

16.2.2.2 Listing of Important Protocol Deviations – Phase 2

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
Concomitant Medications	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.	1	C4591001 1003 10031101
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adv Table Generation: 24NOV2020 (13:02) (CutoffDate: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_EUA_FAEF_RR/adv_i001_pd2			

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
Concomitant Medications	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 1003 10031101
			C4591001 1007 10071276
			C4591001 1007 10071315
			C4591001 1028 10281026
			C4591001 1039 10391019
			C4591001 1130 11301039
			C4591001 1261 12611054
Inclusion/Exclusion	Receipt of blood/plasma products or immunoglobulins within 60 days before enrollment through conclusion of the study.	1	C4591001 1231 12313895
	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)	13	C4591001 1037 10371333
			C4591001 1094 10941191

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1095 10951107
			C4591001 1122 11221034
			C4591001 1170 11701334
			C4591001 1170 11701344
			C4591001 1174 11741066
			C4591001 1205 12051028
			C4591001 1217 12171005
			C4591001 1229 12291165
			C4591001 1231 12311088
			C4591001 1231 12315608

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1265 12651164
	Participant met exclusion criterion #02 (participant having known infection with HIV, HCV or HBV)	9	C4591001 1098 10981155
			C4591001 1098 10981162
			C4591001 1098 10981168
			C4591001 1098 10981169
			C4591001 1170 11701457
			C4591001 1224 12241158
			C4591001 1226 12262255
			C4591001 1251 12511050
			C4591001 1265 12651186

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
	Participant met exclusion criterion #11 (women who are pregnant or breastfeeding)	6	C4591001 1087 10871557
			C4591001 1093 10931058
			C4591001 1096 10961031
			C4591001 1156 11561015
			C4591001 1232 12321213
			C4591001 1241 12411279
	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

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1161 11611014
			C4591001 1161 11611018
	Participant met exclusion criterion #13 (participant receiving treatment with immunosuppressive therapy as specified in protocol)	5	C4591001 1038 10381061
			C4591001 1047 10471122
			C4591001 1047 10471228
			C4591001 1097 10971107
			C4591001 1101 11011077
	Participant met exclusion criterion #05 (previous clinical or microbiological diagnosis of COVID-19)	2	C4591001 1054 10541033
			C4591001 1235 12351167
	Participant met exclusion criterion #16 (Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation)	2	C4591001 1006 10061099

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1134 11341067
	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 1142 11421084
	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
Informed Consent	Subject/LAR did not sign ICD & did not give verbal consent	1	C4591001 1120 11201299
Investigational Product	Dosing/administration error, subject did not receive correct dose of vaccine	151	C4591001 1003 10031120
			C4591001 1068 10681001
			C4591001 1068 10681002
			C4591001 1068 10681003
			C4591001 1068 10681004
			C4591001 1068 10681005

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1068 10681006
			C4591001 1068 10681007
			C4591001 1068 10681008
			C4591001 1068 10681009
			C4591001 1068 10681010
			C4591001 1068 10681011
			C4591001 1068 10681012
			C4591001 1068 10681013
			C4591001 1068 10681014
			C4591001 1068 10681015

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1068 10681016
			C4591001 1068 10681017
			C4591001 1068 10681018
			C4591001 1068 10681019
			C4591001 1068 10681020
			C4591001 1068 10681021
			C4591001 1068 10681022
			C4591001 1068 10681023
			C4591001 1068 10681024
			C4591001 1068 10681025

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			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

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1068 10681036
			C4591001 1068 10681037
			C4591001 1068 10681038
			C4591001 1068 10681039
			C4591001 1068 10681040
			C4591001 1068 10681041
			C4591001 1068 10681042
			C4591001 1068 10681043
			C4591001 1068 10681044
			C4591001 1068 10681045

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1068 10681046
			C4591001 1068 10681047
			C4591001 1068 10681050
			C4591001 1068 10681051
			C4591001 1068 10681052
			C4591001 1068 10681053
			C4591001 1068 10681054
			C4591001 1068 10681055
			C4591001 1068 10681056
			C4591001 1068 10681057

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			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

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1068 10681069
			C4591001 1068 10681071
			C4591001 1068 10681072
			C4591001 1068 10681073
			C4591001 1068 10681074
			C4591001 1068 10681075
			C4591001 1068 10681076
			C4591001 1068 10681077
			C4591001 1068 10681078
			C4591001 1068 10681079

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1068 10681080
			C4591001 1068 10681081
			C4591001 1068 10681082
			C4591001 1068 10681083
			C4591001 1068 10681084
			C4591001 1091 10911001
			C4591001 1091 10911004
			C4591001 1091 10911005
			C4591001 1091 10911008
			C4591001 1091 10911010

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1091 10911012
			C4591001 1091 10911014
			C4591001 1091 10911015
			C4591001 1129 11291091
			C4591001 1141 11411011
			C4591001 1141 11411014
			C4591001 1141 11411023
			C4591001 1141 11411065
			C4591001 1141 11411066
			C4591001 1141 11411068

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1141 11411080
			C4591001 1141 11411093
			C4591001 1141 11411139
			C4591001 1231 12313428
			C4591001 1231 12313429
			C4591001 1231 12313446
			C4591001 1231 12313449
			C4591001 1231 12313456
			C4591001 1231 12313459
			C4591001 1231 12313461

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

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

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1231 12313496
			C4591001 1231 12313497
			C4591001 1231 12313498
			C4591001 1231 12313501
			C4591001 1231 12313503
			C4591001 1231 12313505
			C4591001 1231 12313506
			C4591001 1231 12313508
			C4591001 1231 12313509
			C4591001 1231 12313511

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

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 12313524
			C4591001 1231 12313528
			C4591001 1231 12313530
			C4591001 1231 12313533

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			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

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1231 12313554
			C4591001 1231 12313556
			C4591001 1231 12313562
			C4591001 1231 12313564
			C4591001 1231 12313567
	IP administered that was deemed not suitable for use by Almac	144	C4591001 1024 10241002(2)
			C4591001 1024 10241003(2)
			C4591001 1024 10241004(2)
			C4591001 1024 10241006(2)
			C4591001 1024 10241009

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1024 10241010
			C4591001 1024 10241014(2)
			C4591001 1024 10241015
			C4591001 1024 10241018
			C4591001 1024 10241019
			C4591001 1024 10241021
			C4591001 1024 10241023(2)
			C4591001 1024 10241031
			C4591001 1024 10241032
			C4591001 1024 10241033

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1024 10241037
			C4591001 1024 10241039
			C4591001 1024 10241040
			C4591001 1024 10241041
			C4591001 1024 10241042
			C4591001 1024 10241044
			C4591001 1024 10241046
			C4591001 1024 10241049
			C4591001 1024 10241054
			C4591001 1024 10241055

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			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
			C4591001 1024 10241074

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			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

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1024 10241097
			C4591001 1024 10241100
			C4591001 1024 10241102
			C4591001 1024 10241104
			C4591001 1024 10241108
			C4591001 1044 10441001
			C4591001 1044 10441002
			C4591001 1044 10441004
			C4591001 1044 10441007
			C4591001 1044 10441010

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			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
			C4591001 1044 10441037

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			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

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1044 10441062
			C4591001 1044 10441063
			C4591001 1044 10441067
			C4591001 1044 10441068
			C4591001 1044 10441071
			C4591001 1044 10441073
			C4591001 1044 10441075
			C4591001 1044 10441076
			C4591001 1044 10441079
			C4591001 1044 10441080

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			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 1163 11631117
			C4591001 1163 11631121

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1163 11631124
			C4591001 1163 11631126
			C4591001 1163 11631127
			C4591001 1163 11631131
			C4591001 1163 11631132
			C4591001 1163 11631133
			C4591001 1163 11631136
			C4591001 1163 11631142
			C4591001 1163 11631144
			C4591001 1163 11631145

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1163 11631149
			C4591001 1254 12541002
			C4591001 1254 12541004
			C4591001 1254 12541005
			C4591001 1254 12541008
			C4591001 1254 12541010
			C4591001 1254 12541011
			C4591001 1254 12541014
			C4591001 1254 12541016
			C4591001 1254 12541018

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1254 12541019
			C4591001 1254 12541023
			C4591001 1254 12541025
			C4591001 1254 12541026
			C4591001 1254 12541027
			C4591001 1254 12541029
			C4591001 1254 12541030
			C4591001 1254 12541033
			C4591001 1254 12541035
			C4591001 1254 12541037

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1254 12541038
			C4591001 1254 12541040
			C4591001 1260 12601002
			C4591001 1260 12601003
			C4591001 1260 12601005
			C4591001 1260 12601006
			C4591001 1260 12601008
			C4591001 1260 12601009
			C4591001 1260 12601013
			C4591001 1260 12601014

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1260 12601016
			C4591001 1260 12601017
			C4591001 1260 12601025
			C4591001 1260 12601026
			C4591001 1260 12601027
			C4591001 1260 12601029
			C4591001 1260 12601032
			C4591001 1260 12601033
			C4591001 1260 12601036
Incorrect vaccine allocation/assigned to subject		10	C4591001 1012 10121103

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1054 10541024
			C4591001 1079 10791130
			C4591001 1081 10811053
			C4591001 1088 10881077
			C4591001 1090 10901334
			C4591001 1116 11161226
			C4591001 1177 11771089
			C4591001 1231 12311057
			C4591001 1265 12651026
Other IP deviation		9	C4591001 1037 10371356

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1126 11261053
			C4591001 1161 11611015
			C4591001 1163 11631003
			C4591001 1163 11631007
			C4591001 1163 11631008
			C4591001 1163 11631010
			C4591001 1163 11631011
			C4591001 1163 11631096
	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 1007 10071105
			C4591001 1028 10281241

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1097 10971060
			C4591001 1231 12311499
	IP documentation error – IP preparation form errors	3	C4591001 1163 11631008 (2)
			C4591001 1163 11631013
			C4591001 1163 11631039
	Incorrect IP assigned to subject due to IRT not being utilized	3	C4591001 1121 11211071
			C4591001 1163 11631005
			C4591001 1163 11631006
	Subject was vaccinated despite being ineligible	2	C4591001 1092 10921158
			C4591001 1112 11121270

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
	Administration error, incorrect container, but correct IP administered	1	C4591001 1056 10561445
	Blind compromised	1	C4591001 1068 10681001
Laboratory	Nasal swab can't be analyzed due to incorrect shipping procedure	3	C4591001 1068 10681043 C4591001 1068 10681068 C4591001 1128 11281313
Other	All data considered unreliable due to lack of PI oversight identified as significant quality event	43	C4591001 1161 11611001 C4591001 1161 11611002 C4591001 1161 11611003 C4591001 1161 11611004 C4591001 1161 11611005

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1161 11611006
			C4591001 1161 11611007
			C4591001 1161 11611008
			C4591001 1161 11611009
			C4591001 1161 11611010
			C4591001 1161 11611011
			C4591001 1161 11611012
			C4591001 1161 11611013
			C4591001 1161 11611014
			C4591001 1161 11611015

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1161 11611016
			C4591001 1161 11611017
			C4591001 1161 11611018
			C4591001 1161 11611019
			C4591001 1161 11611020
			C4591001 1161 11611021
			C4591001 1161 11611022
			C4591001 1161 11611023
			C4591001 1161 11611024
			C4591001 1161 11611025

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1161 11611026
			C4591001 1161 11611027
			C4591001 1161 11611028
			C4591001 1161 11611029
			C4591001 1161 11611030
			C4591001 1161 11611031
			C4591001 1161 11611032
			C4591001 1161 11611033
			C4591001 1161 11611034
			C4591001 1161 11611035

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1161 11611036
			C4591001 1161 11611037
			C4591001 1161 11611038
			C4591001 1161 11611040
			C4591001 1161 11611041
			C4591001 1161 11611042
			C4591001 1161 11611043
			C4591001 1161 11611044
Procedures/Tests	Procedure/Test not done	1	C4591001 1146 11461010
<p>Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up. Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives</p>			

16.2.2.3 Listing of Important Protocol Deviations – Phase 2/3 Analysis (All Subjects)

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adv Table Generation: 24NOV2020 (13:02) (Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_EUA_FAEF_RR/adv_i001_pd_all			

16.2.2.4 Listing of Important Protocol Deviations – Subjects Enrolled in Multiple Sites			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
Inclusion/Exclusion	Participant met exclusion criterion #04 (receipt of medications intended to prevent COVID-19)	1	C4591001 1133 11331382
Investigational Product	Subject was enrolled more than once in the study, at different sites	2	C4591001 1056 10561101 C4591001 1133 11331382
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adv Table Generation: 24NOV2020 (15:23) (Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_EUA_FAEF_RR/adv_1001_pd_menrl			