

16.2.2 Listing of Important Protocol Deviations – All Subjects 12 Through 15 Years of Age

Unique Subject Identifier/ Vaccine Group (as Randomized)	Deviation Occurrence Site Identifier	Protocol Deviation Category	Protocol Deviation Subcategory	Protocol Deviation Start Date	Visit Designator
C4591001 1006 10061272/ BNT162b2 (30 µg)	1006	Inclusion/exclusion	Participant met exclusion criterion #01 (participant having other medical or psychiatric condition)	16DEC2020	V1_DAY1_VAX1_L
C4591001 1006 10061287/ Placebo	1006	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	11JUN2021	V2_VAX2_L
C4591001 1006 10061287/ Placebo	1006	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	14MAY2021	V2_VAX2_L
C4591001 1007 10071415/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	03JUN2020	V2_VAX2_L
C4591001 1007 10071415/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	13MAY2021	V2_VAX2_L
C4591001 1007 10071428/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	05JUN2021	V2_VAX2_L
C4591001 1007 10071428/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	05MAY2021	V2_VAX2_L
C4591001 1007 10071429/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	03JUN2021	V2_VAX2_L
C4591001 1007 10071429/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	13MAY2021	V2_VAX2_L
C4591001 1007 10071492/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	03JUN2021	V2_VAX2_L

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C4591001 1007 10071492/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	13MAY2021	V2_VAX2_L	
C4591001 1007 10071499/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	04JUN2021	V2_VAX2_L	
C4591001 1007 10071499/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	13MAY2021	V2_VAX2_L	
C4591001 1007 10071515/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	05JUN2021	V2_VAX2_L	
C4591001 1007 10071515/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	14MAY2021	V2_VAX2_L	
C4591001 1007 10071528/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	03JUN2021	V2_VAX2_L	
C4591001 1007 10071528/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	13MAY2021	V2_VAX2_L	
C4591001 1007 10071543/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	03JUN2021	V2_VAX2_L	
C4591001 1007 10071543/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	13MAY2021	V2_VAX2_L	
C4591001 1007 10071554/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	17JUN2021	V2_VAX2_L	

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C4591001 1007 10071554/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	22MAY2021	V2_VAX2_L	
C4591001 1007 10071573/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	03JUN2021	V2_VAX2_L	
C4591001 1007 10071593/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	21JAN2021	V1_DAY1_VAX1_L	
C4591001 1007 10071601/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	13MAY2021	V2_VAX2_L	
C4591001 1007 10071603/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	05JUN2021	V2_VAX2_L	
C4591001 1007 10071604/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	12JUN2021	V2_VAX2_L	
C4591001 1007 10071604/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	13MAY2021	V2_VAX2_L	
C4591001 1007 10071618/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	03JUN2021	V2_VAX2_L	
C4591001 1007 10071618/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	13MAY2021	V2_VAX2_L	
C4591001 1007 10071635/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	14MAY2021	V2_VAX2_L	

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C4591001 1007 10071654/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	17MAY2021		V2_VAX2_L
C4591001 1007 10071662/ Placebo	1007	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	05JUN2021		V2_VAX2_L
C4591001 1008 10081879/ Placebo	1008	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	12JUN2021		V2_VAX2_L
C4591001 1008 10081879/ Placebo	1008	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	21MAY2021	V202_SURVEIL_SWAB 643544415756058	
C4591001 1009 10091229/ Placebo	1009	Investigational product	Subject was vaccinated despite the site being instructed to discontinue further vaccination	18MAR2021		Unplanned Vaccination
C4591001 1009 10091320/ Placebo	1009	Inclusion/exclusion	Participant met exclusion criterion #01 (participant having other medical or psychiatric condition)	10DEC2020		V1_DAY1_VAX1_L
C4591001 1009 10091366/ Placebo	1009	Investigational product	Subject was vaccinated despite the site being instructed to discontinue further vaccination	26FEB2021		Unplanned Vaccination
C4591001 1013 10131839/ Placebo	1013	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	02JUL2021		V2_VAX2_L
C4591001 1039 10391320/ Placebo	1039	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	13JUN2021		V2_VAX2_L
C4591001 1039 10391320/ Placebo	1039	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	17MAY2021		V2_VAX2_L

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C4591001 1039 10391327/ Placebo	1039	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	05JUN2021	V2_VAX2_L
C4591001 1039 10391327/ Placebo	1039	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	15MAY2021	V2_VAX2_L
C4591001 1044 10441271/ Placebo	1044	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	14JUN2021	V2_VAX2_L
C4591001 1044 10441271/ Placebo	1044	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	24MAY2021	V2_VAX2_L
C4591001 1044 10441293/ Placebo	1044	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	04JUN2021	V101_VAX3
C4591001 1044 10441294/ Placebo	1044	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	04JUN2021	V101_VAX3
C4591001 1044 10441356/ Placebo	1044	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	04JUN2021	V2_VAX2_L
C4591001 1044 10441356/ Placebo	1044	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	14MAY2021	V2_VAX2_L
C4591001 1057 10571389/ Placebo	1057	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	12JUN2021	V2_VAX2_L
C4591001 1057 10571389/ Placebo	1057	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	23MAY2021	V2_VAX2_L

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C4591001 1077 10771282/ Placebo	1077	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	15MAY2021	V2_VAX2_L	
C4591001 1077 10771289/ Placebo	1077	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	14MAY2021	V2_VAX2_L	
C4591001 1077 10771290/ Placebo	1077	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	14MAY2021	V2_VAX2_L	
C4591001 1084 10841543/ Placebo	1084	Investigational product	Other IP deviation	07JUN2021	Vax 4	
C4591001 1084 10841579/ Placebo	1084	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	14MAY2021	V2_VAX2_L	
C4591001 1091 10911455/ Placebo	1091	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	03JUN2021	V2_VAX2_L	
C4591001 1091 10911455/ Placebo	1091	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	13MAY2021	V2_VAX2_L	
C4591001 1091 10911456/ Placebo	1091	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	03JUN2021	V2_VAX2_L	
C4591001 1091 10911456/ Placebo	1091	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	13MAY2021	V2_VAX2_L	
C4591001 1091 10911461/ Placebo	1091	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	09JUN2021	V2_VAX2_L	

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C4591001 1091 10911461/ Placebo	1091	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	19MAY2021	V2_VAX2_L	
C4591001 1139 11391169/ Placebo	1139	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	01JUN2021	V2_VAX2_L	
C4591001 1139 11391169/ Placebo	1139	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	11MAY2021	V2_VAX2_L	
C4591001 1139 11391171/ Placebo	1139	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	09JUN2021	V2_VAX2_L	
C4591001 1139 11391171/ Placebo	1139	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	19MAY2021	V2_VAX2_L	
C4591001 1140 11401357/ Placebo	1140	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	03JUN2021	V2_VAX2_L	
C4591001 1140 11401357/ Placebo	1140	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	13MAY2021	V2_VAX2_L	
C4591001 1147 11471284/ Placebo	1147	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	23JUN2021	V4_MONTH6_L	
C4591001 1147 11471284/ Placebo	1147	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	30MAY2021	V4_MONTH6_L	
C4591001 1147 11471322/ Placebo	1147	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	04JUN2021	V2_VAX2_L	

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C4591001 1147 11471322/ Placebo	1147	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	14MAY2021	V2_VAX2_L
C4591001 1147 11471323/ Placebo	1147	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	04JUN2021	V2_VAX2_L
C4591001 1147 11471323/ Placebo	1147	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	14MAY2021	V2_VAX2_L
C4591001 1147 11471327/ BNT162b2 (30 µg)	1147	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	04JUN2021	V2_VAX2_L
C4591001 1147 11471327/ BNT162b2 (30 µg)	1147	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	07MAY2021	V2_VAX2_L
C4591001 1147 11471335/ Placebo	1147	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	10JUN2021	V2_VAX2_L
C4591001 1147 11471335/ Placebo	1147	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	20MAY2021	V2_VAX2_L
C4591001 1147 11471336/ Placebo	1147	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	12AUG2021	V2_VAX2_L
C4591001 1147 11471336/ Placebo	1147	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	22JUL2021	V2_VAX2_L

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C4591001 1150 11501171/ BNT162b2 (30 µg)	1150	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	01SEP2021	V2_VAX2_L
C4591001 1152 11521698/ Placebo	1152	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	15MAY2021	V2_VAX2_L
C4591001 1152 11521726/ Placebo	1152	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	12JUN2021	V2_VAX2_L
C4591001 1152 11521747/ Placebo	1152	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	20JUL2021	V101_VAX3
C4591001 1152 11521751/ Placebo	1152	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	17MAY2021	V2_VAX2_L
C4591001 1152 11521754/ Placebo	1152	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	20MAY2021	V2_VAX2_L
C4591001 1156 11561336/ Placebo	1156	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	03JUN2021	V2_VAX2_L
C4591001 1156 11561336/ Placebo	1156	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	13MAY2021	V2_VAX2_L
C4591001 1156 11561353/ Placebo	1156	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	10JUN2021	V101_VAX3
C4591001 1156 11561359/ Placebo	1156	Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	08JAN2021	V1_DAY1_VAX1_L

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PFIZER CONFIDENTIAL SDTM Creation: 30SEP2021 (10:35) Source Data: advv Table Generation: 08NOV2021 (14:40) (Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/advv_1001_1_ped6					