

Clinical Study Data Reviewer's Guide

EUA Amendment (12-15 Years of Age)

BioNTech SE and PFIZER INC.

Study C4591001

Clinical Data Reviewer's Guide Revision history

Version	Summary of Major Change(s) and Impact	Version Date
1.0	First approved version of Clinical Data Reviewer's Guide	6-Apr-2021

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Clinical Study Data Reviewer's Guide

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1. Introduction

1.1 Purpose

This document provides context for tabulation datasets and terminology that benefit from additional explanation beyond the Data Definitions document (define.xml). In addition, this document provides a summary of SDTM conformance findings.

1.2 Acronyms

Acronym	Translation
AE	Adverse Event
CBER	Center for Biologics Evaluation and Research
COVID-19	Coronavirus Disease 2019
cSDRG	Clinical Study Data Reviewer's Guide
EUA	Emergency Use Authorization
MedDRA	Medical Dictionary for Regulatory Activities
modRNA	Nucleoside-Modified Messenger Ribonucleic Acid
NAAT	Nucleic Acid Amplification Test
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SDTM	Study Data Tabulation Model
SoA	Schedule of Activities
TAUG	Therapeutic Area User Guide
WOCBP	Woman/Women of Childbearing Potential

1.3 Study Data Standards and Dictionary Inventory

Standard or Dictionary	Versions Used
SDTM	<ul style="list-style-type: none"> •SDTM v1.4 •SDTM-IG v3.2
Controlled Terminology	CDISC SDTM Controlled Terminology, 2020-03-27
Data Definitions	Define-XML v2.0

Standard or Dictionary	Versions Used
Medications Dictionary	WHODD GLOBALV3Mar20, WHO DDE v202003, SNOMED 2020-09-01, UNII 2020-08-18, NDF-RT 2020-09-08
Medical Events Dictionary	MedDRA v23.1

2. Protocol Description

2.1 Protocol Number and Title

Protocol Number: C4591001

Protocol Short Title: A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals.

Note: Protocol Amendment's 13, 14 and beyond mentioned elsewhere in the submission documentation are out of scope for this EUA Amendment and have not been included in this cSDRG.

Protocol Versions:

Amendment 12: 2020-01-08

- Because of a formatting error in protocol amendment 11, exclusion criterion 4 was inadvertently added to exclusion criterion 3 and the subsequent criteria renumbered. This amendment corrects that error.

Amendment 11: 2020-01-04

- Added a potential intensive surveillance period for nasal swabbing, for assessment via NAAT:
 - Corresponding SoA and procedures added

Amendment 10: 2020-12-01

- Added the possibility of administering BNT162b2 to participants who originally received placebo, following any local or national recommendations.
- Added the possibility of administering BNT162b2 to participants who originally received placebo, following completion of the active safety surveillance period.

Amendment 9: 2020-10-29

- To better align with the natural history of SARS-CoV-2 infection, added Phase 2/3 secondary efficacy objectives, estimands, and endpoints to include COVID-19 cases that occur from 14 days after the second dose; also modified the existing secondary efficacy objectives, estimands, and endpoints to include COVID-19 cases that occur from 14 days, as well as 7 days, after the second dose;
 - Made corresponding changes to the study design, study assessments and procedures, and statistical analysis sections.

- Clarified that interim analyses will be conducted after accrual of at least 62, 92, and 120 cases.
- Included any participants 16 through 17 years of age enrolled under this amendment in the reactogenicity subset.
- Clarified that serology data after a postbaseline positive SARS-CoV-2 test result will not be included in the analysis based on the evaluable immunogenicity populations.

Amendment 8: 2020-10-15

- Clarified that for participants who are not in the reactogenicity subset, local reactions and systemic events following vaccination should be detected and reported as AEs.
- Clarified that premenarchal females are not WOCBP.

Amendment 7: 2020-10-06

- Reduced the lower age range to include adolescents 12 to 15 years of age and added corresponding objectives.
- Added that 2 periods of potential COVID-19 symptoms within 4 days will be considered as a single illness.

Amendment 6: 2020-09-08

- Removed exclusion criterion 2 (ie, known infection with HIV, HCV, or HBV) for Phase 3 and added criteria for HIV-positive participants.
- Decreased the lower age limit and removed the upper age limit for inclusion in Phase 2/3 in order to evaluate BNT162b2 30 µg in older adolescents and those over 85 years of age; updated the title and other references to adults to align with this change.
- Clarified that inclusion criterion 4 (ie, participants at higher risk for acquiring COVID-19) is applicable for Phase 2/3 only, and provided some examples

Amendment 5: 2020-07-24

- Clarified that a single vaccine candidate, administered as 2 doses 21 days apart, will be studied in Phase 2/3.
- Stated that the vaccine candidate selected for Phase 2/3 evaluation is BNT162b2 at a dose of 30 µg.
- Renamed Stage 1 to Phase 1, removed Stage 2, and renamed Stage 3 to Phase 2/3.
- Clarified which stopping rules apply to which phase of the study.
- Moved the immunogenicity objectives in Phase 2/3 to become exploratory.
- Modified exclusion criterion 5, so that participants with a previous clinical or microbiological diagnosis of COVID-19 are excluded from all phases of the study.

Amendment 4: 2020-06-30

- BNT162b3 candidate has been added to the protocol.
- Further nonclinical data are available to support the study of the BNT162b3 candidate in humans, and the candidate has been added to the protocol.
- The 6-month safety follow-up telephone contact has been changed to an in-person visit for Stage 3 participants, to allow collection of an immunogenicity blood sample.

Amendment 3: 2020-06-10

- 20-µg dose level is formally included for BNT162b1 and BNT162b2.
- In order to increase flexibility enrolling participants, an extended screening window (increased from 14 to 28 days) for sentinel participants in Stage 1 has been added. This is

considered acceptable since eligible participants are expected to be either healthy or have stable medical conditions.

Amendment 2: 2020-05-27

- Added a 50- μ g dose level for vaccine candidates based on the modRNA platform (ie, BNT162b1, BNT162b2, and BNT162b3).

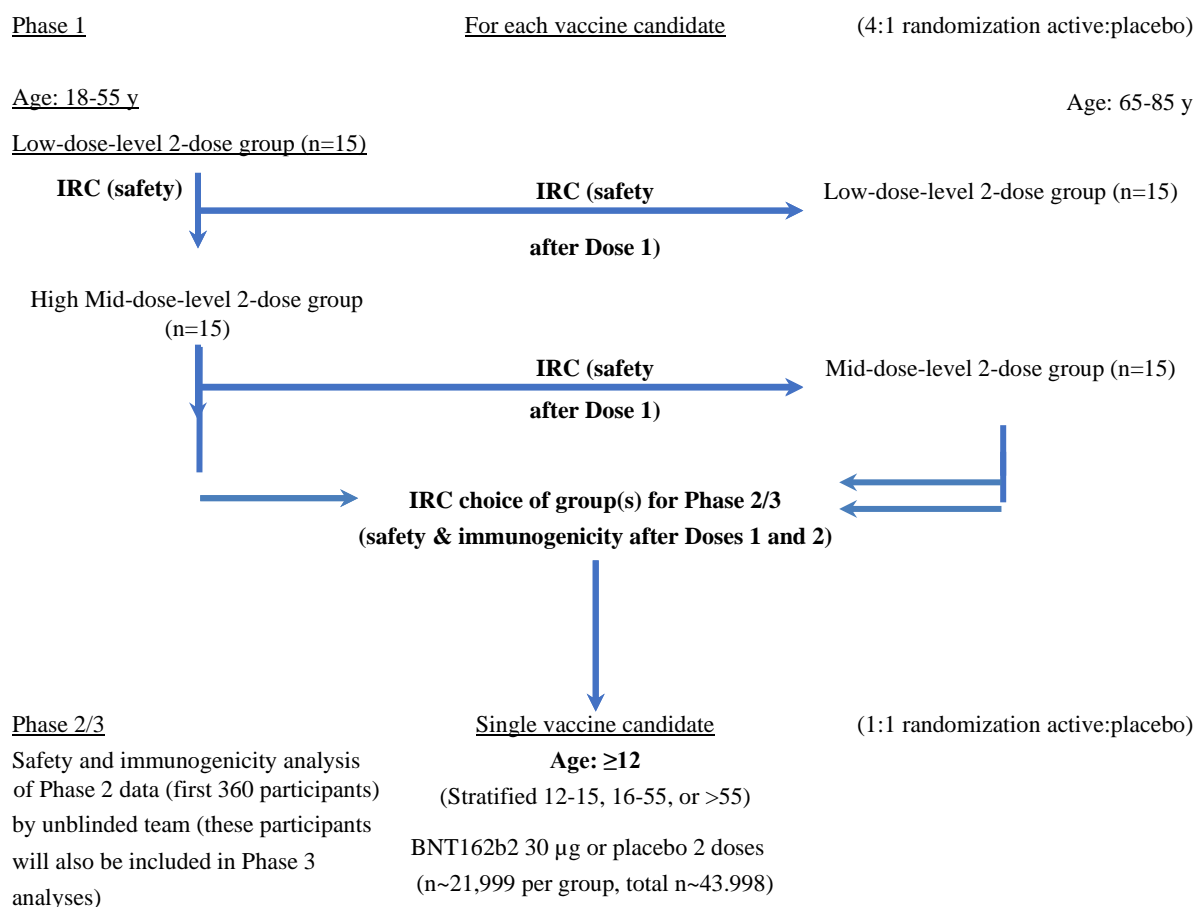
Amendment 1: 2020-05-13

- Decreased the dose levels for BNT162a1 and BNT162c2
- Modified exclusion criteria and prohibited inhaled/nebulized corticosteroids for sentinel participants in Stage 1.

Original Protocol 2020-04-15

2.2 Protocol Design

The study consists of 2 parts. This cSDRG is for subjects in all Phases. Phase 1: to identify preferred vaccine candidate(s) and dose level(s); Phase 2/3: an expanded cohort and efficacy part. These parts, and the progression between them, are detailed in the schema.



Abbreviation: IRC = internal review committee.

The study will evaluate the safety, tolerability, and immunogenicity of 2 different SARS-CoV-2 RNA vaccine candidates against COVID-19 and the efficacy of 1 candidate:

- As a 2-dose (separated by 21 days) schedule;
- At various different dose levels in Phase 1;
- In 3 age groups: (Phase 1: 18 to 55 years of age, 65 to 85 years of age; Phase 2/3: ≥ 12 years of age [stratified as 12-15, 16-55, or >55 years of age]).

Dependent upon safety and/or immunogenicity data generated during the course of this study, or the BioNTech study conducted in Germany (BNT162-01), it is possible that groups in Phase 1 may be started at the next highest dose, groups may not be started, groups may be terminated early, and/or groups may be added with dose levels below the lowest stated dose or intermediate between the lowest and highest stated doses.

The study is observer-blinded, as the physical appearance of the investigational vaccine candidates and the placebo may differ. The participant, investigator, study coordinator, and other site staff will be blinded. At the study site, only the dispenser(s)/administrator(s) are unblinded.

To facilitate rapid review of data in real time, sponsor staff will be unblinded to vaccine allocation for the participants in Phase 1.

2.2.1 Phase 1

Each group (vaccine candidate/dose level/age group) will comprise 15 participants; 12 participants will be randomized to receive active vaccine and 3 to receive placebo.

For each vaccine candidate/dose level/age group, the following apply:

- Additional safety assessments (see protocol, Section 8.2)
- Controlled enrollment (required only for the first candidate and/or dose level studied):
 - No more than 5 participants (4 active, 1 placebo) can be vaccinated on the first day
 - The first 5 participants must be observed by blinded site staff for at least 4 hours after vaccination for any acute reactions
 - Vaccination of the remaining participants will commence no sooner than 24 hours after the fifth participant received his or her vaccination
- Application of stopping rules
- IRC review of safety data to determine escalation to the next dose level in the 18- to 55-year age cohort:
 - Escalation between dose levels will be based on IRC review of at least 7-day post-Dose 1 safety data in this study and/or the BioNTech study conducted in Germany (BNT162-01)

- Note that, since both candidates are based upon the same RNA platform, dose escalation for the second candidate studied may be based upon the safety profile of the first candidate studied being deemed acceptable at the same, or a higher, dose level by the IRC

Groups of participants 65 to 85 years of age will not be started until safety data for the RNA platform have been deemed acceptable at the same, or a higher, dose level in the 18- to 55-year age cohort by the IRC.

In this phase, 13 groups will be studied, corresponding to a total of 195 participants.

The IRC will select 1 vaccine candidate that, in Phase 1, has an established dose level per age group based on induction of a post-Dose 2 immune response, including neutralizing antibodies, which is expected to be associated with protection against COVID-19, for progression into Phase 2/3.

Participants who originally received placebo and become eligible for receipt of BNT162b2 or another COVID-19 vaccine according to local or national recommendations (detailed separately, and available in the electronic study reference portal) will have the opportunity to receive BNT162b2 as part of the study. The investigator will ensure the participant meets at least 1 of the recommendation criteria. Any Phase 1 placebo recipient who has not already been offered the opportunity to receive BNT162b2 will be given this opportunity at the approximate time participants in Phase 2/3 reach Visit 4. Any participant who originally received placebo but then goes on to receive BNT162b2 will move to a new visit schedule (Section 1.3.3).

2.2.2 Phase 2/3

On the basis of safety and/or immunogenicity data generated during the course of this study, and/or the BioNTech study conducted in Germany (BNT162-01), 1 vaccine candidate was selected to proceed into Phase 2/3. Participants in this phase will be ≥ 12 years of age, stratified as follows: 12 to 15 years, 16 to 55 years, or >55 years. The 12- to 15-year stratum will comprise up to approximately 2000 participants enrolled at selected investigational sites. It is intended that a minimum of 40% of participants will be in the >55 -year stratum. Commencement of each age stratum will be based upon satisfactory post-Dose 2 safety and immunogenicity data from the 18- to 55-year and 65- to 85-year age groups in Phase 1, respectively. The vaccine candidate selected for Phase 2/3 evaluation is BNT162b2 at a dose of 30 μg .

Phase 2/3 is event-driven. Under the assumption of a true VE rate of $\geq 60\%$, after the second dose of investigational product, a target of 164 primary-endpoint cases of confirmed COVID-19 due to SARS-CoV-2 occurring at least 7 days following the second dose of the primary series of the candidate vaccine will be sufficient to provide 90% power to conclude true VE $>30\%$ with high probability. The total number of participants enrolled in Phase 2/3 may vary depending on the incidence of COVID-19 at the time of the enrollment, the true underlying VE, and a potential early stop for efficacy or futility.

Assuming a COVID-19 attack rate of 1.3% per year in the placebo group, accrual of 164 first primary-endpoint cases within 6 months, an estimated 20% non-evaluable rate, and 1:1 randomization, the BNT162b2 vaccine candidate selected for Phase 2/3 is expected to comprise approximately 21,999 vaccine recipients. This is the number of participants initially targeted for Phase 2/3 and may be adjusted based on advice from DMC analyses of case accumulation and the

percentage of participants who are seropositive at baseline. Dependent upon the evolution of the pandemic, it is possible that the COVID-19 attack rate may be much higher, in which case accrual would be expected to be more rapid, enabling the study's primary endpoint to be evaluated much sooner.

The first 360 participants enrolled (180 to active vaccine and 180 to placebo, stratified equally between 18 to 55 years and >55 to 85 years) will comprise the "Phase 2" portion. Safety data through 7 days after Dose 2 and immunogenicity data through 1 month after Dose 2 from these 360 participants will be analyzed by the unblinded statistical team, reviewed by the DMC, and submitted to appropriate regulatory authorities for review. Enrollment may continue during this period and these participants would be included in the efficacy evaluation in the "Phase 3" portion of the study.

In Phase 3, up to approximately 2000 participants, enrolled at selected sites, are anticipated to be 12 to 15 years of age. Noninferiority of immune response to prophylactic BNT162b2 in participants 12 to 15 years of age to response in participants 16 to 25 years of age will be assessed based on the GMR of SARS-CoV-2 neutralizing titers using a 1.5-fold margin. A sample size of 225 evaluable participants (or 280 vaccine recipients) per age group will provide a power of 90.8% to declare the noninferiority in terms of GMR (lower limit of 95% CI for GMR >0.67). A random sample of 280 participants from each of the 2 age groups (12 to 15 years and 16 to 25 years) will be selected as an immunogenicity subset for the noninferiority assessment.

The initial BNT162b2 was manufactured using "Process 1"; however, "Process 2" was developed to support an increased scale of manufacture. In the study, each lot of "Process 2"-manufactured BNT162b2 will be administered to approximately 250 participants 16 to 55 years of age. The safety and immunogenicity of prophylactic BNT162b2 in individuals 16 to 55 years of age vaccinated with "Process 1" and each lot of "Process 2" study intervention will be described. A random sample of 250 participants from those vaccinated with study intervention produced by manufacturing "Process 1" will be selected for this descriptive analysis.

Participants are expected to participate for up to a maximum of approximately 26 months. The duration of study follow-up may be shorter among participants enrolled in Phase 1 dosing arms that are not evaluated in Phase 2/3.

The initial BNT162b2 was manufactured using "Process 1"; however, "Process 2" was developed to support an increased scale of manufacture. In the study, each lot of "Process 2"-manufactured BNT162b2 will be administered to approximately 250 participants 16 to 55 years of age. The safety and immunogenicity of prophylactic BNT162b2 in individuals 16 to 55 years of age vaccinated with "Process 1" and each lot of "Process 2" study intervention will be described. A random sample of 250 participants from those vaccinated with study intervention produced by manufacturing "Process 1" will be selected for this descriptive analysis.

Participants are expected to participate for up to a maximum of approximately 26 months. The duration of study follow-up may be shorter among participants enrolled in Phase 1 dosing arms that are not evaluated in Phase 2/3.

Participants ≥ 16 years of age who originally received placebo and become eligible for receipt of BNT162b2 or another COVID-19 vaccine according to local or national recommendations (detailed separately, and available in the electronic study reference portal) will have the

opportunity to receive BNT162b2 as part of the study. The investigator will ensure the participant meets at least 1 of the recommendation criteria.

Any Phase 2/3 placebo recipient ≥ 16 years of age who has not already been offered the opportunity to receive BNT162b2 will be given this opportunity from 6 months after Vaccination 2 (at the time of the originally planned Visit 4).

Any Phase 2/3 placebo recipient ≥ 16 years of age who has not already been offered the opportunity to receive BNT162b2 will be given this opportunity from 6 months after Vaccination 2 (at the time of the originally planned Visit 4).

Any participant who originally received placebo but then goes on to receive BNT162b2 will move to a new visit schedule (Section 1.3.3).

An intensive period of surveillance to evaluate the efficacy of BNT162b2 against asymptomatic SARS-CoV-2 infection may be conducted at selected sites among Phase 2/3 participants following approval of protocol amendment 11. After an initial in-person visit where a blood sample will be collected and a nasal (midturbinate) swab obtained, nasal (midturbinate) swabs will be obtained from consented participants every 2 weeks until Visit 4, or a sufficient number of cases of SARS-CoV-2 infection have accrued to evaluate this objective, whichever is sooner, per the SoA. The swabs will be tested at a central laboratory using NAAT to detect SARS-CoV-2. Participants who originally received placebo and become eligible for receipt of BNT162b2 according to local or national recommendations and then receive BNT162b2 as part of the study will not participate in surveillance for asymptomatic SARS-CoV-2 infection; if they become eligible during the surveillance period, the swabbing every 2 weeks will cease.

2.3 Trial Design Datasets

Are Trial Design datasets included in the submission? - **Yes**

Dataset	Dataset Label
TA	Trial Arms
TE	Trial Elements
TI	Trial Inclusion/Exclusion Criteria
TS	Trial Summary
TV	Trial Visits

2.3.1 TA - Trial Arms

For Phase 1, subjects were randomly assigned to receive either BNT162b1, BNT162b2, or placebo.

For Phase 2/3, subjects were randomly assigned to receive either BNT162b2 or placebo.

The detailed information for ARM and ARMCD was shown in the table below.

ARM	ARMCD
BNT162b1 Phase 1 (10 mcg)	B1_10
BNT162b1 Phase 1 (100/10 mcg)	B1_100
BNT162b1 Phase 1 (20 mcg)	B1_20
BNT162b1 Phase 1 (30 mcg)	B1_30
BNT162b2 Phase 1 (10 mcg)	B2_10
BNT162b2 Phase 1 (20 mcg)	B2_20
BNT162b2 Phase 1 (30 mcg)	B2_30
BNT162b2 Phase 2/3 (30 mcg)	B2_P23_30
Placebo	PLACEBO

2.3.2 TE - Trial Elements

There were ten trial elements in this study for Phase 1 including one screening element and eight vaccination elements: BNT162b1 (10 mcg), BNT162b1 (20 mcg), BNT162b1 (30 mcg), BNT162b1 (100 mcg), BNT162b2 (10 mcg), BNT162b2 (20 mcg), BNT162b2 (30 mcg), and Placebo. There was also one follow-up element.

There were 4 trial elements in this study for Phase 2/3 including one screening element and 2 vaccination elements: BNT162b2 (30 mcg) and Placebo. There was also one follow-up element.

For Placebo subject from Phase 1 that qualified to receive BNT162b2 (30 mcg), additional elements were included: Screening Open Label & Follow-up Open Label.

2.3.3 TI - Trial Inclusion/Exclusion Criteria

See [Appendix I: Inclusion/Exclusion Criteria](#) for the complete text of each inclusion or exclusion criteria.

2.3.4 TS - Trial Summary

The Trial Summary (TS) dataset details a summary of the trial in a structured format. Each record in the Trial Summary dataset contains the value of a parameter, a characteristic of the trial. Trial Summary was used to record basic information about the study such as trial phase, protocol title, and trial objectives, as well as, information about the planned and actual trial characteristics.

In accordance with the FDA business rule, the values for PARAMCD equal to AGEMIN, PLANSUB, and NARMS has been combined into one record. The minimum age for Phase 1 is 18 years while Phase 2/3 is 12. The planned number of arms for Phase 1 is 7 while Phase 2/3 is 2. The planned number of participants for Phase 1 is 195 while Phase2/3 is 21,999.

2.3.5 TV - Trial Visits

The trial visits dataset describes the planned visits of the trial and consists of 19 visits for Phase 1 and 11 visits for Phase 2/3. Each visit and visit description are shown in the table below.

Visits V4_WEEK3_VAX2_S_R; V5_WEEK1_POSTVAX2_S_R; V6_WEEK2_POSTVAX2_S_R; V6_WEEK2_POSTVAX2_S_R; are for subjects who received 100mcg during vaccination 1 for Phase 1. Dose of 100 mcg was deemed too high and the dosing/visit was stopped for approximately 4

months. After 4 months, the subject returned and received 10 mcg at vaccination 2 and completed the rest of the visits.

Visits in the chart below with the suffix of “_S” and “_L”, excluding COVID visits, are related to Phase 1 and Phase 2/3 respectively.

VISITNUM	VISIT	VISITDY	Description
1	COVID_A		COVID-19 illness onset
200	COVID_A1		After the visit of COVID-19 illness onset
2	COVID_B		COVID-19 illness onset
201	COVID_B1		After the visit of COVID-19 illness onset
3	COVID_C		COVID-19 illness onset
202	COVID_C1		After the visit of COVID-19 illness onset
4	COVID_D		COVID-19 illness onset
203	COVID_D1		After the visit of COVID-19 illness onset
5	COVID_E		COVID-19 illness onset
204	COVID_E1		After the visit of COVID-19 illness onset
6	COVID_F		COVID-19 illness onset
205	COVID_F1		After the visit of COVID-19 illness onset
7	COVID_G		COVID-19 illness onset
206	COVID_G1		After the visit of COVID-19 illness onset
8	COVID_H		COVID-19 illness onset
207	COVID_H1		After the visit of COVID-19 illness onset
9	COVID_I		COVID-19 illness onset
208	COVID_I1		After the visit of COVID-19 illness onset
10	COVID_J		COVID-19 illness onset
209	COVID_J1		After the visit of COVID-19 illness onset
11	COVID_K		COVID-19 illness onset
210	COVID_K1		After the visit of COVID-19 illness onset
12	COVID_L		COVID-19 illness onset
211	COVID_L1		After the visit of COVID-19 illness onset
13	COVID_M		COVID-19 illness onset
212	COVID_M1		After the visit of COVID-19 illness onset
14	COVID_N		COVID-19 illness onset
213	COVID_N1		After the visit of COVID-19 illness onset
15	COVID_O		COVID-19 illness onset
214	COVID_O1		After the visit of COVID-19 illness onset
16	COVID_P		COVID-19 illness onset
215	COVID_P1		After the visit of COVID-19 illness onset
17	COVID_Q		COVID-19 illness onset
216	COVID_Q1		After the visit of COVID-19 illness onset
18	COVID_R		COVID-19 illness onset
217	COVID_R1		After the visit of COVID-19 illness onset
19	COVID_S		COVID-19 illness onset
218	COVID_S1		After the visit of COVID-19 illness onset

VISITNUM	VISIT	VISITDY	Description
20	COVID_T		COVID-19 illness onset
219	COVID_T1		After the visit of COVID-19 illness onset
60776	End of Treatment		Start of end of treatment visit
60777	Follow-Up		First day of follow-up visit
60772	POT_COVID_CONVA		28 to 35 days after potential COVID-19 illness visit
60771	POT_COVID_ILL		Optimally within 3 days after potential COVID-19 illness onset
51231792	REVAX_CONTACT		Start of contact
60747	SCR		Informed consent
20210	SSWAB_WEEK10		Surveillance swab sample collection at week 10
20212	SSWAB_WEEK12		Surveillance swab sample collection at week 12
20214	SSWAB_WEEK14		Surveillance swab sample collection at week 14
20216	SSWAB_WEEK16		Surveillance swab sample collection at week 16
20218	SSWAB_WEEK18		Surveillance swab sample collection at week 18
20202	SSWAB_WEEK2		Surveillance swab sample collection at week 2
20220	SSWAB_WEEK20		Surveillance swab sample collection at week 20
20222	SSWAB_WEEK22		Surveillance swab sample collection at week 22
20224	SSWAB_WEEK24		Surveillance swab sample collection at week 13
20226	SSWAB_WEEK26		Surveillance swab sample collection at week 14
20228	SSWAB_WEEK28		Surveillance swab sample collection at week 15
20204	SSWAB_WEEK4		Surveillance swab sample collection at week 4
20206	SSWAB_WEEK6		Surveillance swab sample collection at week 6
20208	SSWAB_WEEK8		Surveillance swab sample collection at week 8
60765	V1_DAY1_VAX1_L	1	Day 1
60748	V1_DAY1_VAX1_S	1	Day 1
60757	V10_MONTH24_S	749	714 to 742 days after visit 4
51231793	V101_VAX3		Open label vaccination 1
51231794	V102_VAX4		Open label vaccination 2
51231795	V103_MONTH1		28 to 35 Days after visit 102
51231796	V104_MONTH6		175 to 189 days after visit 102
51231797	V105_MONTH18		532 to 560 days after visit 102
60749	V2_DAY2_POSTVAX1_S	2	1 to 3 days after visit 1
60766	V2_VAX2_L	21	19 to 23 days after visit 1 or 56 to 70 days after visit 1
56985855	V201_SURVEIL_CONSENT		Infection Surveillance Consent
60767	V3_MONTH1_POSTVAX2_L	51	28 to 35 days after visit 2
60750	V3_WEEK1_POSTVAX1_S	7	6 to 8 days after visit 1
60768	V4_MONTH6_L	173	154 to 168 days after visit 2
60751	V4_WEEK3_VAX2_S	21	19 to 23 days after visit 1
1165454	V4_WEEK3_VAX2_S_R		NA
60769	V5_MONTH12_L	371	350 to 378 days after visit 2
60752	V5_WEEK1_POSTVAX2_S	28	6 to 8 days after visit 4
1165455	V5_WEEK1_POSTVAX2_S_R		6 to 8 days after visit 4_R
60770	V6_MONTH24_L	733	714 to 742 days after visit 2
60753	V6_WEEK2_POSTVAX2_S	35	12 to 16 days after visit 4

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VISITNUM	VISIT	VISITDY	Description
1165456	V6_WEEK2_POSTVAX2_S_R		12 to 16 days after visit 4_R
60754	V7_MONTH1_S	52	28 to 35 days after visit 4
1165457	V7_MONTH1_S_R		28 to 35 days after visit 4_R
60755	V8_MONTH6_S	182	154 to 168 days after visit 4
60756	V9_MONTH12_S	385	350 to 378 days after visit 4

3. Subject Data Description

3.1 Overview

Are the submitted data taken from an ongoing study? **Yes**

For analysis, a data cutoff of 13Mar2021 was applied on the SDTM data. Furthermore, any data related to the booster portion of the Phase 1 subjects was also programmatically excluded from SDTM data. Details about the cutoff algorithm applied to the SDTM data can be found in [Appendix II](#).

Were the SDTM datasets used as sources for the analysis datasets? **Yes**

Do the submission datasets include screen failures? **Yes**

If yes, which datasets include screen failure data?

Dataset	Dataset Label
AE	Adverse Events
CE	Clinical Events
CM	Concomitant Medications
CO	Comments
DM	Demographics
DS	Disposition
DV	Protocol Deviations
FACE	Findings About Events or Interventions
HO	Healthcare Encounters
IE	Inclusion/Exclusion Criteria Not Met
IS	Immunogenicity Specimen Assessments
LB	Laboratory Test Results
MB	Microbiology Specimen
MH	Medical History
PE	Physical Examination
SE	Subject Elements
SUPPAE	Supplemental Qualifiers for AE
SUPPCE	Supplemental Qualifiers for CE
SUPPCM	Supplemental Qualifiers for CM
SUPPDM	Supplemental Qualifiers for DM
SUPPDS	Supplemental Qualifiers for DS
SUPPDV	Supplemental Qualifiers for DV

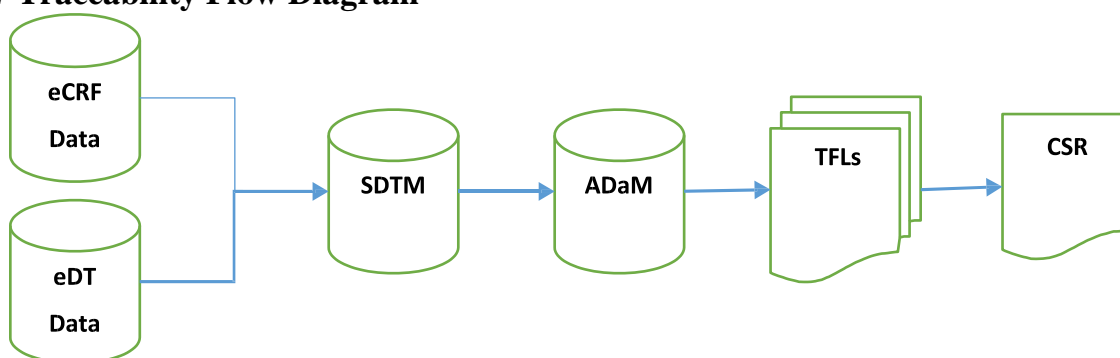
Dataset	Dataset Label
SUPPHO	Supplemental Qualifiers for HO
SUPPIE	Supplemental Qualifiers for IE
SUPPIS	Supplemental Qualifiers for IS
SUPPLB	Supplemental Qualifiers for LB
SUPPMB	Supplemental Qualifiers for MB
SUPPMH	Supplemental Qualifiers for MH
SUPPPE	Supplemental Qualifiers for PE
SV	Subject Visits
VS	Vital Signs

Were any domains planned, but not submitted because no data were collected? **No**

Are the submitted data a subset of collected data? **No**

Is adjudication data present? **No**

3.2 Traceability Flow Diagram



3.3 Annotated CRFs

Collected fields and pages that have not been tabulated have been annotated as "Not Submitted". Pfizer collects certain data elements to facilitate operational processes including data cleaning and dynamically creating additional forms in the electronic data capture system. All fields and pages that have been annotated as "Not Submitted" meet this criterion and are described below.

Explanation of data fields [Not Submitted]

aCRF page Number(s)	Data Collection Field	Explanation of why [NOT SUBMITTED]
24, 91, 93	1. Lowest Level Term, 2. Lowest Level Term Code, 3. High Level Term, 4. High Level Term Code, 5. High Level Group Term,	Coding is done after data extraction during SDTM mapping

aCRF page Number(s)	Data Collection Field	Explanation of why [NOT SUBMITTED]
	6. High Level Group Term Code, 7. Primary System Organ Class 8. Primary System Organ Class Code	
14	Cohort Selection	Not needed for analysis. The whole page is annotated as NOT SUBMITTED.
35	Inform Enrollment	Not needed for analysis. The whole page is annotated as NOT SUBMITTED.
36	HIV Status	Not needed for analysis. The whole page is annotated as NOT SUBMITTED.
63	Casebook Signature Form	Not needed for analysis. The whole page is annotated as NOT SUBMITTED.
84	Further Vaccination Confirmation	Not needed for analysis. The whole page is annotated as NOT SUBMITTED.
89	Inform Screening	Not needed for analysis. The whole page is annotated as NOT SUBMITTED.
95, 96, 97	Stratification	Not needed for analysis. The whole page is annotated as NOT SUBMITTED.
98	Subject Status	Not needed for analysis. The whole page is annotated as NOT SUBMITTED.
105	Unplanned assessments	Not needed for analysis. The whole page is annotated as NOT SUBMITTED.
12, 15, 16, 24, 40, 41, 42, 70, 72, 76, 77, 82, 83, 91, 93, 106, 108, 110	Comparison Term	Not needed for analysis.
15, 16, 76, 110	Concomitant Medications Pre-specified	Not needed for analysis.
33	COVID-19 Surveillance Visit	Not needed for analysis.
18, 19, 20, 21	1. Follow-Up Contact Category 2. Was contact made? 3. If No, why? 4. Comments	Not needed for analysis.
30, 31, 32, 33, 34	Erroneous Visit	Not needed for analysis.
18, 19, 20, 21, 105	Contact Outcome	Not needed for analysis.
36	Select appropriate response - What is the subject HIV status?	Not needed for analysis. The whole page is annotated as NOT SUBMITTED.
40	1. Category of Clinical Event 2. Was a diagnosis obtained for Potential COVID-19 Illness? (NO)	Not needed for analysis.

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aCRF page Number(s)	Data Collection Field	Explanation of why [NOT SUBMITTED]
41, 42	Was a diagnosis obtained? (NO)	Not needed for analysis.
64, 65	Lab Sub-Panel	Not needed for analysis.
87, 90, 100	Sample Collected?	Not needed for analysis.
75, 87, 88, 90, 100	Sample ID	Not needed for analysis.
81	CISR Category	Not needed for analysis.
91, 93	Event Pre-specified	Not needed for analysis.
102	1. Were fever or systemic symptoms present on the last day the Subject Diary was completed? 2. Were injection site reactions present on the last day the Subject Diary was completed?	Not needed for analysis.
108	Container Number	Not needed for analysis.

3.4 SDTM Subject Domains

Dataset - Dataset Label	Efficacy	Safety	Other	SUPP--	Related Using RELREC
AE - Adverse Events		X		X	DS, CE
CE - Clinical Events		X		X	AE, FACE, VS
CM - Concomitant Medications		X		X	
CO - Comments			X		
DD - Death Details			X		
DI - Device Identifiers			X		MB, LB
DM - Demographics			X	X	
DS - Disposition			X	X	AE
DV - Protocol Deviations			X	X	
EC - Exposure as Collected			X	X	
EX - Exposure			X	X	
FACE - Findings About Events or Interventions		X		X	CE
FAHO - Findings About Events or Interventions		X			HO

Dataset - Dataset Label	Efficacy	Safety	Other	SUPP--	Related Using RELREC
HO - Healthcare Encounters		X		X	FAHO
IE - Inclusion/Exclusion Criteria Not Met			X	X	
IS - Immunogenicity Specimen Assessment	X			X	
LB - Laboratory Test Results		X		X	DI
MB - Microbiology Specimen			X	X	DI
MH - Medical History			X	X	
MO - Morphology			X	X	
PE - Physical Examination			X	X	
PR - Procedures			X	X	
SE - Subject Elements			X		
SV - Subject Visits			X		
VS - Vital Signs		X		X	CE

3.4.1 AE - Adverse Events

Adverse events dataset consists of one record per adverse event per subject.

The entry of a “Y” for the serious adverse event variable, AESER, indicates the AE meets the criteria as serious per investigator report and the definition in the CRF guidance.

Adverse events, medication errors, newly diagnosed chronic medical conditions and reactogenicity are included in the AE dataset and distinguished by AECAT. To implement the CDISC Vaccines TAUG flat model, records of reactogenicity are added to AE domain from CE with AECAT= “REACTOGENICITY”, when the duration of reactogenicity events go beyond the planned observation period. AECAT = ”AEMERES” represents AE as a result of a study medication error collected in SUPPAE.

A relationship has been defined in RELREC between the disposition event where DSDECOD= ADVERSE EVENT or DEATH and the adverse event leading to discontinuation. The observations are related by AESEQ and DSSEQ. A relationship has also been defined between the adverse events and clinical event summary records and are related by AELNKGRP and CELNKGRP.

QNAM	Description
AEAENO	Associated Adverse Event Identifier
AECMGIV	Concomitant Medication Given
AEMEFL	Medication Error Associated With AE
AEMERES	Is AE a Result of a Medication Error
AEMOD	Updated with unsolicited AE data
AENDGIV	Was a Non-Drug Treatment given

QNAM	Description
AERELTXT	Event Due to Other Specify
AESUBJDC	Discontinued because of this AE
DICTVER	Dictionary Name and Version

3.4.2 CE - Clinical Events

Clinical Events dataset consists of one record per event per subject.

Clinical Events implements Vaccines TAUG flat model for reactogenicity records, where it summarizes each symptom event per vaccination per subject. CECAT = "REACTOGENICITY". The corresponding daily assessments from the e-diary are in FACE.

Unplanned assessments occurring during the diary period will be utilized along with the e-diary data in creating the summary records in CE, even if the assessment was not required per protocol (no symptom reported or symptom was reported but not severe). The worst reported severity will be mapped for each symptom in the summary record and stop date will reflect the latest symptom date from the e-diary or unplanned assessment, or from Symptom Resolved Dates form if continued past the diary period.

Reactogenicity exclusions are as follows:

- If subject is not part of reactogenicity subset but has unplanned reactogenicity assessments (unplanned temp or unplanned assessment of local reaction/systemic event), or has unplanned assessments without any diary data, then these unplanned assessments were dropped from FACE/VS and summary CE records were not generated.
- If an unplanned assessment exists with an assessment date (CEDTC) falling after the stop date recorded on the Symptom Resolved Dates CRF, these records were dropped from FACE for that visit. Only data up through the stop date from Symptom Resolved Dates in the CRF were used to create the CE records.
- If a subject has diary data and their symptom did not occur during the diary period but was on the unplanned assessment after diary period, then the unplanned assessment was dropped (symptom must begin during diary period to be part of reactogenicity).
- If there were unplanned assessments after the diary period and the Symptom Resolved Dates form was present but did not have a stop date or 'ongoing' recorded for that symptom, then the unplanned assessments were dropped.

Potential COVID-19 illness from the ILLNESS DETAILS - POTENTIAL COVID-19 ILLNESS CRF is included with CECAT = "EFFICACY". The investigator's diagnosis is in CETERM. Subjects who progress to severe disease, as defined in the protocol, will have data entered on the ILLNESS DETAILS - SEVERE COVID-19 ILLNESS CRF which is reported in the CE domain with CECAT = 'SEVERE COVID-19 ILLNESS' and CESCAT (Subcategory) denoting whether there was significant acute renal, hepatic, or neurologic dysfunction.

As agreed with CBER, CE includes event records for "COVID-19 like illness" and "COVID-19 confirmed" in the CE domain for subjects who were assigned to a vaccination arm (DM.ARM is not "SCREEN FAILURE" or "NOT ASSIGNED") as follows:

- The “COVID-19 confirmed” events are based on the “Clinical disease endpoint case flag” (CDECASE) in SUPPDM.
- “COVID-19 like illness” is flagged “Y” when a subject has at least one pre-specified symptom. Please note that a subject may have more than one occurrence of “COVID-19 like illness” if symptoms presented during different illness visits, but only has one record for “COVID-19 confirmed” that has a visit associated when the case was assessed to be positive.
- When there is confirmed COVID-19, the assessment of each pre-specified symptom corresponding to that symptomatic period (i.e., corresponding COVID Illness visit) will additionally be included in the CE domain, with CESCAT = “SIGNS AND SYMPTOMS OF DISEASE”.
- As start and stop dates were not collected for each symptom individually, CESTDTC and CEENDTC was not populated for each symptom but the date first symptom started and date last symptom resolved was mapped to CESTDTC and CEENDTC in the “COVID-19 like illness” and “COVID-19 confirmed” records.
- The individual symptoms have VISIT and collection date (CEDTC) populated from the relevant COVID Illness visit.
- Toxicity grade for a COVID-19 like illness is collected in the ILLNESS DETAILS - POTENTIAL COVID-19 ILLNESS CRF so CETOXGR is populated instead of CESEV in the “COVID-19 like illness” and “COVID-19 confirmed” records. It is not collected for each symptom individually.
- For COVID illness, CRF will collect toxicity grade as 0 for asymptomatic subjects. If an illness visit is performed for asymptomatic participant, toxicity grade will be reported as "0" while the participant is asymptomatic. If participant later experiences symptoms, the appropriate toxicity grade will be updated.

A relationship has been defined in RELREC been defined between the adverse events and clinical event summary records and are related by AELNKGRP and CELNKGRP. A relationship has also been defined between clinical event summary records and findings about records. The observations are related by CELNKGRP and FALNKGRP. A relationship has also been defined between clinical event summary records and temperature vital signs records using CELNKGRP and VSLNKGRP.

QNAM	Description
CEDRVFL	Derived Flag
CEEVAL	Evaluator
DICTVER	Dictionary Name and Version
ONGNXVIS	Reported Ongoing at Next Visit
RCENDTC	Reported Clinical Event End Date

QNAM = “CEDRVFL” is used to indicate that an entire record is derived.

3.4.3 CM - Concomitant Medications

Concomitant Medications dataset consists of one record per recorded medication occurrence or constant-dosing interval per subject.

QNAM	Description
CMCLAS1	Medication Class 1
CMCLAS2	Medication Class 2
CMCLSCD1	Medication Class Code 1
CMCLSCD2	Medication Class Code 2
CMCODE	Standardized Medication Code
DICTVER	Dictionary Name and Version

3.4.4 CO - Comments

Comments dataset consists of one record per comment per subject.

3.4.5 DD – Death Details

Death details dataset consists of one record per finding per subject, for primary and any secondary causes of death.

3.4.6 DI - Device Identifiers

Device identifiers dataset consists of one record per device identifier per device.

A relationship has been defined in RELREC between the device identifier records and the corresponding laboratory and microbiology records. The observations are related by SPDEVID.

3.4.7 DM - Demographics

Demographics dataset consists of one record per subject.

Specify Other Race and Ethnicity have been submitted in SUPPDM.

The following subject issues were observed in this dataset (analysis rules for these subjects are described in the Analysis Data Reviewers Guide):

- The following subjects were enrolled into the study more than once.

Duplicated Subject #	SUBJID at 1 st Site	SUBJID at 2 nd site
1	10561101	11331382
2	11101123	11331405
3	11491117	12691090
4	12691070	11351357
5	11341006	10891112
6	11231105	10711213

- Subjects C4591001 1081 10811053, C4591001 1088 10881077, C4591001 1177 11771089 and C4591001 1231 12311057 received an additional dose at an unscheduled visit after receiving one dose of [BNT162b2 (30 mcg)] and one dose of placebo.
- Subjects C4591001 1080 10801222 and C4591001 1149 11491108 have values of NOT ASSIGNED for randomized group due to the randomization number not entered on the CRF. Both subjects withdrew from the study prior to administration of study drug.

Split Sites:

Pfizer created multiple virtual site ID's and spread the enrollment across these virtual site ID's despite it being a single physical site with a single office and a single investigator. See example below. The SITEID will be the original SITEID (1231) and the USUBJID will reflect the new virtual site (e.g., 4444, 5555) used for analysis.

SDTM DEMOGRAPHY					
STUDYID	DOMAIN	USUBJID	SUBJID	SITEID	INVID
C4591001	DM	C4591001 1231 12311003	12311003	1231	1464295
C4591001	DM	C4591001 4444 44441001	44441001	1231	1464295
C4591001	DM	C4591001 4444 44441002	44441002	1231	1464295

QNAM	Description
CDECASE	Clinical disease endpoint case flag
RACE1	Race1
RACE2	Race2
RACE3	Race3
RACE4	Race4

As agreed with CBER, CDECASE qualifier in SUPPDM is populated for each subject from the ADaM primary endpoint case flag for the first primary efficacy endpoint, as defined in the protocol. This flag is derived based on ADSL and ADC19EF ADaM datasets.

3.4.8 DS - Disposition

Disposition dataset consists of one record per disposition status or protocol milestone per subject.

If Participants terminated early, the appropriate reason for discontinuation as per protocol are recorded in the End of Treatment (EOT) and Follow-up (FUP) visit Disposition pages. DSPHASE in SUPPDS corresponds to the pages and can be used to link the records with multiple disposition per EPOCH.

A relationship has been defined in RELREC between the disposition event where DSDECOD= ADVERSE EVENT or DEATH and the adverse event leading to discontinuation. The observations are related by AESEQ and DSSEQ.

QNAM	Description
DSPHASE	Disposition Phase
DSRANGRP	Randomization Group

3.4.9 DV - Protocol Deviations

Protocol Deviations dataset consists of one record per protocol deviation per subject

QNAM	Description
ACTSITE	Actual Site of Deviation Occurrence
CAPE	Confirmed Analysis Population Exclusion
DESGTOR	Visit Designator
DVTERM1	Protocol Deviation Term 1
SOURCE	Source of the data

3.4.10 EC - Exposure as Collected

Exposure as collected dataset consists of one record per protocol-specified study treatment, collected-dosing interval, per subject, per mood.

QNAM	Description
ECADJ1	Reason for Dose Adjustment 1
ECADJ2	Reason for Dose Adjustment 2
ECCD	Standardized Medication Code
ECDECOD	Standardized Medication Name
ECDOSADJ	Dose Adjusted From Planned
ECDOSAJO	Reason Dose Adjusted Other Specify
ECOSBV	Observed Post Dose For Specified Time
ECOSBVD	Details Of Subject Observation
ECOSBVT	Timeframe Subject Was Observed
ECTDV	Temporary Delay of Vaccination
FDDTC	Date of First Delay

3.4.11 EX - Exposure

Exposure dataset consists of one record per constant dosing interval per subject.

- A third exposure record will exist in the domain for C4591001 1231 12311057 and C4591001 1177 11771089 due to the subjects receiving an additional dose at an unscheduled visit.
- Participants ≥ 16 years of age who originally received placebo and became eligible for receipt of BNT162b2 or another COVID-19 vaccine will have additional vaccination records.
- For subjects with temporary delay of vaccination without treatment information and vaccination date, data will not be used or retained in SDTM.

QNAM	Description
EXADJ1	Reason for Dose Adjustment 1
EXADJ2	Reason for Dose Adjustment 2
EXCD	Standardized Medication Code
EXDECOD	Standardized Medication Name
EXDOSADJ	Dose Adjusted From Planned
EXDOSAJ0	Reason Dose Adjusted Other Specify
EXOBSV	Observed Post Dose For Specified Time
EXOBSVD	Details Of Subject Observation
EXOBSVT	Timeframe Subject Was Observed
EXTDV	Temporary Delay of Vaccination
FDDTC	Date of First Delay

3.4.12 FACE - Findings About Events or Interventions

Findings About dataset consists of one record per finding per object per time point per time point reference per visit per subject.

FACE implements flat model for reactogenicity records, including e-diary and unplanned assessments of reactogenicity findings. Unplanned assessments are under FACAT = "REACTOGENICITY - UNPLANNED ASSESSMENT" while diary data has FACAT = "REACTOGENICITY". FASTAT = "NOT DONE" records are generated for any missed diary days and are flagged with FADRVFL = "Y".

Subjects not part of reactogenicity subset should not have any e-diary data, unplanned assessments or Symptom Resolved Dates form completed.

- Programming does not generate any 'NOT DONE' records for these subjects. Any e-diary and Symptom Resolved Dates CRF data that was completed is dropped if subject is not part of reactogenicity subset.
- Unplanned assessments without an e-diary will be dropped from reactogenicity datasets and would be counted only as an adverse event or COVID-19 symptom in the relevant domain.

Signs and symptoms of COVID-19 are included with FACAT = "EFFICACY".

A relationship has been defined in RELREC between clinical event summary records and findings about records. The observations are related by CELNKGRP and FALNKGRP.

QNAM	Description
CLTYP	Collection Type
FALANG	Language Version of Instrument

3.4.13 FAHO - Findings About Events or Interventions

Findings About dataset consists of one record per finding per object per time point per time point reference per visit per subject.

A relationship has been defined in RELREC been defined between healthcare encounter events and the corresponding findings about event records. The observations are related by HOLNKID and FALNKID.

3.4.14 HO - Healthcare Encounters

Healthcare Encounters dataset consists of one record per healthcare encounter per subject.

A relationship has been defined in RELREC been defined between healthcare encounter events and the corresponding findings about event records. The observations are related by HOLNKID and FALNKID.

QNAM	Description
HCUHSP	Hospitalized due to COVID-19 illness?
HCUICU	Been in ICU due to COVID-19 illness?
HCUIDIS	Disease Name

3.4.15 IE - Inclusion/Exclusion Criteria Not Met

Inclusion/Exclusion Criteria Not Met dataset consists of one record per inclusion/exclusion criterion not met per subject.

QNAM	Description
IEDESC	Details

3.4.16 IS - Immunogenicity Specimen Assessment

Immunogenicity Specimen Assessment dataset consists of one record per test per visit per subject.

QNAM	Description
ETRKDOR	Data Origin

3.4.17 LB - Laboratory Test Results

Laboratory Test Results dataset consists of one record per analyte per planned time point number per time point reference per visit per subject.

A relationship has been defined in RELREC between the device identifier records and the corresponding laboratory records. The observations are related by SPDEVID.

QNAM	Description
LBSCATYN	Lab Sub-Panel Collected
LBSTTYPE	Standardized Unit

QNAM	Description
LBTSTID	Laboratory Test Identifier
LBUID	Lab ID
LBUNEVFL	Not Evaluable Flag

3.4.18 MB - Microbiology Specimen

Microbiology Specimen dataset consists of one record per microbiology specimen finding per time point per visit per subject.

SARS-CoV-2 test results from local labs will have MBCAT = "CONFIRMATION OF INFECTION" (as collected in the CRF) and central labs have MBCAT = "VIROLOGY".

A relationship has been defined in RELREC between the device identifier records and the corresponding microbiology records. The observations are related by SPDEVID.

QNAM	Description
ETRKDOR	Data Origin
MBSCATYN	Lab Sub-Panel Collected
MBSTTYPE	Standardized Unit
MBTSTID	Laboratory Test Identifier
MBUID	Lab ID
TRADEOTH	Other Trade Name

3.4.19 MH - Medical History

Medical History dataset consists of one record per medical history event per subject.

QNAM	Description
DICTVER	Dictionary Name and Version

3.4.20 MO - Morphology

Morphology dataset consists of one record per Morphology finding per location per time point per visit per subject.

QNAM	Description
ASPECIFY	Overall Assessment Detail
LOCOTH	Location of Assessment Detail
METHOTH	Imaging Method Other Detail

3.4.21 PE - Physical Examination

Physical Examination dataset consists of one record per body system or abnormality, per visit, per subject.

QNAM	Description
PECLSIG	Clinically Significant Findings

3.4.22 PR – Procedures

Subject Procedures dataset consists of one record per recorded procedure per occurrence per subject.

QNAM	Description
DICTVER	Dictionary Name and Version
PRBDSYCD	Body System or Organ Class Code
PRBODSYS	Body System or Organ Class
PRHLGT	High Level Group Term
PRHLGTCD	High Level Group Term Code
PRHLT	High Level Term
PRHLTCD	High Level Term Code
PRLLT	Lowest Level Term
PRLLTCD	Lowest Level Term Code
PRPTCD	Preferred Term Code
PRSOC	Primary System Organ Class
PRSOCCD	Primary System Organ Class Code

3.4.23 SE - Subject Elements

Subject Elements dataset consists of one record per actual element per subject.

3.4.24 SV - Subject Visits

Subject Visits dataset consists of one record per actual visit per subject.

3.4.25 VS - Vital Signs

Vital Signs dataset consists of one record per vital sign measurement per time point per visit per subject.

To implement the CDISC Vaccines TAUG flat model, temperature records from e-diary are mapped to VS domain with VSCAT= “REACTOGENICITY”. Any unplanned temperature assessments by the investigator post vaccination are included with VSCAT = “REACTOGENICITY - UNPLANNED TEMPERATURE”. VSSTAT = “NOT DONE” records are generated for any missed diary days and are flagged with VSDRVFL = “Y”.

Non-reactogenicity vital signs have VSCAT = “GENERAL VITAL SIGNS”.

A relationship has also been defined between clinical event summary records and temperature vital signs records using CELNKGRP and VSLNKGRP.

QNAM	Description
CLTYP	Collection Type
VSCOLSRT	Collected Summary Result Type

CLTYP in SUPPVS will be “DIARY CARD” for assessments by the subject in the e-diary or “CRF” if recorded by the investigator.

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4. Data Conformance Summary

4.1 Conformance Inputs

Was a validator used to evaluate conformance?

Yes

If yes, specify the version(s) of the validation rules:

**Pinnacle 21 Enterprise version 4.1.4
Validation Engine version 1907.2**

Were sponsor-defined validation rules used to evaluate conformance?

No

Were the SDTM datasets evaluated in relation to define.xml?

Yes

Was define.xml evaluated?

Yes

Provide any additional compliance evaluation information:

Pinnacle Validation Engine FDA 2010.1 was also used to evaluate the data. See [Appendix III](#) for key issues using v2010.1.

4.2 Issues Summary

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD0080	AE start date is after the latest Disposition date	Error	AE	4558 (11.54%)	At the time of data extraction, study is still ongoing and disposition status is collected at the completion or discontinuation of each stage of the study therefore may not have occurred at the time of this data snapshot.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD0091	AEOUT is not 'FATAL', when AESDTH='Y'	Error	AE	3 (5.88%)	Subject C4591001 1135 11351033 - official death certificate and autopsy results are pending so the cause of death can be updated. Query is present to track the issue. Subject C4591001 1088 10881126 - Primary cause of death is already reported as Cardiac Arrest, there is a blank extra log line on the form that has already been queried to be deleted.
SD1202	AESTDTC date is after RFPENDTC	Error	AE	367 (1.32%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD1204	AEENDTC date is after RFPENDTC	Error	AE	477 (1.85%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD2010	Value for AEHLT not found in MedDRA dictionary	Error	AE	1 (< 0.1%)	Manual coding done on the day of snapshot due to a leading space in the Verbatim Term which prevented auto coding. Once the update is done by site to the Verbatim Term this will be resolved.
SD2012	Value for AEHLGT not found in MedDRA dictionary	Error	AE	1 (< 0.1%)	At the time of data extraction study is still ongoing and complete data was not obtained at database release.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
TS0012	Analysis Required variable AESEV not found	Error	AE	1 (100.00%)	AESEV not collected in the CRF for the study. AETOXGR (Toxicity Grade) variable used for severity.
TS0053	Neither AESEV or AETOXGR is populated	Error	AE	2627 (6.65%)	Reactogenicity events that are present after the diary period were added to AE domain and severity or toxicity grades were not captured after end of diary period. Refer to Appendix 3 for more details on roadmap for mapping of reactogenicity data.
SD1076	Model permissible variable added into standard domain	Notice	AE	5 (18.52%)	Model permissible variables were added to the domain CE for the study protocol needs: AELNKGRP AELAT AETPTREF AERFTDTC AEELTM
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	AE	25248 (63.92%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: •VACCINATION •OPEN LABEL FOLLOW-UP •REPEAT SCREENING 1
SD0021	Missing End Time-Point value	Warning	AE	3 (< 0.1%)	Data is reported as collected. At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD0022	Missing Start Time-Point value	Warning	AE	1 (< 0.1%)	Data is reported as collected. At the time of data extraction study is still ongoing and complete data was not obtained at database release.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1021	Unexpected character value in AEHLGT variable	Warning	AE	1 (< 0.1%)	At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD1097	No Treatment Emergent info for Adverse Event	Warning	AE	39501 (100.00%)	In Vaccine studies Treatment Emergent flag is not required per communication from CBER/OVRR.
SD1143	No Details info for AESMIE Adverse Event in SUPPAE domain	Warning	AE	199 (100.00%)	Description of Other Medically Important Serious Adverse Events are not collected on the CRF. Therefore, AESOSP information is not mapped to SUPPAE.
SD1201	Duplicate records in AE domain	Warning	AE	5 (< 0.1%)	There are no exacted duplicate records. AESPID values for these records are unique that differentiates the records.
SD1333	AEOUT = RECOVERED/RESOLVED, but an end date is not provided	Warning	AE	1 (< 0.1%)	Data is reported as collected. At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD0005	Duplicate value for CESEQ variable	Error	CE	1 (< 0.1%)	This is a false positive by P21 and is part of a known issue for SD0005 -- rule logic is flagging falsely (per P21 support). The team confirmed that there is only one record with USUBJID='C4591001 1231 12315324' and CESEQ=460000000004 in CE domain.
SD0041	Value for CEOCCUR is populated for unsolicited Intervention or Event	Error	CE	94560 (97.38%)	At the request of CBER, records with CETERM=COVID-19 like illness and COVID-19 have been added for all subjects, with CEOCCUR = Y or N. These are considered derived records rather than spontaneous. (References: IND 19736.92).

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1082	Variable length is too long for actual data	Error	CE	1 (2.94%)	According to FDA technical conformance guide section 3.3.3: The allotted length for each column containing character (text) data should be set to the maximum length of the variable used across all datasets in the study except for SUPPQUAL datasets. Pinnacle 21 provides false positive information since it only checks the length of the variable within the data set.
SD1202	CESTDTC date is after RFPENDTC	Error	CE	10 (< 0.1%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD1203	CEDTC date is after RFPENDTC	Error	CE	11 (< 0.1%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD1204	CEENDTC date is after RFPENDTC	Error	CE	113 (0.25%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1331	CESTDTC is after CEDTC	Error	CE	10 (< 0.1%)	Data is reported as collected. At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD2012	Value for CEHLGT not found in MedDRA dictionary	Error	CE	1 (< 0.1%)	Manually coded as "Virus infectious disorders".

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1076	Model permissible variable added into standard domain	Notice	CE	22 (56.41%)	<p>Model permissible variables were added to the domain CE for the study protocol needs:</p> <ul style="list-style-type: none"> • CERFTDTC • CEHLGTCD • CELLTCD • CELAT • CEEVINTX • CEDUR • CEBDSYCD • CESOCCD • CELNKGRP • VISITNUM • CEHLGT • CEHLTCD • CETOXGR • CEPTCD • CETPTNUM • CESOC • CEHLT • VISIT • CETPT • CELOC • CETPTREF • CELLT

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	CE	50541 (13.33%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: •VACCINATION •OPEN LABEL FOLLOW-UP •REPEAT SCREENING 1
SD0021	Missing End Time-Point value	Warning	CE	5155 (1.36%)	Data is reported as collected. At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD0022	Missing Start Time-Point value	Warning	CE	5156 (1.36%)	The CESTDTC is missing for CECAT='REACTOGENICITY' where when CEOCCUR='N' and is as per the CBER/OVRR flat model implementation. For CECAT='EFFICACY', CESTDTC is not collected on the CRF "Illness details " page.
SD0031	Missing values for CESTDTC, CESTRF and CESTRTPT, when CEENDTC, CEENRF or CEENRTPT is provided	Warning	CE	1 (< 0.1%)	Data is reported as collected. At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD0065	USUBJID/VISIT/VISITNUM values do not match SV domain data	Warning	CE	10 (< 0.1%)	This rule fired for subjects who had missing visits in SV domain. At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD1201	Duplicate records in CE domain	Warning	CE	100952 (26.63%)	CETPTREF is different for all specified CETERMs either VACCINATION 1 or VACCINATION 2. Therefore, these records are not true duplicates.
SD1339	Missing EPOCH value, when a start or observation date is provided	Warning	CE	11809 (17.33%)	For events domains --STDTC is used to derive EPOCH. Since CESTDTC is missing for these records, EPOCH is not derived.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD0035	Missing value for CMDOSU, when CMDOSE, CMDOSTXT or CMDOSTOT is provided	Error	CM	153 (25.89%)	At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD1202	CMSTDTC date is after RFPENDTC	Error	CM	34 (0.59%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD1204	CMENDTC date is after RFPENDTC	Error	CM	3 (10.34%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD1344	Value for CMDECOD not found in WHODrug dictionary	Error	CM	528 (6.61%)	Pfizer internal dictionary version (202003) was customized to add these terms from a newer dictionary, however these are not present in WHODRUG 202003.
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	CM	4456 (55.80%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: •VACCINATION •OPEN LABEL FOLLOW-UP •REPEAT SCREENING 1
SD0021	Missing End Time-Point value	Warning	CM	7917 (99.15%)	End date was not collected for SCR visit

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD0022	Missing Start Time-Point value	Warning	CM	4 (< 0.1%)	Data is reported as collected. At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD0077	Invalid referenced record	Error	CO	2 (< 0.1%)	For two records we have comments entered in CO, they are unrelated any specific domain. Subject C4591001 1170 11701321 test results were discarded by accident. Subject C4591001 1055 10551150 have no test results Therefore, we have records in CO but not present in MB domain.
SD1082	Variable length is too long for actual data	Error	CO	3 (30.00%)	According to FDA technical conformance guide section 3.3.3: The allotted length for each column containing character (text) data should be set to the maximum length of the variable used across all datasets in the study except for suppqual datasets. Pinnacle 21 provides false positive information since it only checks the length of the variable within the data set.
SD1203	CODTC date is after RFPENDTC	Error	CO	9 (< 0.1%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1076	Model permissible variable added into standard domain	Notice	CO	2 (8.00%)	Model permissible variables were added to the domain CE for the study protocol needs: VISIT VISITNUM
SD0065	USUBJID/VISIT/VISITNUM values do not match SV domain data	Warning	CO	194 (0.14%)	This rule fired for records coming from comments captured related to Immunogenicity data which was not used to derive SV.
SD0002	NULL value in DDTESTCD variable marked as Required	Error	DD	2 (4.17%)	Subject C4591001 1135 11351033 - official death certificate and autopsy results are awaited so that cause of death can be updated. Query is present to track the issue. subject C4591001 1088 10881126 - Primary cause of death is already reported as Cardiac Arrest, there is a blank extra log line on the form that has already been queried to be deleted.
SD0002	NULL value in DDTEST variable marked as Required	Error	DD	2 (4.17%)	Subject C4591001 1135 11351033 - official death certificate and autopsy results are awaited so that cause of death can be updated. Query is present to track the issue. subject C4591001 1088 10881126 - Primary cause of death is already reported as Cardiac Arrest, there is a blank extra log line on the form that has already been queried to be deleted.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1203	DDDTTC date is after RFPENDTC	Error	DD	23 (47.92%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD1076	Model permissible variable added into standard domain	Notice	DD	1 (1.43%)	Model permissible variable was added to the domain DD for the study protocol needs: • DDCAT
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	DD	14 (29.17%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: • VACCINATION • REPEAT SCREENING 1
SD0047	Missing value for DDORRES, when DDSTAT or DDRVFL is not populated	Warning	DD	2 (100.00%)	Subject C4591001 1135 11351033 - official death certificate and autopsy results are pending so that cause of death can be updated. Query is present to track the issue. subject C4591001 1088 10881126 - Primary cause of death is already reported as Cardiac Arrest, there is a blank extra log line on the form that has already been queried to be deleted.
SD1117	Duplicate records	Warning	DD	1 (2.17%)	Not a true duplicate, subject C4591001 1094 10941112 has two secondary causes of death "COVID-19 Infection" and "Pneumonia".

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1320	Missing value for DDSTRESC, when DDSTAT is null	Warning	DD	2 (4.17%)	Subject C4591001 1135 11351033 - official death certificate and autopsy results are pending so that cause of death can be updated. Query is present to track the issue. subject C4591001 1088 10881126 - Primary cause of death is already reported as Cardiac Arrest, there is a blank extra log line on the form that has already been queried to be deleted.
DD0050	Domain/SASDatasetName mismatch for split dataset	Error	DEFINE	1 (100.00%)	Per SDTM IG v3.2, sponsors may choose to split a domain of topically related information into physically separate datasets. Currently our internal approach is to split FA by topic hence we have dataset with names FACE, SUPPFACE, FAHO.
SD0002	NULL value in SPDEVID variable marked as Required	Error	DI	3 (3.80%)	This rule fired for 3 records in DI domain where SPDEVID was null. At the time of data extraction study is still ongoing and complete SPDEVID data was not obtained at the time of the snapshot.
SD1234	Missing TYPE Parameter for Device	Error	DI	39 (100.00%)	Device Type Parameter information is not available for the Medical Device used in the study.
SD2003	Invalid value for ACTARM	Error	DM	160 (0.34%)	Screen failures have ACTARM='NOT ASSIGNED' instead of propcase 'Not Assigned'.
TS0006	No Baseline (ALT) test results for Subject	Error	DM	46329 (99.58%)	Per protocol safety lab data is not collected for Phase 2/3. Lab data could be collected for COVID illness visits, which would be during study conduct and will not be used to set the baseline flag.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
TS0007	No Baseline (ALP) test results for Subject	Error	DM	46329 (99.58%)	Per protocol safety lab data is not collected for Phase 2/3. Lab data could be collected for COVID illness visits, which would be during study conduct and will not be used to set the baseline flag.
TS0008	No Baseline (AST) test results for Subject	Error	DM	46329 (99.58%)	Per protocol safety lab data is not collected for Phase 2/3. Lab data could be collected for COVID illness visits, which would be during study conduct and will not be used to set the baseline flag.
TS0009	No Baseline (BILI) test results for Subject	Error	DM	46329 (99.58%)	Per protocol safety lab data is not collected for Phase 2/3. Lab data could be collected for COVID illness visits, which would be during study conduct and will not be used to set the baseline flag.
TS0023	No (WEIGHT) results for subject	Error	DM	2 (< 0.1%)	This rule fired for 2 subjects who had no WEIGHT in VS dataset. At the time of data extraction study is still ongoing and complete data was not obtained at database release. USUBJID = C4591001 1161 11611005 and C4591001 1161 11611018
TS0024	No (HEIGHT) results for subject	Error	DM	2 (< 0.1%)	This rule fired for 2 subjects who had no HEIGHT in VS dataset. At the time of data extraction study is still ongoing and complete data was not obtained at database release. USUBJID = C4591001 1161 11611005 and C4591001 1161 11611018

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
TS0039	No (ALT) test results	Error	DM	45949 (98.76%)	Per protocol safety lab data is not collected for Phase 2/3. Lab data could be collected for COVID illness visits, which would be during study conduct and will not be used to set the baseline flag.
TS0040	No (ALP) test results	Error	DM	45950 (98.77%)	Per protocol safety lab data is not collected for Phase 2/3. Lab data could be collected for COVID illness visits, which would be during study conduct and will not be used to set the baseline flag.
TS0041	No (AST) test results	Error	DM	45950 (98.77%)	Per protocol safety lab data is not collected for Phase 2/3. Lab data could be collected for COVID illness visits, which would be during study conduct and will not be used to set the baseline flag.
TS0042	No (BILI) test results	Error	DM	45948 (98.76%)	Per protocol safety lab data is not collected for Phase 2/3. Lab data could be collected for COVID illness visits, which would be during study conduct and will not be used to set the baseline flag.
TS0047	No (SYSBP) test results for subject	Error	DM	45149 (97.04%)	Per protocol blood pressure is not collected for Phase 2/3. Lab data could be collected for COVID illness visits, which would be during study conduct and will not be used to set the baseline flag.
TS0048	No (DIABP) test results for subject	Error	DM	45149 (97.04%)	Per protocol blood pressure is not collected for Phase 2/3. Lab data could be collected for COVID illness visits, which would be during study conduct and will not be used to set the baseline flag.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
TS0049	No (HR) or (PULSE) test results for subject	Error	DM	45149 (97.04%)	Per protocol heart rate or pulse are not collected for Phase 2/3. Lab data could be collected for COVID illness visits, which would be during study conduct and will not be used to set the baseline flag.
TS0043	No (GGT) test results	Notice	DM	46524 (100.00%)	Per protocol GGT(Gamma-Glutamyl Transferase) is not collected.
CT2002	RACE value not found in 'Race' extensible codelist	Warning	DM	1166 (2.42%)	New terms were added to extensible codelist RACE (C74457) for the study protocol needs: • MULTIPLE Multiple RACE values collected for few subjects. Therefore, RACE value set as 'MULTIPLE' in DM and all the collected RACE values mapped to SUPPDM.
SD0006	No baseline flag record in MB for subject	Warning	DM	107 (0.23%)	Per protocol safety lab data is not collected for Phase 2/3. Lab data could be collected for COVID illness visits, which are during study conduct and will not be used to set the baseline flag.
SD0006	No baseline flag record in VS for subject	Warning	DM	2 (< 0.1%)	At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD0006	No baseline flag record in LB for subject	Warning	DM	32928 (70.78%)	Per protocol safety lab data is not collected for Phase 2/3. Lab data could be collected for COVID illness visits, which are during study conduct and will not be used to set the baseline flag.
SD1032	No records for 'SCRNFAIL' subject are found in IE domain	Warning	DM	1 (< 0.1%)	Subject C4591001 1162 11621371 was a screen failure due to subject meeting delayed criteria, and not Inclusion/Exclusion related.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1258	RFSTDTC is populated for subject who did not receive treatment	Warning	DM	112 (7.15%)	There were 112 subjects that were randomized but not treated. Therefore, RFSTDTC was populated for those records when ACTARM was 'Not Treated'. the actual dosing start date RFXSTDTC is not populated
SD1334	RFICDTC is after RFSTDTC	Warning	DM	1 (< 0.1%)	Subject C4591001 1161 11611011 did not sign informed consent at visit1 (01AUG2020). Site had subject come in to sign consent on 19AUG2020.
SD1335	RFICDTC is after RFXSTDTC	Warning	DM	1 (< 0.1%)	Subject C4591001 1161 11611011 did not sign informed consent at visit1 (01AUG2020). Site had subject come in to sign consent on 19AUG2020.
SD2236	ACTARMCD does not equal ARMCD	Warning	DM	120 (0.25%)	There were 120 subjects in the analysis with treatment errors: 112 subjects were not treated; 8 subjects received the wrong treatment instead of their randomized treatment
SD2237	ACTARM does not equal ARM	Warning	DM	120 (0.25%)	There were 120 subjects in the analysis with treatment errors: 112 subjects were not treated; 8 subjects received the wrong treatment instead of their randomized treatment.
SD0002	NULL value in DSDECOD variable marked as Required	Error	DS	1 (< 0.1%)	At the time of data extraction study is still ongoing and complete data was not obtained at database release
SD0002	NULL value in DSTERM variable marked as Required	Error	DS	1 (< 0.1%)	At the time of data extraction study is still ongoing and complete data was not obtained at database release

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1319	DSSTDTC is before RFICDTC	Error	DS	2 (< 0.1%)	Subject C4591001 1161 11611011 did not sign informed consent at visit1 (01AUG2020). Site had subject come in to sign consent on 19AUG2020.
SD1331	DSSTDTC is after DSDTC	Error	DS	520 (0.38%)	There were labs that the site had to wait for to assess screen failure status, it is expected that the SF date would be after the SCR DOV.
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	DS	66212 (23.34%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: •VACCINATION •REPEAT SCREENING 1
CT2005	DSDECOD value not found in 'Completion/Reason for Non-Completion' extensible codelist when DSCAT == 'DISPOSITION EVENT'	Warning	DS	210 (0.17%)	New terms were added to extensible codelist Completion/Reason for Non-Completion (C66727) for the study protocol needs: • NO LONGER MEETS ELIGIBILITY CRITERIA • REFUSED FURTHER STUDY PROCEDURES • MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT
SD1201	Duplicate records in DS domain	Warning	DS	438 (0.15%)	The values of DSPHASE in SUPPDS are generated from two different CRF pages ("VACCINATION" "FOLLOW-UP"); However, these appear to be true duplicates in DS due to same information being entered on both CRFs.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1318	No records for subject are found in DV domain	Warning	DS	1 (0.27%)	Study was ongoing at the time of the data extraction therefore DV data is not complete and reconciled for all subjects at that time (record missing for subjects C4591001 1084 10841290). Dataset will be updated and reconciled for final deliverables at time of study completion.
SD1202	DVSTDTC date is after RFPENDTC	Error	DV	185 (0.66%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD1319	DVSTDTC is before RFICDTC	Error	DV	4347 (11.71%)	At the time of data extraction study is still ongoing and complete data was not obtained at database release.
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	DV	22665 (61.07%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: •VACCINATION •OPEN LABEL FOLLOW-UP •REPEAT SCREENING 1
SD1201	Duplicate records in DV domain	Warning	DV	823 (2.22%)	DVSPID values are unique for these records. Therefore, these are not true duplicates.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1082	Variable length is too long for actual data	Error	EC	1 (5.00%)	According to FDA technical conformance guide section 3.3.3: The allotted length for each column containing character (text) data should be set to the maximum length of the variable used across all datasets in the study except for suppqual datasets. Pinnacle 21 provides false positive information since it only checks the length of the variable within the data set.
SD1202	ECSTDTC date is after RFPENDTC	Error	EC	1 (< 0.1%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD1204	ECENDTC date is after RFPENDTC	Error	EC	1 (< 0.1%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD1282	ECTPTREF variable is present when ECELTM, ECTPTNUM, and ECTPT are missing	Error	EC	1 (100.00%)	Based on CDISC TAUG, ECTPTREF can be populated for Vaccine studies; ECELTM, ECTPTNUM, and ECTPT are not necessary.
SD1076	Model permissible variable added into standard domain	Notice	EC	2 (9.09%)	Model permissible variables were added to the domain CE for the study protocol needs: VISIT VISITNUM

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	EC	92370 (72.08%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: •VACCINATION •REPEAT SCREENING 1
SD1082	Variable length is too long for actual data	Error	EX	1 (5.26%)	According to FDA technical conformance guide section 3.3.3: The allotted length for each column containing character (text) data should be set to the maximum length of the variable used across all datasets in the study except for suppqual datasets. Pinnacle 21 provides false positive information since it only checks the length of the variable within the data set.
SD1202	EXSTDTC date is after RFPENDTC	Error	EX	1 (< 0.1%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD1204	EXENDTC date is after RFPENDTC	Error	EX	1 (< 0.1%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD1282	EXTPTREF variable is present when EXELTM, EXTPTNUM, and EXTPT are missing	Error	EX	1 (100.00%)	Based on CDISC TAUG, ECTPTREF can be populated for Vaccine studies; ECELTM, ECTPTNUM, and ECTPT are not necessary.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1076	Model permissible variable added into standard domain	Notice	EX	2 (6.90%)	Model permissible variables were added to the domain CE for the study protocol needs: VISIT VISITNUM
CT2002	EXDOSU value not found in 'Unit' extensible codelist	Warning	EX	127736 (99.70%)	New terms were added to extensible codelist Unit (C71620) for the study protocol needs: • mcg
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	EX	92370 (72.09%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: •VACCINATION •REPEAT SCREENING 1
SD0082	Exposure end date is after the latest Disposition date	Warning	EX	8857 (6.91%)	At the time of data extraction, study is still ongoing and disposition status is collected at the completion or discontinuation of each stage of the study therefore may not have occurred at the time of this data snapshot.
SD1340	EX record is present, when subject is not treated	Warning	EX	3 (< 0.1%)	This check fired for 3 subjects, all randomized and not treated due to medication error without associated adverse event (2 active, 1 placebo). USUBJID in (C4591001 1163 11631005, C4591001 1163 11631006, C4591001 1163 11631008)
SD1203	FADTC date is after RFPENDTC	Error	FA	271 (< 0.1%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD2239	Inconsistent value for FATPT	Error	FA	3347 (0.16%)	Values are populated correctly as per Vaccine TAUG. P21 rule is expecting same TPT/TPTNUM used across subject/DTC. Since DTC differs, P21 check fired, however there is an inherent assumption in the rule that for different times on same date, the timepoint should be different (e.g. 1 HR and 3 HRS timepoints cannot have same date/time values), which does not apply here.
SD1076	Model permissible variable added into standard domain	Notice	FA	12 (22.64%)	Model permissible variables were added to the domain FA for the study protocol needs: <ul style="list-style-type: none"> • FATPTNUM • FADRVFL • FAEVLINT • FATPTREF • FAENRTPT • FALNKID • FAEVINTX • FARFTDTC • FALNKGRP • FAENTPT • FATPT • FAREFID

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	FA	2045291 (95.49%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: •VACCINATION •OPEN LABEL FOLLOW-UP •REPEAT SCREENING 1
CT2002	FASTRESU value not found in 'Unit' extensible codelist	Warning	FA	3817 (0.18%)	New term was added to extensible codelist Unit (C71620) for the study protocol needs: • VISITS/CONTACTS
CT2002	FAORRESU value not found in 'Unit' extensible codelist	Warning	FA	10814 (0.50%)	New terms were added to extensible codelist Unit (C71620) for the study protocol needs: • CALIPER UNIT • VISITS/CONTACTS
SD0016	Missing value for FASTRESC, when FADRVFL='Y'	Warning	FA	226050 (95.35%)	As per CBER guidance, the records were derived for missed diary days and FADRVFL flag is used to indicate that data was not collected.
SD0026	Missing value for FAORRESU, when FAORRES is provided	Warning	FA	1 (< 0.1%)	Result collected is a date which has no associated units.
SD0029	Missing value for FASTRESU, when FASTRESC is provided	Warning	FA	1 (< 0.1%)	Result collected is a date which has no associated units.
SD0065	USUBJID/VISIT/VISITNUM values do not match SV domain data	Warning	FA	1 (< 0.1%)	This rule fired for subjects who had missing visits in SV domain. At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD1021	Unexpected character value in FAOBJ variable	Warning	FA	1 (< 0.1%)	At the time of data extraction study is still ongoing and complete data was not obtained at database release. Query in place to update the data.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1117	Duplicate records	Warning	FA	19 (< 0.1%)	The FAOBJ which appears to be duplicate for records, which are not pre-specified for collection on the CRF, however the verbatim term is unique for these records and are coded to same preferred term.
SD1122	Missing value for FASTRESN	Warning	FA	1 (< 0.1%)	FASTRESC is a date and has no associated units.
SD1124	Missing value for FAREASND, when FASTAT is 'NOT DONE'	Warning	FA	173 (< 0.1%)	Reason for NOT DONE not collected on the CRF.
TS0050	Missing PC dataset	Warning	GLOBAL	1 (100.00%)	Not applicable for this study
TS0051	Missing PP dataset	Warning	GLOBAL	1 (100.00%)	Not applicable for this study
SD1082	Variable length is too long for actual data	Error	HO	1 (5.56%)	According to FDA technical conformance guide section 3.3.3: The allotted length for each column containing character (text) data should be set to the maximum length of the variable used across all datasets in the study except for SUPPQUAL datasets. Pinnacle 21 provides false positive information since it only checks the length of the variable within the data set.
SD1202	HOSTDTC date is after RFPENDTC	Error	HO	1 (1.09%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1204	HOENDTC date is after RFPENDTC	Error	HO	3 (3.57%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD1076	Model permissible variable added into standard domain	Notice	HO	4 (14.81%)	Model permissible variables were added to the domain CE for the study protocol needs: VISIT VISITNUM HOEVINTX HOLNKID
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	HO	27042 (42.07%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: •VACCINATION •OPEN LABEL FOLLOW-UP •REPEAT SCREENING 1
SD0021	Missing End Time-Point value	Warning	HO	3817 (5.94%)	For 3331 records Start and End dates are missing as they are not collected on the HEALTHCARE UTILIZATION ASSESSMENT CRF.
SD0022	Missing Start Time-Point value	Warning	HO	3817 (5.94%)	HOSTDTC is missing as start date is not collected on the source CRF - HEALTHCARE UTILIZATION ASSESSMENT.
SD0065	USUBJID/VISIT/VISITNUM values do not match SV domain data	Warning	HO	5 (< 0.1%)	This rule fired for subjects who had missing visits in SV domain. At the time of data extraction study is still ongoing and complete data was not obtained at database release.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1021	Unexpected character value in HOTERM variable	Warning	HO	1 (< 0.1%)	At the time of data extraction study is still ongoing and complete data was not obtained at database release. Query in place to update the data
SD1201	Duplicate records in HO domain	Warning	HO	9661 (15.03%)	There are no exact duplicate records. At least one variable value used in KEY variables: STUDYID USUBJID HOCAT HOTERM VISITNUM HOSTDTC differentiates the records.
SD1274	HOTERM equals 'OTHER'	Warning	HO	10166 (15.82%)	As per the CRF 'OTHER' is collected in the study.
SD1339	Missing EPOCH value, when a start or observation date is provided	Warning	HO	144 (0.22%)	For HO domain --DTC is used to derive EPOCH. Since HODTC is missing for these records, EPOCH is not derived.
SD1082	Variable length is too long for actual data	Error	IE	1 (8.33%)	According to FDA technical conformance guide section 3.3.3: The allotted length for each column containing character (text) data should be set to the maximum length of the variable used across all datasets in the study except for suppqual datasets. Pinnacle 21 provides false positive information since it only checks the length of the variable within the data set.
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	IE	15 (1.00%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: •REPEAT SCREENING 1

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1203	ISDTC date is after RFPENDTC	Error	IS	2 (< 0.1%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD1076	Model permissible variable added into standard domain	Notice	IS	1 (2.56%)	Model permissible variable was added to the domain IS for the study protocol needs: • ISTSTDTL
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	IS	4637 (4.15%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: • VACCINATION • REPEAT SCREENING 1
CT2002	ISORRESU value not found in 'Unit' extensible codelist	Warning	IS	111616 (100.00%)	New terms were added to extensible codelist Unit (C71620) for the study protocol needs: • NA • UML • NONE
SD0029	Missing value for ISSTRESU, when ISSTRESC is provided	Warning	IS	5623 (75.88%)	This rule fired for Immunogenicity tests for "N-binding antibody", "SARS-CoV-2 serum neutralizing titer 50", "SARS-CoV-2 serum neutralizing titer 90". Original units for these tests was "NA" hence there's no standard units populated.
SD1117	Duplicate records	Warning	IS	356 (0.32%)	Not true duplicates, repeat tests are indicated by ISTSTDTL variable in IS

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD0005	Duplicate value for LBSEQ variable	Error	LB	30766 (99.33%)	This is a false positive by P21 and is part of a known issue for SD0005 -- rule logic is flagging falsely (per P21 support). LBSEQ values are unique for each record within LB domain and within each Unique Subject Identifier (USUBJID), Sponsor Device Identifier (SPDEVID) variables value.
SD0007	Inconsistent value for Standard Units	Error	LB	362 (1.18%)	This check fired for several lab tests with inconsistencies in standard units. As a standard course of action, laboratory unit inconsistencies are reviewed by the clinical team. At the time of data extraction, study is still ongoing and disposition status is collected at the completion or discontinuation of each stage of the study therefore may not have occurred at the time of this data snapshot.
SD1082	Variable length is too long for actual data	Error	LB	1 (3.85%)	According to FDA technical conformance guide section 3.3.3: The allotted length for each column containing character (text) data should be set to the maximum length of the variable used across all datasets in the study except for suppqual datasets. Pinnacle 21 provides false positive information since it only checks the length of the variable within the data set.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1203	LBDTC date is after RFPENDTC	Error	LB	201 (0.37%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD1076	Model permissible variable added into standard domain	Notice	LB	1 (2.78%)	Model permissible variable was added to the domain MB for the study protocol needs: • SPDEVID
CT2002	LBORRESU value not found in 'Unit' extensible codelist	Warning	LB	12963 (16.14%)	New terms were added to extensible codelist Unit (C71620) for the study protocol needs: • 10 ³ /uL • x10 ⁶ /uL • 10 ³ /uL • 10 ³ /mm ³ • /mL • /uL • 10 ⁶ /cu mm
CT2002	LBTESTCD value not found in 'Laboratory Test Code' extensible codelist	Warning	LB	1074 (1.34%)	New term was added to extensible codelist Laboratory Test Code (C65047) for the study protocol needs: • HIVR_US • HYSLOW

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	LB	32460 (40.41%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: <ul style="list-style-type: none"> •VACCINATION •OPEN LABEL FOLLOW-UP •REPEAT SCREENING 1
CT2002	LBSTRESU value not found in 'Unit' extensible codelist	Warning	LB	297 (0.37%)	New terms were added to extensible codelist Unit (C71620) for the study protocol needs: <ul style="list-style-type: none"> • 10^3/uL • /mL • 10^3/mm3 • /uL • 10^6/cu mm
CT2002	LBTEST value not found in 'Laboratory Test Name' extensible codelist	Warning	LB	1074 (1.34%)	New term was added to extensible codelist Laboratory Test Name (C67154) for the study protocol needs: <ul style="list-style-type: none"> • HIV RNA (Ultrasensitive) • Hys Law Criteria
SD0026	Missing value for LBORRESU, when LBORRES is provided	Warning	LB	72 (0.24%)	Data is reported as collected. At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD0029	Missing value for LBSTRESU, when LBSTRESC is provided	Warning	LB	72 (0.24%)	Data is reported as collected. At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD0065	USUBJID/VISIT/VISITNUM values do not match SV domain data	Warning	LB	15 (< 0.1%)	This rule fired for subjects who had missing visits in SV domain. At the time of data extraction study is still ongoing and complete data was not obtained at database release.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1124	Missing value for LBREASND, when LBSTAT is 'NOT DONE'	Warning	LB	12187 (99.75%)	Reason for NOT DONE is not collected on the CRF Signs and Symptoms form or raw data for COVID illness visits.
TS0057	LBSTRESN is populated but LBSTNRHI is not populated	Warning	LB	303 (1.00%)	Data is reported as collected. At the time of data extraction study is still ongoing and complete data is not obtained at database release; Some normal ranges have not been entered.
SD0005	Duplicate value for MBSEQ variable	Error	MB	6686 (98.82%)	This is a false positive by P21. It is not an issue with MBSEQ but is an issue with not having a unique record for USUBJID and SPDEVID -- rule logic is flagging falsely (per P21 support). MBSEQ values are unique for each record within MB domain and within each Unique Subject Identifier (USUBJID), Sponsor Device Identifier (SPDEVID) variables value.
SD1082	Variable length is too long for actual data	Error	MB	2 (8.33%)	According to FDA technical conformance guide section 3.3.3: The allotted length for each column containing character (text) data should be set to the maximum length of the variable used across all datasets in the study except for suppqual datasets. Pinnacle 21 provides false positive information since it only checks the length of the variable within the data set.
SD1203	MBDTC date is after RFPENDTC	Error	MB	100 (0.11%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1076	Model permissible variable added into standard domain	Notice	MB	1 (2.50%)	Model permissible variable was added to the domain MB for the study protocol needs: • SPDEVID
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	MB	59913 (45.69%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: • VACCINATION • OPEN LABEL FOLLOW-UP • REPEAT SCREENING 1
CT2002	MBSPEC value not found in 'Specimen Type' extensible codelist	Warning	MB	123851 (94.44%)	New terms were added to extensible codelist Specimen Type (C78734) for the study protocol needs: • NASAL_SWAB • NASAL_SWAB_SELF • RESPIRATORY SECRETIONS
SD0065	USUBJID/VISIT/VISITNUM values do not match SV domain data	Warning	MB	13 (< 0.1%)	This rule fired for subjects who had missing visits in SV domain. At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD1023	VISIT/VISITNUM values do not match TV domain data	Warning	MB	73 (< 0.1%)	These records having VISIT=COVID_A, COVID_AR1, COVID_B, COVID_BR1, COVID_C, COVID_D, POT_COVID_REPEAT_SWAB are illness visits and considered unplanned and not included in the TV domain.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1082	Variable length is too long for actual data	Error	MH	2 (10.53%)	According to FDA technical conformance guide section 3.3.3: The allotted length for each column containing character (text) data should be set to the maximum length of the variable used across all datasets in the study except for suppqual datasets. Pinnacle 21 provides false positive information since it only checks the length of the variable within the data set.
SD1144	MHSTDTC date is after RFSTDTC	Error	MH	1 (< 0.1%)	At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD1204	MHENDTC date is after RFPENDTC	Error	MH	1 (< 0.1%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD1331	MHSTDTC is after MHDTC	Error	MH	3 (< 0.1%)	As per the protocol, AEs that occurred prior to dosing were collected on the Medical History CRF. Therefore, for some records MHSTDTC is greater than MHDTC.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1076	Model permissible variable added into standard domain	Notice	MH	12 (28.57%)	Model permissible variables were added to the domain MH for the study protocol needs: <ul style="list-style-type: none"> • VISIT • MHSOCCD • MHSOC • MHBDSYCD • VISITNUM • MHLTCD • MHHLT • MHHLGT • MHLT • MHHLGTCD • MHPTCD • MHHLTCD
SD0021	Missing End Time-Point value	Warning	MH	9 (< 0.1%)	Data is reported as collected. At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD0022	Missing Start Time-Point value	Warning	MH	29 (< 0.1%)	Data is reported as collected. At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD0031	Missing values for MHSTDTC, MHSTRF and MHSTRTP, when MHENDTC, MHENRF or MHENRTPT is provided	Warning	MH	21 (< 0.1%)	Data is reported as collected. At the time of data extraction study is still ongoing and complete data was not obtained at database release.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1201	Duplicate records in MH domain	Warning	MH	112 (< 0.1%)	There are no exact duplicate records. At least one variable value used in KEY variables: STUDYID USUBJID MHCAT MHTERM MHDTC MHSPID MHENRTPT differentiates the records.
SD1082	Variable length is too long for actual data	Error	MO	1 (6.67%)	According to FDA technical conformance guide section 3.3.3: The allotted length for each column containing character (text) data should be set to the maximum length of the variable used across all datasets in the study except for suppqual datasets. Pinnacle 21 provides false positive information since it only checks the length of the variable within the data set.
SD1203	MODTC date is after RFPENDTC	Error	MO	4 (1.88%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	MO	147 (43.36%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: • VACCINATION
CT2002	MOMETHOD value not found in 'Method' extensible codelist	Warning	MO	15 (4.42%)	New term was added to extensible codelist Method (C85492) for the study protocol needs: • OTHER
CT2002	MOLOC value not found in 'Anatomical Location' extensible codelist	Warning	MO	50 (14.75%)	New term was added to extensible codelist Anatomical Location (C74456) for the study protocol needs: • OTHER

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD0065	USUBJID/VISIT/VISITNUM values do not match SV domain data	Warning	MO	1 (0.31%)	This rule fired for subjects who had missing visits in SV domain. At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD1117	Duplicate records	Warning	MO	6 (1.77%)	Not true duplicate. Domain is unique based on USUBJID, MOTESTCD, MOLOC, MOMETHOD, MODTC and values of SUPPMO.QNAM=METHOTH.
SD1082	Variable length is too long for actual data	Error	PE	1 (8.33%)	According to FDA technical conformance guide section 3.3.3: The allotted length for each column containing character (text) data should be set to the maximum length of the variable used across all datasets in the study except for suppqual datasets. Pinnacle 21 provides false positive information since it only checks the length of the variable within the data set.
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	PE	8680 (51.67%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: •VACCINATION
SD1082	Variable length is too long for actual data	Error	PR	1 (6.25%)	According to FDA technical conformance guide section 3.3.3: The allotted length for each column containing character (text) data should be set to the maximum length of the variable used across all datasets in the study except for suppqual datasets. Pinnacle 21 provides false positive information since it only checks the length of the variable within the data set.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1204	PRENDTC date is after RFPENDTC	Error	PR	1 (5.56%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD1331	PRSTDTC is after PRDTC	Error	PR	20 (57.14%)	Data is reported as collected. At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD1076	Model permissible variable added into standard domain	Notice	PR	1 (3.85%)	Model permissible variable was added to the domain PR for the study protocol needs: •PRDTC
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	PR	18 (31.03%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: •VACCINATION •REPEAT SCREENING 1
SD0021	Missing End Time-Point value	Warning	PR	19 (32.76%)	End date is not collected for the records with PRCAT=TRANSFUSION DETAILS, these are from the Transfusion CRF page where only the date of transfusion is collected. For other records with missing end date, data is reported as collected. At the time of data extraction study is still ongoing and complete data was not obtained at database release.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD0072	Invalid RDOMAIN	Error	RELREC	3819 (48.86%)	As per SDTM IG 3.2 section 4.1.1.7 Splitting Domains: "In RELREC, if a dataset level relationship is defined for a split Findings About domain, then RDOMAIN may contain the four-character dataset name". P21 doesn't recognize FACE or FAHO as valid RDOMAINS.
SD0013	SESTDTC is after SEENDTC	Error	SE	3 (< 0.1%)	Subject C4591001 1161 11611011 did not sign informed consent at visit1 (01AUG2020). The site had the subject come in to sign consent on 19AUG2020. For subjects C4591001 1044 10441163, C4591001 1232 12321112 SEENDTC=max(rfendtc, rfpndtc), which is the last available dosing date after cutoff of 13-March-2021, as a result SESTDTC is greater than SEENDTC.
SD1202	SESTDTC date is after RFPENDTC	Error	SE	1 (< 0.1%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1204	SEENDTC date is after RFPENDTC	Error	SE	2 (< 0.1%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	SE	73526 (39.31%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: •VACCINATION •OPEN LABEL FOLLOW-UP •REPEAT SCREENING 1
SD1202	SVSTDTC date is after RFPENDTC	Error	SV	1 (< 0.1%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD1204	SVENDTC date is after RFPENDTC	Error	SV	1 (< 0.1%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD1076	Model permissible variable added into standard domain	Notice	SV	1 (5.88%)	Model permissible variable was added to the domain SV for the study protocol needs: • SVREFID

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	SV	159295 (59.86%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: •VACCINATION •OPEN LABEL FOLLOW-UP •REPEAT SCREENING 1
SD1060	Duplicate VISITNUM	Warning	SV	3 (< 0.1%)	Subject C4591001 1013 10131294 had two records for VISIT=200 but with different visit date. This has been queried for data issue by data management. Subjects C4591001 1091 10911387 and C4591001 1241 12411482 appear to be duplicates, however SVREFID makes them unique. Data is reported as collected. At the time of data extraction study is still ongoing and complete data was not obtained at database release.
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	TA	12 (38.71%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: •VACCINATION •OPEN LABEL FOLLOW-UP •REPEAT SCREENING 1
SD2243	Invalid TSVCDREF value for PCLAS	Error	TS	1 (100.00%)	Due to the novel nature of the treatment, PCLAS is not available in NDF-RT. TSVAL is set to "Vaccines, Nucleic Acid" from CSP dictionary, CUI number "C0600412" is used in TSVALCD, and "CSP" is used in TSVCDREF.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD2260	Invalid TSVAL value for TRT	Error	TS	2 (100.00%)	Due to the novel nature of the treatment, there is no standard name for BNT162b1/BNT162b2 from FDA substance registration system.
SD2261	Invalid TSVALCD value for TRT	Error	TS	2 (100.00%)	There is no corresponding code for BNT162b1/BNT162b2 from UNII
SD2263	Invalid TSVAL value for PCLAS	Error	TS	1 (100.00%)	Due to the novel nature of the treatment, NDF-RT TSVAL is set to "Vaccines, Nucleic Acid" from CSP dictionary. And CUI number "C0600412" is used in TSVALCD.
SD2264	Invalid TSVALCD value for PCLAS	Error	TS	1 (100.00%)	Due to the novel nature of the treatment, PCLAS is not available in NDF-RT. TSVAL is set to "Vaccines, Nucleic Acid" from CSP dictionary. And CUI number "C0600412" is used in TSVALCD.
SD2265	TSVAL/TSVALCD value mismatch for PCLAS	Error	TS	1 (100.00%)	Due to the novel nature of the treatment, TSPARMCD=PCLAS is not available in NDF-RT. TSVAL is set to "Vaccines, Nucleic Acid" from CSP dictionary. And CUI number "C0600412" is used in TSVALCD.
SD1076	Model permissible variable added into standard domain	Notice	TS	1 (10.00%)	Model permissible variable was added to the domain TS to accommodate the character length greater than 200: • TSVAL1
CT2005	TSVAL value not found in 'Trial Blinding Schema Response' extensible codelist when TSPARMCD == 'TBLIND'	Warning	TS	1 (100.00%)	New term was added to extensible codelist TBLIND (C66735) for the study protocol needs: •OBSERVER BLIND

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
CT2005	TSVAL value not found in 'Trial Phase Response' extensible codelist when TSPARMCD == 'TPHASE'	Warning	TS	1 (100.00%)	New term was added to extensible codelist TPHASE (C66737) for the study protocol needs: •PHASE I/II/III TRIAL
SD1203	VSDTC date is after RFPENDTC	Error	VS	81 (< 0.1%)	At the time of data extraction, study is still ongoing and RFPENDTC is derived as the maximum of date of disposition, Subject Visits, date of death. Therefore, for ongoing subjects may not yet include completion date of the current study phase where individual dates from that phase may already be reported.
SD2239	Inconsistent value for VSTPT	Error	VS	6132 (1.46%)	Values are populated correctly as per Vaccine TAUG. P21 rule is expecting same TPT/TPTNUM used across subject/DTC. Since DTC differs, P21 check fired, however there is an inherent assumption in the rule that for different times on same date, the timepoint should be different (e.g. 1 HR and 3 HRS timepoints cannot have same date/time values), which does not apply here.
SD1076	Model permissible variable added into standard domain	Notice	VS	6 (13.64%)	Model permissible variables were added to the domain VS for the study protocol needs: • VSEVINTX • VSLNKGRP • VSEVLINT • VSLNKID • VSREFID • VSEVAL

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	VS	410819 (98.01%)	New term was added to extensible codelist EPOCH (C99079) for the study protocol needs: •VACCINATION •OPEN LABEL FOLLOW-UP •REPEAT SCREENING 1
SD0016	Missing value for VSSTRESC, when VSDRVFL='Y'	Warning	VS	22605 (100.00%)	As per CBER guidance, the records were derived for missed diary days and VSDRVFL flag is used to indicate that data was not collected.
SD0027	Missing value for VSORRES, when VSORRESU is provided	Warning	VS	1 (< 0.1%)	At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD0030	Missing value for VSSTRESC, when VSSTRESU is provided	Warning	VS	1 (< 0.1%)	Data is reported as collected. At the time of data extraction study is still ongoing and complete data was not obtained at database release.
SD1117	Duplicate records	Warning	VS	1 (< 0.1%)	Data reported as collected. These visits were unplanned COVID illness visits (VISIT=COVID_A) and the VSORRES values differ for these records.
SD1124	Missing value for VSREASND, when VSSTAT is 'NOT DONE'	Warning	VS	271 (1.18%)	Reason for NOT DONE was not collected.

4.3 Additional Conformance Details

There are no additional details to be documented.

Appendix I: Inclusion/Exclusion Criteria

Protocol/ Amendment Version	Category	IETESTCD	Full Text of Criterion
1.0	INCLUSION	IN01A00	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 stage)
6.0	INCLUSION	IN01A05	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)
7.0	INCLUSION	IN01A06	Male or female participants between the ages of 18 and 55 years, inclusive, and 65 and 85 years, inclusive (Phase 1), or ≥ 16 years (Phase 2/3), at randomization
8.0	INCLUSION	IN01A07	Male or female participants between the ages of 18 and 55 years, inclusive, and 65 and 85 years, inclusive (Phase 1), or ≥ 12 years (Phase 2/3), at randomization. Note that participants <18 years of age cannot be enrolled in the EU
1.0	INCLUSION	IN02A00	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures
1.0	INCLUSION	IN03A00	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study. Note: Healthy participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, can be included

Protocol/ Amendment Version	Category	IETESTCD	Full Text of Criterion
6.0	INCLUSION	IN03A05	Healthy participants who are determined by medical history, physical examination (if required), and clinical judgment of the investigator to be eligible for inclusion in the study. Note: Healthy participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, can be included
7.0	INCLUSION	IN03A06	Healthy participants who are determined by medical history, physical examination (if required), and clinical judgment of the investigator to be eligible for inclusion in the study. Note: Healthy participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, can be included. Specific criteria for Phase 3 participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) can be found in Section 10.8
1.0	INCLUSION	IN04A00	Capable of giving personal signed informed consent as described in Appendix 1, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol
8.0	INCLUSION	IN04A07	Capable of giving personal signed informed consent/have parent(s)/legal guardian capable of giving signed informed consent as described in Appendix 1, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol
6.0	INCLUSION	IN05A05	Participants who, in the judgment of the investigator, are at risk for acquiring COVID-19
7.0	INCLUSION	IN05A06	Phase 2/3 only: Participants who, in the judgment of the investigator, are at higher risk for acquiring COVID-19 (including, but not limited to, use of mass transportation, relevant demographics, front line essential workers and others)

Protocol/ Amendment Version	Category	IETESTCD	Full Text of Criterion
1.0	EXCLUSION	EX01A00	Other medical or psychiatric condition including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that may increase the risk of study participation or, in the investigator's judgment, make the participant inappropriate for the study
1.0	EXCLUSION	EX02A00	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
7.0	EXCLUSION	EX02A06	Phase 1 & 2 only: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
1.0	EXCLUSION	EX03A00	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)
1.0	EXCLUSION	EX04A00	Receipt of medications intended to prevent COVID 19
1.0	EXCLUSION	EX05A00	Stages 1 and 2 only: Previous clinical or microbiological diagnosis of COVID-19
6.0	EXCLUSION	EX05A05	Previous clinical or microbiological diagnosis of COVID-19
8.0	EXCLUSION	EX05A07	Previous clinical (based on COVID-19 symptoms/signs alone, if a SARS-CoV-2 NAAT result was not available) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID-19
1.0	EXCLUSION	EX06A00	Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19, including those with any of the following risk factors: Hypertension, Diabetes mellitus, Chronic pulmonary disease, Asthma, Current vaping or smoking, History of chronic smoking within the prior year, BMI >30 kg/m ² , Anticipating the need for immunosuppressive treatment within the next 6 months

Protocol/ Amendment Version	Category	IETESTCD	Full Text of Criterion
2.0	EXCLUSION	EX06A01	Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19, including those with any of the following risk factors: Hypertension, Diabetes mellitus, Chronic pulmonary disease, Asthma, Current vaping or smoking, History of chronic smoking within the prior year, Chronic liver disease, Stage 3 or worse chronic kidney disease (glomerular filtration rate <60 mL/min/1.73 m ²), Resident in a long-term facility, BMI >30 kg/m ² , Anticipating the need for immunosuppressive treatment within the next 6 months
6.0	EXCLUSION	EX06A05	Phase 1 only: Individuals at high risk for severe COVID-19, including those with any of the following risk factors: Hypertension, Diabetes mellitus, Chronic pulmonary disease, Asthma, Current vaping or smoking, History of chronic smoking within the prior year, Chronic liver disease, Stage 3 or worse chronic kidney disease (glomerular filtration rate <60 mL/min/1.73 m ²), Resident in a long-term facility, BMI >30 kg/m ² , Anticipating the need for immunosuppressive treatment within the next 6 months
1.0	EXCLUSION	EX07A00	Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)
6.0	EXCLUSION	EX07A05	Phase 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)
1.0	EXCLUSION	EX08A00	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination.
1.0	EXCLUSION	EX09A00	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention including but not limited to: systemic or cutaneous lupus erythematosus, autoimmune arthritis/rheumatoid arthritis, Guillain-Barre syndrome, multiple sclerosis, Sjogren's syndrome, idiopathic thrombocytopenia purpura, glomerulonephritis, autoimmune thyroiditis, giant cell arteritis (temporal arteritis), psoriasis, and insulin-dependent diabetes mellitus (type 1)

Protocol/ Amendment Version	Category	IETESTCD	Full Text of Criterion
5.0	EXCLUSION	EX09A04	Sentinel participants in Stage 1 only: Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention, including but not limited to: systemic or cutaneous lupus erythematosus, autoimmune arthritis/rheumatoid arthritis, Guillain-Barre syndrome, multiple sclerosis, Sjogren's syndrome, idiopathic thrombocytopenia purpura, glomerulonephritis, autoimmune thyroiditis, giant cell arteritis (temporal arteritis), psoriasis, and insulin-dependent diabetes mellitus (type 1)
6.0	EXCLUSION	EX09A05	Phase 1 only: Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention, including but not limited to: systemic or cutaneous lupus erythematosus, autoimmune arthritis/rheumatoid arthritis, Guillain-Barre syndrome, multiple sclerosis, Sjogren's syndrome, idiopathic thrombocytopenia purpura, glomerulonephritis, autoimmune thyroiditis, giant cell arteritis (temporal arteritis), psoriasis, and insulin-dependent diabetes mellitus (type 1)
1.0	EXCLUSION	EX10A00	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection
1.0	EXCLUSION	EX11A00	Women who are pregnant or breastfeeding
1.0	EXCLUSION	EX12A00	Previous vaccination with any coronavirus vaccine
1.0	EXCLUSION	EX13A00	Individuals who receive treatment with immunosuppressive therapy, including cytotoxic agents or systemic corticosteroids, eg, for cancer or an autoimmune disease, or planned receipt throughout the study. If systemic corticosteroids have been administered short term (<14 days) for treatment of an acute illness, participants should not be enrolled into the study until corticosteroid therapy has been discontinued for at least 28 days before study intervention administration. Inhaled/nebulized, intra-articular, intrabursal, or topical (skin or eyes) corticosteroids are permitted

Protocol/ Amendment Version	Category	IETESTCD	Full Text of Criterion
2.0	EXCLUSION	EX13A01	Individuals who receive treatment with immunosuppressive therapy, including cytotoxic agents or systemic corticosteroids, eg, for cancer or an autoimmune disease, or planned receipt throughout the study. If systemic corticosteroids have been administered short term (<14 days) for treatment of an acute illness, participants should not be enrolled into the study until corticosteroid therapy has been discontinued for at least 28 days before study intervention administration. Inhaled/nebulized (except for sentinel subjects in Stage 1 – see exclusion 14), intra-articular, intrabursal, or topical (skin or eyes) corticosteroids are permitted
1.0	EXCLUSION	EX14A00	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study
1.0	EXCLUSION	EX15A00	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation
1.0	EXCLUSION	EX16A00	Previous participation in other studies involving study intervention containing lipid nanoparticles
1.0	EXCLUSION	EX17A00	Sentinel participants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit
6.0	EXCLUSION	EX17A05	Phase 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit
1.0	EXCLUSION	EX18A00	Sentinel participants in Stage 1 only: Any screening hematology and/or blood chemistry laboratory value that meets the definition of a \geq Grade 1 abnormality. Note: With the exception of bilirubin, participants with any stable Grade 1 abnormalities (according to the toxicity grading scale) may be considered eligible at the discretion of the investigator. (Note: A "stable" Grade 1 laboratory abnormality is defined as a report of Grade 1 on an initial blood sample that remains \leq Grade 1 upon repeat testing on a second sample from the same participant)

Protocol/ Amendment Version	Category	IETESTCD	Full Text of Criterion
6.0	EXCLUSION	EX18A05	Phase 1 only: Any screening hematology and/or blood chemistry laboratory value that meets the definition of a \geq Grade 1 abnormality Note: With the exception of bilirubin, participants with any stable Grade 1 abnormalities (according to the toxicity grading scale) may be considered eligible at the discretion of the investigator. (Note: A "stable" Grade 1 laboratory abnormality is defined as a report of Grade 1 on an initial blood sample that remains \leq Grade 1 upon repeat testing on a second sample from the same participant.)
1.0	EXCLUSION	EX19A00	Sentinel participants in Stage 1 only: Positive test for HIV, hepatitis B surface antigen (HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at the screening visit
6.0	EXCLUSION	EX19A05	Phase 1 only: Positive test for HIV, hepatitis B surface antigen (HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at the screening visit
1.0	EXCLUSION	EX20A00	Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention
6.0	EXCLUSION	EX20A05	Phase 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention
1.0	EXCLUSION	EX21A00	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
7.0	EXCLUSION	EX21A06	Investigator site staff or Pfizer/BioNTech employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members
2.0	EXCLUSION	EX22A01	Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized corticosteroids.

Protocol/ Amendment Version	Category	IETESTCD	Full Text of Criterion
6.0	EXCLUSION	EX22A05	Phase 1 only: Regular receipt of inhaled/nebulized corticosteroids

Appendix II: Data Cutoff Algorithm in Standard Domains

Records are included in SDTM datasets as specified below with &cutoff equal to 13 March 2021

SDTM Domain	Cutoff Description
AE	<p>Apply util_partial_datetime_imputation.sas to AESTDTC and AEENDTC to derive ASTDT AND AENDT respectively.</p> <pre>%util_partial_datetime_imputation(_isodate =AESTDTC/AEENDTC ,_impdate = ASTDT/AENDT ,_impdateflag = %str(ASTDTC/AENDTC) ,_imputation_rule_date = %str(START/STOP));</pre> <p>All records with ASTDT <= &cutoff are included.</p> <p>In addition,</p> <p>If .<ASTDT <= &cutoff and AEENDT > cutoff date, then</p> <ul style="list-style-type: none"> - AEENDTC and AEENDY is set to missing - AEENRTPT = 'ONGOING' - AEENTPT = 'Last Subject Encounter' - AEOUT = 'NOT RECOVERED/NOT RESOLVED' - AESDTH = 'N' <p>end;</p> <p>else if AESTDTC = ' ' and AEENDTC ne ' ' and AENDT <= &cutoff then the record is included.</p> <p>If AESTDTC and AEENDTC are both missing, then the record is included.</p> <p>DROP ASTDT and AENDT</p>

SDTM Domain	Cutoff Description
DM	<p>Include all records with DMDTC <= &cutoff</p> <p>If RFPENDTC > &cutoff then RFPENDTC = ' '</p> <p> If RFSTDTC > &cutoff then do;</p> <p> If randomization date > &cutoff then do;</p> <p> RFSTDTC=' '; RFENDTC=' '; RFXSTDTC=' '; RFXENDTC=' ';</p> <p> arm='NOT ASSIGNED'; armcd='NOTASSGN';</p> <p> end;</p> <p> else if randomization date <= &cutoff then do;</p> <p> set RFSTDTC = randomization date;</p> <p> RFENDTC=randomization date; RFXSTDTC=' ';</p> <p> RFXENDTC=' ';</p> <p> end;</p> <p> Else if RFSTDTC <= &cutoff then do;</p> <p> If RFENDTC > &cutoff then set RFENDTC=&cutoff;</p> <p> RFXENDTC=&cutoff;</p> <p> </p> <p> If DTHDTC > &cutoff then do;</p> <p> set DTHDTC = ' ';</p> <p> set DTHFL = ' ';</p> <p> end;</p>
EC	<p>Include all records with ECSTDTC <= &cutoff</p> <p>If ECENDTC > &cutoff then do; ECENDTC = &cutoff; ECENDY = ECENDTC – RFSTDTC +1; end;</p>
EX	<p>Include all records with EXSTDTC <= &cutoff</p> <p>If EXENDTC > &cutoff then do; EXENDTC = &cutoff; EXENDY = EXENDTC – RFSTDTC +1; end;</p>
DD/CE/DV/FACE/FAHO/HO/IE/IS/LB/MB/MO/PE/PR/SV/VS/SE	<p>Include all records with (DDDTC/ CEDTC/ DVSTDTC/ (Datepart) FADTC /HODTC/ IEDTC/ ISDTC/ (datepart) LBDTC/ MBDTC/ MODTC/ PEDTC/ PRSTDTC/ SVSTDTC/ VSDTC/ SESTDTC) <= &cutoff</p>

SDTM Domain	Cutoff Description
DS/MH	Include all records with DSDTC <= &cutoff and (DSSTDTC/MHSTDTC) <= &cutoff
CM	<p>Apply util_partial_datetime_imputation.sas to CMSTDTC and CMENDTC to derive ASTDT AND AENDT respectively.</p> <pre>%util_partial_datetime_imputation(_isodate =CMSTDTC/CMENDTC ,_impute = ASTDT/AENDT ,_impute_flag = %str(ASTDTF/AENDTF) ,_imputation_rule_date = %str(START/STOP));</pre> <p>All records with ASTDT <= &cutoff are included.</p> <p>In addition,</p> <p>If .<ASTDT <= &cutoff and AENDT > cutoff date, then</p> <ul style="list-style-type: none"> - CMENDTC is set to missing - CMENRTPT = 'ONGOING' - CMENTPT = 'Last Subject Encounter' - <p>end;</p> <p>else if CMSTDTC = '' and CMENDTC ne '' and CMENDTC<= &cutoff then the record is included.</p> <p>If CMSTDTC and CMENDTC are both missing then the record is included.</p> <p>DROP ASTDT and AENDT</p>
CO	If RDOMAIN = 'IS' then retain all obs where CODTC<= cutoff, else for all other values of RDOMAIN, match with USUBJID /SEQ.

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SDTM Domain	Cutoff Description
RELREC	Include all records if USUBJID = ' '. for each domain in RDOMAIN, match with USUBJID /SEQ if index(idvar,'SEQ')>0; else match with USUBJID/LNKID if index(idvar,'LNKID')>0.

Appendix III: FDA 2010.1 Issue Summary

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1352	Duplicate records in EC domain	Warning	EC	15 (< 0.1%)	This is a false positive as per P21. ECSEQ values are unique for each record within EC domain and within each Unique Subject Identifier (USUBJID), Name of Treatment (ECTRT), Start Date/Time of Treatment (ECSTDTC) and Mood (ECMOOD).
SD1149	Expected variable with missing value for all records	Warning	MB	2 (25.00%)	As data is not collected for MBRESCAT and MBGRPID, this field is currently set to NULL for all records.
SD1149	Expected variable with missing value for all records	Warning	MO	1 (16.67%)	MOBLFL is derived based on last non-missing value on or before DM.RFSTDTC. All records with MODTC populated are after their respective RFSTDTC, therefore NULL values are expected for all the records.