951139
			C4591001 1096 10961026
			C4591001 1096 10961109
			C4591001 1096 10961216
			C4591001 1096 10961234
			C4591001 1096 10961256
			C4591001 1096 10961292
			C4591001 1096 10961318
			C4591001 1096 10961371
			C4591001 1098 10981008
			C4591001 1098 10981178
			C4591001 1098 10981201
			C4591001 1098 10981203
			C4591001 1098 10981212

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1098 10981224
			C4591001 1098 10981227
			C4591001 1098 10981237 (2)
			C4591001 1107 11071013
			C4591001 1107 11071024 (2)
			C4591001 1109 11091275
			C4591001 1109 11091352
			C4591001 1110 11101053
			C4591001 1110 11101060
			C4591001 1110 11101177
			C4591001 1110 11101188
			C4591001 1110 11101207
			C4591001 1110 11101210 (2)
			C4591001 1110 11101234
			C4591001 1110 11101244

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1111 11111051
			C4591001 1111 11111063
			C4591001 1111 11111065
			C4591001 1111 11111100
			C4591001 1111 11111206
			C4591001 1112 11121062
			C4591001 1112 11121083
			C4591001 1112 11121135
			C4591001 1112 11121243
			C4591001 1114 11141015
			C4591001 1114 11141054
			C4591001 1114 11141102
			C4591001 1114 11141120
			C4591001 1116 11161008
			C4591001 1116 11161012 (2)



### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1116 11161094
			C4591001 1116 11161253
			C4591001 1117 11171114
			C4591001 1118 11181124
			C4591001 1120 11201002
			C4591001 1120 11201096
			C4591001 1120 11201109 (2)
			C4591001 1120 11201164
			C4591001 1120 11201212 (2)
			C4591001 1120 11201242 (2)
			C4591001 1120 11201287
			C4591001 1120 11201317
			C4591001 1121 11211007 (3)
			C4591001 1121 11211029 (2)
			C4591001 1121 11211042 (2)

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Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1121 11211057 (2)
			C4591001 1121 11211059
			C4591001 1121 11211067
			C4591001 1121 11211071 (2)
			C4591001 1121 11211079
			C4591001 1121 11211087
			C4591001 1121 11211104
			C4591001 1122 11221002
			C4591001 1122 11221003
			C4591001 1122 11221038
			C4591001 1122 11221050
			C4591001 1123 11231104
			C4591001 1123 11231145
			C4591001 1123 11231193
			C4591001 1123 11231214

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1123 11231244
			C4591001 1123 11231249
			C4591001 1123 11231273
			C4591001 1124 11241015
			C4591001 1124 11241025
			C4591001 1124 11241052
			C4591001 1124 11241103
			C4591001 1124 11241120 (2)
			C4591001 1124 11241140
			C4591001 1125 11251043
			C4591001 1126 11261045
			C4591001 1126 11261080
			C4591001 1126 11261135
			C4591001 1126 11261147
			C4591001 1126 11261151

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1127 11271009
			C4591001 1127 11271041 (2)
			C4591001 1127 11271051
			C4591001 1127 11271089
			C4591001 1127 11271098
			C4591001 1128 11281010
			C4591001 1128 11281026
			C4591001 1128 11281036
			C4591001 1128 11281079
			C4591001 1128 11281083
			C4591001 1128 11281112
			C4591001 1128 11281132
			C4591001 1128 11281177
			C4591001 1128 11281185
			C4591001 1128 11281227

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1128 11281265
			C4591001 1128 11281335
			C4591001 1129 11291037
			C4591001 1129 11291064
			C4591001 1129 11291072
			C4591001 1129 11291174
			C4591001 1129 11291199
			C4591001 1130 11301028
			C4591001 1130 11301094 (2)
			C4591001 1133 11331089
			C4591001 1133 11331104
			C4591001 1133 11331130
			C4591001 1133 11331304 (2)
			C4591001 1133 11331314
			C4591001 1133 11331406

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1133 11331424
			C4591001 1133 11331425
			C4591001 1133 11331438 (2)
			C4591001 1133 11331555
			C4591001 1134 11341069
			C4591001 1134 11341073
			C4591001 1134 11341206
			C4591001 1135 11351092
			C4591001 1135 11351241 (2)
			C4591001 1135 11351426 (2)
			C4591001 1135 11351555
			C4591001 1139 11391042
			C4591001 1140 11401172
			C4591001 1140 11401176
			C4591001 1140 11401191

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1142 11421112
			C4591001 1145 11451014
			C4591001 1145 11451023
			C4591001 1145 11451040
			C4591001 1147 11471001
			C4591001 1147 11471007 (3)
			C4591001 1147 11471023
			C4591001 1147 11471036
			C4591001 1147 11471047
			C4591001 1147 11471117
			C4591001 1149 11491025 (2)
			C4591001 1149 11491040
			C4591001 1149 11491307
			C4591001 1152 11521099
			C4591001 1152 11521134 (2)

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1152 11521137
			C4591001 1152 11521192 (2)
			C4591001 1152 11521347 (2)
			C4591001 1152 11521425
			C4591001 1156 11561024 (2)
			C4591001 1156 11561038
			C4591001 1157 11571069
			C4591001 1157 11571161
			C4591001 1163 11631005
			C4591001 1163 11631041
			C4591001 1166 11661013
			C4591001 1166 11661105
			C4591001 1167 11671071 (2)
			C4591001 1167 11671132
			C4591001 1169 11691014



### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1169 11691023
			C4591001 1169 11691034
			C4591001 1169 11691045
			C4591001 1169 11691057
			C4591001 1169 11691069
			C4591001 1170 11701026
			C4591001 1170 11701045
			C4591001 1170 11701081
			C4591001 1170 11701110
			C4591001 1170 11701113
			C4591001 1170 11701171
			C4591001 1170 11701173
			C4591001 1170 11701209
			C4591001 1170 11701224
			C4591001 1170 11701231 (2)

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1170 11701296
			C4591001 1170 11701413
			C4591001 1171 11711071
			C4591001 1171 11711132
			C4591001 1171 11711181
			C4591001 1171 11711183
			C4591001 1171 11711186
			C4591001 1171 11711247
			C4591001 1171 11711250
			C4591001 1171 11711261
			C4591001 1177 11771076
			C4591001 1177 11771157
			C4591001 1177 11771189
			C4591001 1177 11771369
			C4591001 1177 11771476

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1178 11781060
			C4591001 1178 11781065
			C4591001 1178 11781068
			C4591001 1203 12031013
			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 12261467 (2)
			C4591001 1226 12262132
			C4591001 1226 12262138

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1231 12311081
			C4591001 1231 12311132 (2)
			C4591001 1231 12311145
			C4591001 1231 12311230
			C4591001 1231 12311237
			C4591001 1231 12311379
			C4591001 1231 12311647
			C4591001 1231 12311855
			C4591001 1231 12311975 (2)
			C4591001 1231 12312528
			C4591001 1231 12312856
			C4591001 1231 12313059
			C4591001 1231 12313346
			C4591001 1231 12313391
			C4591001 1231 12314046

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1231 12314324
			C4591001 1231 12314974
			C4591001 1231 12315141
			C4591001 1231 12315286
			C4591001 1231 12315386
			C4591001 1231 12315578
			C4591001 1231 12315582 (2)
			C4591001 1232 12321054
			C4591001 1232 12321110
			C4591001 1232 12321202
			C4591001 1241 12411211
			C4591001 1241 12411449
			C4591001 1241 12411465 (2)
			C4591001 1241 12411569 (2)
			C4591001 1241 12412120

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1248 12481041
			C4591001 1251 12511072 (2)
			C4591001 1251 12511264
			C4591001 1254 12541007
			C4591001 1254 12541013
			C4591001 1254 12541167
			C4591001 1258 12581076
			C4591001 1264 12641159
			C4591001 1265 12651015 (2)
			C4591001 1265 12651050
			C4591001 1265 12651087
			C4591001 1265 12651153 (2)
			C4591001 1269 12691014
			C4591001 1269 12691026
			C4591001 1269 12691047

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1269 12691066
			C4591001 1269 12691088
			C4591001 1270 12701003
			C4591001 1270 12701008
			C4591001 1270 12701057
			C4591001 1270 12701069
			C4591001 1270 12701118
			C4591001 1270 12701137
			C4591001 4444 44441327
			C4591001 4444 44441389
			C4591001 4444 44442088
			C4591001 4444 44442130
			C4591001 4444 44442247
	Receipt of blood/plasma products or immunoglobulins within 60 days before enrollment through conclusion of the study.	17	C4591001 1007 10071192
			C4591001 1042 10421023

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1055 10551102
			C4591001 1084 10841470
			C4591001 1091 10911241
			C4591001 1096 10961012
			C4591001 1096 10961305
			C4591001 1107 11071037
			C4591001 1107 11071065
			C4591001 1107 11071121
			C4591001 1125 11251154
			C4591001 1131 11311222
			C4591001 1167 11671228
			C4591001 1170 11701482
			C4591001 1218 12181027
			C4591001 1231 12313697
			C4591001 1231 12313895



### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 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.	20	C4591001 1027 10271054 (2) C4591001 1028 10281059 C4591001 1037 10371146 C4591001 1046 10461261 C4591001 1055 10551182 C4591001 1072 10721037 C4591001 1084 10841077 C4591001 1084 10841403 C4591001 1128 11281138 (3) C4591001 1128 11281241 C4591001 1128 11281250 C4591001 1129 11291037 C4591001 1140 11401020 (2) C4591001 1177 11771204 (2) C4591001 1178 11781282

### 16.2.2 Listing of Important Protocol Deviations – All Subjects $\geq 16$ Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1223 12231159 (3)
			C4591001 1226 12262078
			C4591001 1231 12314401
			C4591001 1235 12351205
			C4591001 1254 12541144
	Subject received systemic corticosteroids ( $\geq 20$ mg/day of prednisone or equivalent) for $\geq 14$ days is prohibited from 28 days prior to enrollment to specified visits/cohorts per protocol.	13	C4591001 1003 10031101
			C4591001 1007 10071276
			C4591001 1007 10071315
			C4591001 1028 10281026
			C4591001 1039 10391019
			C4591001 1055 10551196
			C4591001 1084 10841077
			C4591001 1130 11301039
			C4591001 1177 11771131
			C4591001 1220 12201029

16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 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).	2	C4591001 1221 12211002 (2)	
			C4591001 1247 12471244	
	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).	3	C4591001 1261 12611054	
			C4591001 1097 10971023	
	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)	14	C4591001 1142 11421084	
			C4591001 1178 11781282	
				C4591001 1178 11781315
				C4591001 1229 12291135†
				C4591001 1044 10441152†
				C4591001 1081 10811093
C4591001 1094 10941191†				
C4591001 1095 10951107				
			C4591001 1096 10961036	

<b>16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age</b>			
<b>Protocol Deviation Category</b>	<b>Protocol Deviation Subcategory</b>	<b>Number of Subjects</b>	<b>Subject (Number of Deviations if &gt;1)</b>
			C4591001 1117 11171036
			C4591001 1117 11171186
			C4591001 1120 11201038
			C4591001 1122 11221034†
			C4591001 1161 11611023
			C4591001 1203 12031048
			C4591001 1231 12311088
			C4591001 1231 12313140
			C4591001 1231 12315608
	Participant failed to meet inclusion criterion #04 (Participants who, in the judgment of the investigator, are at risk for acquiring COVID-19)	1	C4591001 1129 11291117
	Participant met exclusion criterion #01 (participant having other medical or psychiatric condition)	4	C4591001 1006 10061246
			C4591001 1096 10961036
			C4591001 1117 11171036
			C4591001 1117 11171186
	Participant met exclusion criterion #02 (participant having known infection with HIV, HCV or HBV)	8	C4591001 1098 10981155

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1098 10981162
			C4591001 1098 10981168†
			C4591001 1098 10981169†
			C4591001 1170 11701457†
			C4591001 1224 12241158†
			C4591001 1226 12262255†
			C4591001 1251 12511050
	Participant met exclusion criterion #05 (previous clinical or microbiological diagnosis of COVID-19)	6	C4591001 1054 10541033
			C4591001 1231 12311191
			C4591001 1231 12311549
			C4591001 1231 12313211
			C4591001 1235 12351167
			C4591001 1248 12481132
	Participant met exclusion criterion #08 (Immunocompromised individual with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination)	1	C4591001 1022 10221167
	Participant met exclusion criterion #11 (women who are pregnant or breastfeeding)	23	C4591001 1003 10031186

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 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
			C4591001 1226 12261313

<b>16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age</b>			
<b>Protocol Deviation Category</b>	<b>Protocol Deviation Subcategory</b>	<b>Number of Subjects</b>	<b>Subject (Number of Deviations if &gt;1)</b>
			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)	6	C4591001 1022 10221092
			C4591001 1038 10381061
			C4591001 1047 10471122
			C4591001 1047 10471228
			C4591001 1097 10971107
			C4591001 1101 11011077
	Participant met exclusion criterion #16 (Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation)	7	C4591001 1006 10061099
			C4591001 1016 10161194

16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1073 10731023
			C4591001 1081 10811114
			C4591001 1081 10811186
			C4591001 1133 11331085
			C4591001 1134 11341067
	Participant met exclusion criterion #19 ( Phase 1 only: any screening hematology and/or blood chemistry laboratory value that meets the definition of a $\geq$ grade 1 abnormality)	5	C4591001 1002 10021053^
			C4591001 1003 10031017^
			C4591001 1003 10031021^
			C4591001 1003 10031047^
			C4591001 1003 10031070^
	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
			C4591001 1161 11611002
			C4591001 1161 11611008
			C4591001 1161 11611011



16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
Investigational product	Blind compromised	5	C4591001 116111611014
			C4591001 116111611018
			C4591001 106810681001
			C4591001 109610961195
			C4591001 109610961197
Dosing/administration error, subject did not receive correct dose of vaccine		160	C4591001 109610961212
			C4591001 113111311044
			C4591001 100310031120
			C4591001 106810681001
			C4591001 106810681002
			C4591001 106810681003
			C4591001 106810681004
			C4591001 106810681005
			C4591001 106810681006
			C4591001 106810681007

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 10681008
			C4591001 10681009
			C4591001 10681010
			C4591001 10681011
			C4591001 10681012
			C4591001 10681013
			C4591001 10681014
			C4591001 10681015
			C4591001 10681016
			C4591001 10681017
			C4591001 10681018
			C4591001 10681019
			C4591001 10681020
			C4591001 10681021
			C4591001 10681022

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1068 10681023
			C4591001 1068 10681024
			C4591001 1068 10681025
			C4591001 1068 10681026
			C4591001 1068 10681027
			C4591001 1068 10681028
			C4591001 1068 10681029
			C4591001 1068 10681030
			C4591001 1068 10681031
			C4591001 1068 10681032
			C4591001 1068 10681033
			C4591001 1068 10681034
			C4591001 1068 10681035
			C4591001 1068 10681036
			C4591001 1068 10681037

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 10681068
			C4591001 10681038
			C4591001 10681039
			C4591001 10681040
			C4591001 10681041
			C4591001 10681042
			C4591001 10681043
			C4591001 10681044
			C4591001 10681045
			C4591001 10681046
			C4591001 10681047
			C4591001 10681050
			C4591001 10681051
			C4591001 10681052
			C4591001 10681053
			C4591001 10681054

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1068 10681055
			C4591001 1068 10681056
			C4591001 1068 10681057
			C4591001 1068 10681058
			C4591001 1068 10681059
			C4591001 1068 10681060
			C4591001 1068 10681061
			C4591001 1068 10681062
			C4591001 1068 10681063
			C4591001 1068 10681064
			C4591001 1068 10681065
			C4591001 1068 10681066
			C4591001 1068 10681068
			C4591001 1068 10681069
			C4591001 1068 10681071

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1068 10681072
			C4591001 1068 10681073
			C4591001 1068 10681074
			C4591001 1068 10681075
			C4591001 1068 10681076
			C4591001 1068 10681077
			C4591001 1068 10681078
			C4591001 1068 10681079
			C4591001 1068 10681080
			C4591001 1068 10681081
			C4591001 1068 10681082
			C4591001 1068 10681083
			C4591001 1068 10681084
			C4591001 1091 10911001
			C4591001 1091 10911004

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1091 10911005
			C4591001 1091 10911008
			C4591001 1091 10911010
			C4591001 1091 10911012
			C4591001 1091 10911014
			C4591001 1091 10911015
			C4591001 1129 11291091
			C4591001 1136 11361027
			C4591001 1136 11361039
			C4591001 1136 11361057
			C4591001 1136 11361059
			C4591001 1136 11361079
			C4591001 1136 11361083
			C4591001 1136 11361084
			C4591001 1136 11361105

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 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 11411066
			C4591001 1141 11411068
			C4591001 1141 11411080
			C4591001 1141 11411093
			C4591001 1141 11411139
			C4591001 1169 11691033
			C4591001 1231 12313429
			C4591001 1231 12313446
			C4591001 1231 12313449
			C4591001 1231 12313456



### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1231 12313459
			C4591001 1231 12313461
			C4591001 1231 12313467
			C4591001 1231 12313468 (2)
			C4591001 1231 12313469 (2)
			C4591001 1231 12313478
			C4591001 1231 12313479
			C4591001 1231 12313480
			C4591001 1231 12313483
			C4591001 1231 12313486
			C4591001 1231 12313487
			C4591001 1231 12313492
			C4591001 1231 12313496
			C4591001 1231 12313497
			C4591001 1231 12313498

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1231 12313501
			C4591001 1231 12313503
			C4591001 1231 12313505
			C4591001 1231 12313506
			C4591001 1231 12313508
			C4591001 1231 12313509
			C4591001 1231 12313511
			C4591001 1231 12313512
			C4591001 1231 12313514
			C4591001 1231 12313515
			C4591001 1231 12313517
			C4591001 1231 12313518
			C4591001 1231 12313519
			C4591001 1231 12313524
			C4591001 1231 12313528

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1231 12313530
			C4591001 1231 12313533
			C4591001 1231 12313534
			C4591001 1231 12313536
			C4591001 1231 12313537
			C4591001 1231 12313538
			C4591001 1231 12313541
			C4591001 1231 12313542
			C4591001 1231 12313546
			C4591001 1231 12313549
			C4591001 1231 12313551
			C4591001 1231 12313553
			C4591001 1231 12313554
			C4591001 1231 12313556
			C4591001 1231 12313562

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1231 12313564
			C4591001 1231 12313567
	IP administered that was deemed not suitable for use by Almac	121	C4591001 1024 10241002
			C4591001 1024 10241003
			C4591001 1024 10241004
			C4591001 1024 10241006
			C4591001 1024 10241014
			C4591001 1024 10241023
			C4591001 1024 10241031
			C4591001 1024 10241032
			C4591001 1024 10241033
			C4591001 1024 10241037
			C4591001 1024 10241039
			C4591001 1024 10241040
			C4591001 1024 10241041

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 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 10241049
			C4591001 1024 10241054
			C4591001 1024 10241055
			C4591001 1024 10241057
			C4591001 1024 10241059
			C4591001 1024 10241061
			C4591001 1024 10241065
			C4591001 1024 10241066
			C4591001 1024 10241067
			C4591001 1024 10241068
			C4591001 1024 10241071
			C4591001 1024 10241072

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1024 10241074
			C4591001 1024 10241077
			C4591001 1024 10241078
			C4591001 1024 10241081
			C4591001 1024 10241083
			C4591001 1024 10241084
			C4591001 1024 10241085
			C4591001 1024 10241087
			C4591001 1024 10241091
			C4591001 1024 10241094
			C4591001 1024 10241096
			C4591001 1024 10241097
			C4591001 1024 10241100
			C4591001 1024 10241102
			C4591001 1024 10241104

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1024 10241108
			C4591001 1044 10441001
			C4591001 1044 10441002
			C4591001 1044 10441004
			C4591001 1044 10441007
			C4591001 1044 10441010
			C4591001 1044 10441015
			C4591001 1044 10441016
			C4591001 1044 10441018
			C4591001 1044 10441028
			C4591001 1044 10441029
			C4591001 1044 10441031
			C4591001 1044 10441032
			C4591001 1044 10441034
			C4591001 1044 10441036

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1044 10441037
			C4591001 1044 10441041
			C4591001 1044 10441045
			C4591001 1044 10441047
			C4591001 1044 10441048
			C4591001 1044 10441049
			C4591001 1044 10441050
			C4591001 1044 10441052
			C4591001 1044 10441054
			C4591001 1044 10441055
			C4591001 1044 10441060
			C4591001 1044 10441062
			C4591001 1044 10441063
			C4591001 1044 10441067
			C4591001 1044 10441068



### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1044 10441071
			C4591001 1044 10441073
			C4591001 1044 10441075
			C4591001 1044 10441076
			C4591001 1044 10441079
			C4591001 1044 10441080
			C4591001 1044 10441083
			C4591001 1044 10441085
			C4591001 1044 10441088
			C4591001 1044 10441089
			C4591001 1044 10441090
			C4591001 1044 10441092
			C4591001 1044 10441093
			C4591001 1044 10441094
			C4591001 1096 10961011

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1096 10961027
			C4591001 1096 10961059
			C4591001 1096 10961068
			C4591001 1096 10961149
			C4591001 1096 10961209
			C4591001 1096 10961245
			C4591001 1096 10961246
			C4591001 1096 10961247
			C4591001 1096 10961324
			C4591001 1129 11291091
			C4591001 1163 11631117
			C4591001 1163 11631121
			C4591001 1163 11631124
			C4591001 1163 11631126
			C4591001 1163 11631127

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1163 11631131
			C4591001 1163 11631132
			C4591001 1163 11631133
			C4591001 1163 11631136
			C4591001 1163 11631142
			C4591001 1163 11631144
			C4591001 1163 11631145
			C4591001 1163 11631149
			C4591001 1232 12321354
			C4591001 1232 12321373
			C4591001 1232 12321382
			C4591001 1232 12321383
			C4591001 1232 12321385
			C4591001 1232 12321389†
			C4591001 1232 12321390

<b>16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age</b>			
<b>Protocol Deviation Category</b>	<b>Protocol Deviation Subcategory</b>	<b>Number of Subjects</b>	<b>Subject (Number of Deviations if &gt;1)</b>
			C4591001 1232 12321394
			C4591001 1232 12321395
			C4591001 1232 12321398
	Incorrect IP assigned to subject due to IRT not being utilized	4	C4591001 1121 11211071
			C4591001 1163 11631005 (2)
			C4591001 1163 11631006 (2)
			C4591001 1163 11631008
	Incorrect vaccine allocation/assigned to subject	11	C4591001 1012 10121103
			C4591001 1054 10541024
			C4591001 1079 10791130
			C4591001 1081 10811053
			C4591001 1088 10881077 (2)
			C4591001 1090 10901334
			C4591001 1116 11161226
			C4591001 1169 11691049

<b>16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age</b>			
<b>Protocol Deviation Category</b>	<b>Protocol Deviation Subcategory</b>	<b>Number of Subjects</b>	<b>Subject (Number of Deviations if &gt;1)</b>
			C4591001 1177 11771089
			C4591001 1231 12311057
			C4591001 1265 12651026
	Other IP deviation	23	C4591001 1037 10371356
			C4591001 1081 10811204
			C4591001 1096 10961195
			C4591001 1096 10961197
			C4591001 1101 11011024
			C4591001 1126 11261053
			C4591001 1129 11291115
			C4591001 1129 11291166
			C4591001 1161 11611015
			C4591001 1163 11631003 (2)
			C4591001 1163 11631007
			C4591001 1163 11631008 (3)

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1163 11631010
			C4591001 1163 11631011
			C4591001 1163 11631013
			C4591001 1163 11631030
			C4591001 1163 11631039
			C4591001 1163 11631062
			C4591001 1163 11631064
			C4591001 1163 11631092
			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†

<b>16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age</b>			
<b>Protocol Deviation Category</b>	<b>Protocol Deviation Subcategory</b>	<b>Number of Subjects</b>	<b>Subject (Number of Deviations if &gt;1)</b>
	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.	6	C4591001 1007 10071105  C4591001 1028 10281241 C4591001 1028 10281294 C4591001 1097 10971060 C4591001 1231 12311499 C4591001 1247 12471244
Laboratory	Nasal swab can't be analyzed due to incorrect shipping procedure	4	C4591001 1068 10681043 C4591001 1068 10681068 C4591001 1083 10831154 C4591001 1128 11281313
Other	Efficacy data considered potentially unreliable due to lack of PI oversight identified as significant quality event	33	C4591001 1161 11611001 C4591001 1161 11611003 C4591001 1161 11611004 C4591001 1161 11611007

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1161 11611008
			C4591001 1161 11611009
			C4591001 1161 11611010
			C4591001 1161 11611014
			C4591001 1161 11611017
			C4591001 1161 11611020
			C4591001 1161 11611021
			C4591001 1161 11611022
			C4591001 1161 11611023
			C4591001 1161 11611024
			C4591001 1161 11611025
			C4591001 1161 11611026
			C4591001 1161 11611027
			C4591001 1161 11611028
			C4591001 1161 11611029



### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1161 11611030
			C4591001 1161 11611031
			C4591001 1161 11611032
			C4591001 1161 11611033
			C4591001 1161 11611034
			C4591001 1161 11611035
			C4591001 1161 11611036
			C4591001 1161 11611037
			C4591001 1161 11611038
			C4591001 1161 11611040
			C4591001 1161 11611041
			C4591001 1161 11611042
			C4591001 1161 11611043
			C4591001 1161 11611044
	Safety and efficacy data considered potentially unreliable due to lack of PI oversight identified as significant quality event.	10	C4591001 1161 11611002

16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1161 11611005
			C4591001 1161 11611006
			C4591001 1161 11611011
			C4591001 1161 11611012
			C4591001 1161 11611013
			C4591001 1161 11611015
			C4591001 1161 11611016
			C4591001 1161 11611018
			C4591001 1161 11611019
Procedures/tests	Procedure/Test not done	1	C4591001 1146 11461010
	Subject had a vaccination diary activated, but was not part of the reactogenicity subset	31	C4591001 1098 10981168† (2)
			C4591001 1098 10981169†
			C4591001 1110 11101279†
			C4591001 1112 11121174
			C4591001 1133 11331537

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1219 12191001
			C4591001 1219 12191002
			C4591001 1219 12191003
			C4591001 1219 12191004
			C4591001 1219 12191005
			C4591001 1219 12191007
			C4591001 1219 12191008
			C4591001 1219 12191009
			C4591001 1219 12191010
			C4591001 1219 12191011
			C4591001 1219 12191012
			C4591001 1219 12191013
			C4591001 1219 12191014
			C4591001 1219 12191015
			C4591001 1219 12191016

### 16.2.2 Listing of Important Protocol Deviations – All Subjects ≥16 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1219 12191017
			C4591001 1219 12191018
			C4591001 1219 12191042
			C4591001 1219 12191043
			C4591001 1219 12191044
			C4591001 1219 12191045
			C4591001 1219 12191048
			C4591001 1235 12351150
			C4591001 1235 12351152
			C4591001 1235 12351153
			C4591001 1235 12351155

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