Clinical Study Data Reviewer's Guide

ModernaTX, Inc.

Study mRNA-1273-P201

Clinical Study Data Reviewer's Guide

Contents

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
aCRF	Annotated Case Report Form
eCRF	Electronic Case Report Form
eDT	Electronic Data Transfer (e.g. central lab data, ECG vendor data, PK data, etc.)

1.3 Study Data Standards and Dictionary Inventory

Standard or Dictionary	Versions Used
SDTM	•SDTM v1.4 •SDTM-IG v3.2
Controlled Terminology	CDISC SDTM Controlled Terminology, 2020-06-26
Data Definitions	Define-XML v2.0
Medications Dictionary	WHODD GLOBAL B3 Mar20, SNOMED 2020-09-01, UNII 2020-08-18, NDF-RT 2020-09-08
Medical Events Dictionary	MedDRA v23.0
Other standards (optional)	CDISC TAUG-VAX 1.1

2. Protocol Description

2.1 Protocol Number and Title

Protocol Number: mRNA-1273-P201

Protocol Title: A PHASE 2a, RANDOMIZED, OBSERVER-BLIND, PLACEBO-CONTROLLED, DOSE-CONFIRMATION STUDY TO EVALUATE THE SAFETY, REACTOGENICITY, AND IMMUNOGENICITY OF MRNA-1273 SARS-COV-2 VACCINE IN ADULTS AGED 18 YEARS AND OLDER

Protocol Versions: Amendment 3

2.2 Protocol Design

Figure 1: Study Flow Schema

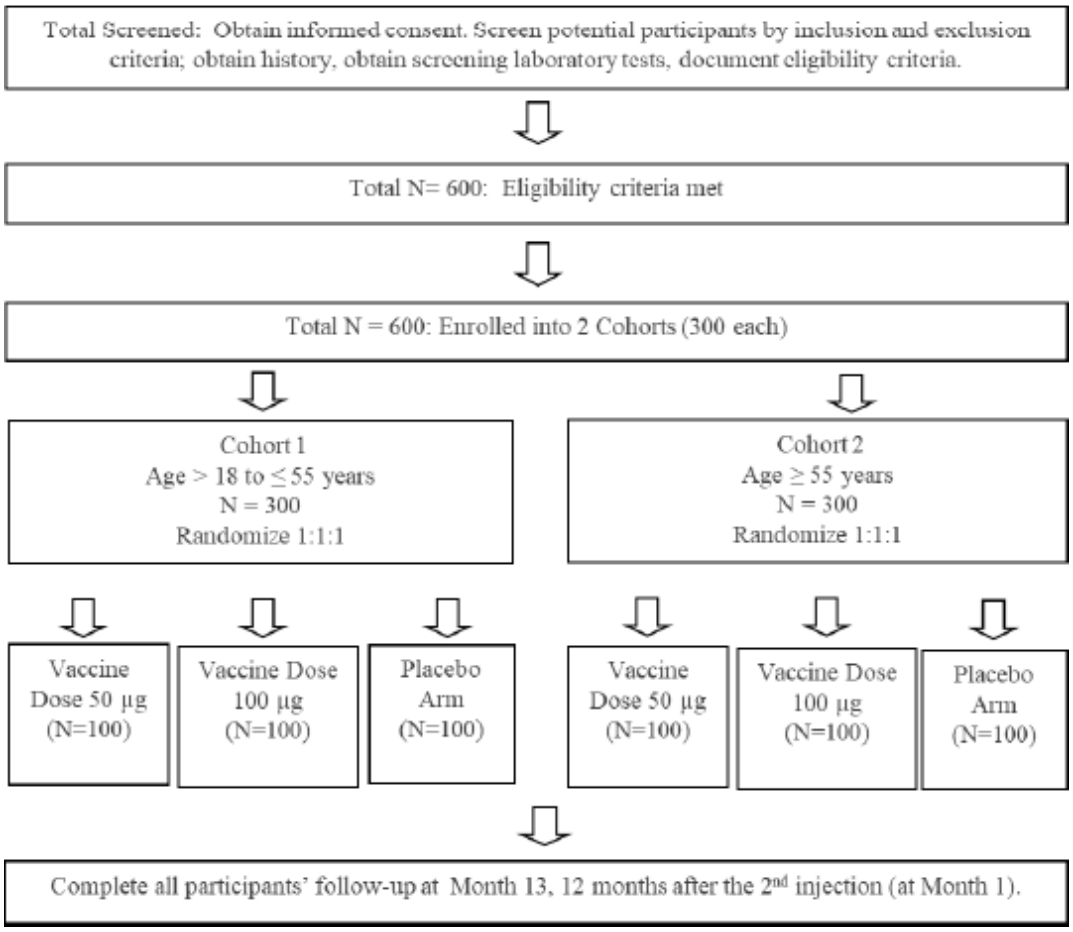
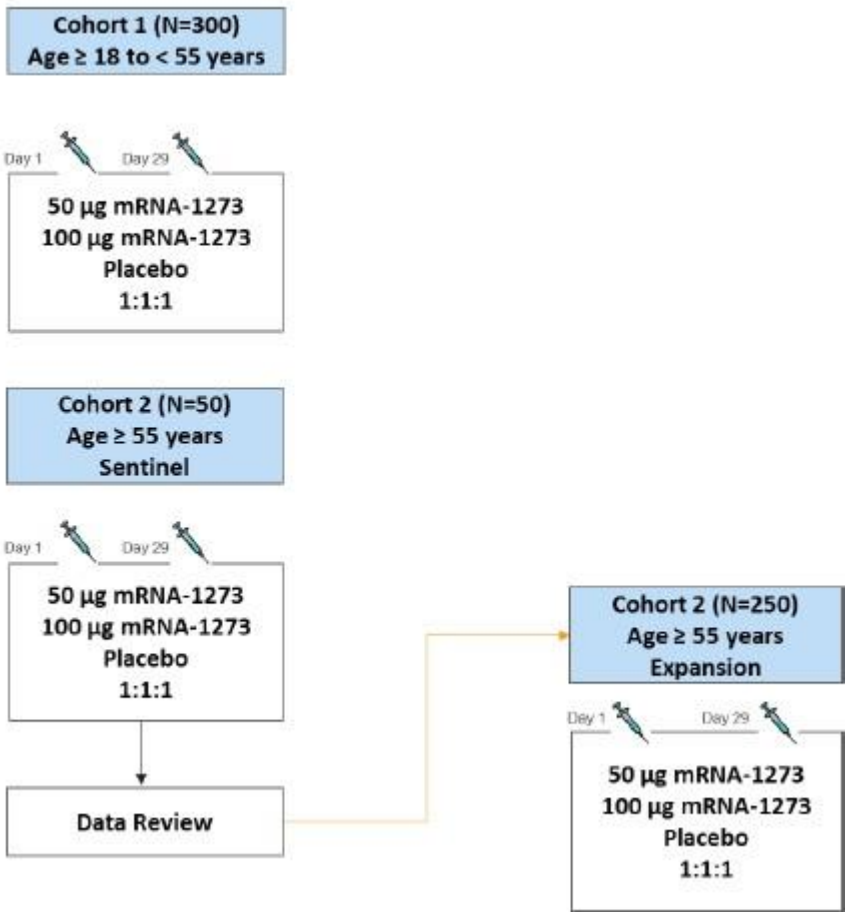


Figure 2: Sentinel and Expansion Cohort Schema



2.3 Trial Design Datasets

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

(If no, delete the remainder of this section. If yes, refer to cSDRG Completion Guidelines Section 2.3 and provide additional information below.)

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

3. Subject Data Description

3.1 Overview

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

If yes, describe the data cut or database status:

Per protocol, a primary interim analysis of safety and immunogenicity data will be triggered after all participants have completed Day 57 study procedures. All data relevant to the primary study analysis through Day 57 will be cleaned (data are as clean as possible).

For the primary analysis, subject-specific cut-off date is applied to all SDTM subject domains using the date of Day 57 Visit

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
CM	Concomitant Medications
CO	Comments
DM	Demographics
DS	Disposition
DV	Protocol Deviations
FA	Findings About Events or Interventions
IE	Inclusion/Exclusion Criteria Not Met
IS	Immunogenicity Specimen Assessments
LB	Laboratory Test Results
MB	Microbiology Specimen
MH	Medical History
RP	Reproductive System Findings
SE	Subject Elements
SS	Subject Status
SUPPCM	Supplemental Qualifiers CM
SUPPDM	Supplemental Qualifiers DM

SUPPDV	Supplemental Qualifiers DV
SUPPDS	Supplemental Qualifiers DS
SUPPIS	Supplemental Qualifiers IS
SUPPLB	Supplemental Qualifiers LB
SUPPMB	Supplemental Qualifiers MB
SUPPMH	Supplemental Qualifiers MH
SUPPRP	Supplemental Qualifiers RP
SUPPXM	Supplemental Qualifiers XM
SV	Subject Visits
VS	Vital Signs
XM	Multiple Participations

XM domain has similar structure of DM domain and keeps initial information for re-screened subjects.

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

DD – Deaths Details. There are no deaths reported in the study.

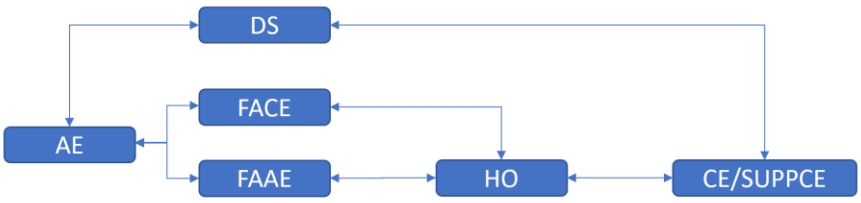
Are the submitted data a subset of collected data? **No**

Additional Content of Interest

Key analysis data points include:

- Unsolicited Safety Analysis: AE Domain
- Solicited Safety Analysis: FACE Domain, FAAE Domain, VS Domain where VSCAT= REACTOGENICITY
- SARS-CoV-2-specific bAb and SARS-CoV-2-specific nAb analysis: IS Domain

3.2 Traceability Flow Diagram



3.3 Annotated CRFs

Collected fields and pages that have not been tabulated have been annotated as "Not Submitted". ModernaTX, Inc. 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.

Explanation of data fields [Not Submitted]

aCRF page Number(s)	Data Collection Field	Explanation of why [NOT SUBMITTED]
Page 3	Was this visit performed	This question is to support data management clean/query data only
Page 7	Did participant meet all eligibility	This is redolently information
Page 9	Were any significant condition report	To support data management
Page 26	What was the study treatment?	This is redolently
Page 34	Were any prior/concomitant medications and/or vaccinations taken?	Support data management
Page 37	Were any concomitant procedures performed?	Support data management
Page 39	Did the participant experience any adverse event?	Support data management
Page 44	Is the participant continuing to the next visit?	Support data management
Page 47	PC date Open /Close	ePRO system data

3.4 SDTM Subject Domains

Dataset - Dataset Label	Efficacy	Safety	Other	Custom	SUPP--	Related Using RELREC
AE - Adverse Events		X			X	CE, FA, HO
CE - Clinical Events		X			X	AE, FA, VS
CM - Concomitant Medications			X		X	
CO - Comments			X			
DM - Demographics			X		X	
DS - Disposition			X		X	
DV - Protocol Deviations			X		X	
EC - Exposure as Collected			X			
ER - Environmental and Social Factors		X			X	
EX - Exposure			X			
FAAE - Findings About Events or Interventions		X			X	
FACE - Findings About Events or Interventions		X			X	
FAOT - Findings About Events or Interventions		X			X	
HO - Healthcare Encounter		X			X	AE
IE - Inclusion/Exclusion Criteria Not Met			X			
IS - Immunogenicity Specimen Assessments	X				X	
LB - Laboratory Test Results		X			X	
MB - Microbiology Specimen	X				X	
MH - Medical History			X		X	
PR - Procedures		X			X	
RP - Reproductive System Findings			X		X	

SE - Subject Elements			X			
SS - Subject Status			X			
SV - Subject Visits			X			
VE - Visit Events			X		X	
VS - Vital Signs		X			X	CE, FA
XM - Multiple Participations				X	X	

A single subject is screened and /or enrolled more than once

The variable SUBJID uniquely identifies each subject that participate in the study. Unique USUBJID with different SUBJID cases are found due to multiple screenings and /or multiple enrollments per subject. SUBJID is included in related domains: IE, LB, VS, FAOT and DS beside DM. It may cause validation error.

Done or Not Done Data from e-Diary (ePRO)

Per Submitting Study Datasets for Vaccines to the Office of Vaccines Research and Review Guidelines, Check Box to indicate whether the reactogenicity event did or did not occur during the prespecified time frame. A check box in the annotated CRF should also capture whether the reactogenicity event was collected every day. However, for this study, Done or Not Done check box was not included in ePRO, instead ePRO used data entering window to collect daily event data. FACE and CE mapping assumptions are

a. --STAT = NOT DONE if Patient did not enter a symptom data within window open duration
b. --STAT = Blank if Patient entered a symptom data within window open duration
c. Not Done Reason will be set to "Symptom data was not entered by patient"

DM Domain vs. XM Domain

For subjects with multiple enrollments within a single study, the primary enrollment is submitted in DM, additional enrollments are included in custom domain (XM) with a similar structure to DM.

3.4.1 AE - Adverse Events

Solicited AE occurred within 7 days should be mapped to FACE, CE domains and Solicited AE lasted beyond 7 days should be mapped to both AE and FAAE, but discrepancy data cases could be found due to patient failed to enter the event data during data entering window opened. Per CCG, any event that is not entered on the e-diary but verbally reported, must then be documented as an unsolicited AE.

QNAM	Description
AEDICNM	Coder Dictionary Name

QNAM	Description
AEDICVR	Coder Dictionary Version
AEMAFL	Medically-attended AE?
AESOFL	Solicited Adverse Reaction?
AETRTEM	Treatment Emergent Flag
DSSPID	DS Sponsor-Defined Identifier
HOSPID	HO Sponsor-Defined Identifier
REMOVEFL	AR Remove Flag

DSSPID: Create a link between AE and DS if it indicates the event leading to discontinue treatment or study

HOSPID: Create a link between AE and HO if medically attended indicates the event requires hospitalization or ICU (see table 3.4.1 line 3)

REMOVEFL: All solicited AR captured in AE form are flagged as remove except for SAE or last beyond day 7 of each vaccine (see Table 3.4.1)

Case1: Remove flag is added in SDTM.SUPPAE if AR is captured via AE, but it is not SAE or last beyond day 7 of each vaccine (Table 3.4.1 line 1)

Table 3.4.1

	SDTM.AE										SUPPAE				
Line #	USUBJID	AESEQ	AESPID	AEDECOD	AESEV	AESER	AESHOSP	AETOXGR	AESTDY	AEENDY	AEMAFL	AESOFL	REMOVEFL	DSSPID	HOSPID
1	mRNA-1273-P201-US205-1103	3	AE-003	Headache	SEVERE	N	N	3	6	7	N	Y	Y		
2	mRNA-1273-P201-US208-1092	2	AE-003	Fatigue	MILD	N	N	1	1	13	N	Y			
3	mRNA-1273-P201-US208-1123	3	AE-001	Pneumonia	SEVERE	Y	Y	3	33	58	Y	N		DS-001	HO-001

3.4.2 CE - Clinical Events

QNAM	Description
AESEVX	AE Severity/Intensity
AESPID	AE Sponsor-Defined Identifier
CEEVAL	CE Evaluator
DSSPID	DS Sponsor-Defined Identifier
HOSPID	HO Sponsor-Defined Identifier
MAAEFL	Medically Attended Flag
REASND	Reason for Missing CESTDTC/CEENDTC

CE data contains solicited symptom data captured in both AE and e-Diary within 7 days. It is based on one record per subject (USUBJID), per symptom (CETERM), and per vaccine reference (CETPTREF). CESTDTC (earliest date with CEOCCUR=Y) /CEENDTC (last date with symptom occurred) are mapped by following both **Submitting Study Datasets for Vaccines to the Office of Vaccines Research and Review Guidelines and CDISC TAUG-VAX 1.1.** CESDTC, CEENDTC and CEDUR will be set to missing if patient missed one or more days to enter symptom data within observed period (7 days) . The last no missing assessed date within 7 days observed period is mapped to CEDTC. Table 3.4.2.1 illustrated data mapping and link among domains.

Case 1: Subject symptom fatigue data was found from both e-Diary and RAW.AE, but grade rating is different. Grade 3 from subject (CE.CESEQ=14) was mapped to CE.CETOXGR (2), grade 1 from investigator was mapped to SUPPCE.QVAL(GRADE 1/MILD) where SUPPCE.QNAM=AESEVX.

Table 3.4.2.1

CECAT = REACTOGENICITY								SUPPCE				
USUBJID	CESEQ	CETERM	CEOCCUR	CETOXGR	CESTDTC	CEENDTC	CETPTREF	CERFTDTC	AESPID	AESEVX	MAAEFL	HOSPID
mRNA-1273-P201-US205-1033	4	Pain	Y	2	2020-07-08T04:03	2020-07-10T15:41	DOSE 2	2020-07-07T10:16			Y	HO-102
mRNA-1273-P201-US205-1033	10	Arthralgia	Y	3	2020-07-08T04:05	2020-07-12T22:53	DOSE 2	2020-07-07T10:16	AE-002	GRADE 3/SEVERE	Y	HO-102
mRNA-1273-P201-US205-1033	12	Chills	Y	2	2020-07-08T04:05	2020-07-09T10:01	DOSE 2	2020-07-07T10:16			Y	HO-102
mRNA-1273-P201-US205-1033	14	Fatigue	Y	2	2020-07-08T04:05	2020-07-15T16:36	DOSE 2	2020-07-07T10:16	AE-005	GRADE 1/MILD	Y	HO-102
mRNA-1273-P201-US205-1033	16	Fever	Y	2	2020-07-08T03:59	2020-07-09T10:00	DOSE 2	2020-07-07T10:16			Y	HO-102
mRNA-1273-P201-US205-1033	18	Headache	Y	2	2020-07-08T04:05	2020-07-12T22:53	DOSE 2	2020-07-07T10:16			Y	HO-102
mRNA-1273-P201-US205-1033	20	Myalgia	Y	3	2020-07-08T04:05	2020-07-10T09:07	DOSE 2	2020-07-07T10:16	AE-004	GRADE 3/SEVERE	Y	HO-102

3.4.3 CM - Concomitant Medications

CMSOL will be used to flag Medication due to Medical Attended, but it is no link between Medical Attend Event and Medication took. This is because data was reported via Patient e-Diary which means they are not in the same data collect system and no link could be created.

QNAM	Description
ATCLEV1C	ATC Level 1 Code
ATCLEV1T	ATC Level 1
ATCLEV2C	ATC Level 2 Code
ATCLEV2T	ATC Level 2
ATCLEV3C	ATC Level 3 Code
ATCLEV3T	ATC Level 3
ATCLEV4C	ATC Level 4 Code
ATCLEV4T	ATC Level 4
CMDICNM	Coder Dictionary Medication Name
CMDICVR	Coder Dictionary Version
CMFOTHSP	Other Frequency, Specify
CMONGOYN	Ongoing

CMPROTCD	Name of Medication Product Code
CMROTHSP	Other Route of Admin, Specify
CMSOL	Medication taken for Solicited Event ?
CMTRADCD	Trade Name of Medication Code
CMTRADE	Trade Name of Medication
CMTRTTN	Medication Trade Name
CMUOTHSP	Dose Unit Other, Specify

3.4.4 DM - Demographics

QNAM	Description
COHORT	Cohort
MULRACE	Multiple Race
PREVNUM	Previous Participant Number
PREVSCR	Was this participant screened previously
PROTVER	Protocol Version
RACEOTH	If Race is Other, specify
SENTL	Sentinel participant

3.4.5 DS - Disposition

QNAM	Description
AESPID	AE Sponsor-Defined Identifier
ENROLLYN	Was participant enrolled in the study

3.4.6 DV - Protocol Deviations

There are situations where the protocol deviations are on the site level, not the subject level. For example, IP temperature excursion (not administered to subject) - In-transit temperature excursion occurred for the initial shipment of vaccine received on 26May2020. According to current SDTM standard, all tabulation data sets including DV are designed for subject data. For site level deviations, the deviations are not associated with any specific subjects, they can not be directly included in DV dataset.

QNAM	Description
DVSIG	Significant
DVTERM1	Protocol Deviation Term 1

DVTERM2	Protocol Deviation Term 2
DVTERM3	Protocol Deviation Term 3
SEVDES	Severity Code and Description
SPECTPT	Specify Timepoint

3.4.7 ER - Environmental and Social Factors

QNAM	Description
EXPOSEOT	Other exposure specify

3.4.8 FAAE - Findings About Events or Interventions

Individual daily symptom event lasted beyond day 7 collected from e-Diary is mapped to FAAE, the event also collected via AE Form. --LNKGRP variables are created to link them together.

QNAM	Description
AESPID	AE Sponsor-Defined Identifier
CRFTMPT	CRF Timepoint
CRFTMPTN	CRF Timepoint Number
HOSPID	HO Sponsor-Defined Identifier
MAAEFL	Medically Attended Flag

- All e-Diary symptoms last and beyond day 7 are mapped to FAAE with FAEVAL = STUDY SUBJECT
- All solicited AR last and beyond day 7 and reported in AE Form are mapped FAAE with FAEVAL=INVESTOGATOR

It contains one record per subject (USUBJID), per symptom, per timepoint (Daily) and per dose reference. Start day should be 8 if data source is from raw.AE, data extracted date is used if data source is from raw.AE and symptom stop date is missing.

Table 3.4.8
Case 1: Symptom assessment captured via e-Diary last and beyond day-7 of each vaccine will be mapped to FAAE (see Line 7-11)
Case 2: Symptom reported via AE if any symptom started within 7 days of each vaccine and ended after 7 days of each vaccine (see Table 3.4.1 Line 2 and Table 3.4.8 Line 1-6)

Table 3.4.8

	SDTM.FAAE										SDTM.SUPPFAAE
Line #	USUBJID	FASEQ	FAOBJ	FACAT	FAORRES	FAEVAL	FADY	FATPT	FATPTNUM	FATPTREF	MAAEFL
1	mRNA-1273-P201-US208-1092	5	Fatigue	REACTOGENICITY	GRADE 1/MILD	INVESTIGATOR	8	DAY 8	8	DOSE 1	
2	mRNA-1273-P201-US208-1092	7	Fatigue	REACTOGENICITY	GRADE 1/MILD	INVESTIGATOR	9	DAY 9	9	DOSE 1	
3	mRNA-1273-P201-US208-1092	8	Fatigue	REACTOGENICITY	GRADE 1/MILD	INVESTIGATOR	10	DAY 10	10	DOSE 1	
4	mRNA-1273-P201-US208-1092	10	Fatigue	REACTOGENICITY	GRADE 1/MILD	INVESTIGATOR	11	DAY 11	11	DOSE 1	
5	mRNA-1273-P201-US208-1092	12	Fatigue	REACTOGENICITY	GRADE 1/MILD	INVESTIGATOR	12	DAY 12	12	DOSE 1	
6	mRNA-1273-P201-US208-1092	13	Fatigue	REACTOGENICITY	GRADE 1/MILD	INVESTIGATOR	13	DAY 13	13	DOSE 1	
7	mRNA-1273-P201-US208-1092	6	Fatigue	REACTOGENICITY	NO INTERFERENCE WITH ACTIVITY	STUDY SUBJECT	8	DAY 8	8	DOSE 1	
8	mRNA-1273-P201-US208-1092	9	Fatigue	REACTOGENICITY	NO INTERFERENCE WITH ACTIVITY	STUDY SUBJECT	10	DAY 10	10	DOSE 1	
9	mRNA-1273-P201-US208-1092	11	Fatigue	REACTOGENICITY	NO INTERFERENCE WITH ACTIVITY	STUDY SUBJECT	11	DAY 11	11	DOSE 1	
10	mRNA-1273-P201-US208-1092	14	Fatigue	REACTOGENICITY	NO INTERFERENCE WITH ACTIVITY	STUDY SUBJECT	13	DAY 12	12	DOSE 1	
11	mRNA-1273-P201-US208-1092	15	Fatigue	REACTOGENICITY	NONE	STUDY SUBJECT	13	DAY 13	13	DOSE 1	

3.4.9 FACE - Findings About Events or Interventions

QNAM	Description
AESPID	AE Sponsor-Defined Identifier
CRFTMPT	CRF Timepoint
CRFTMPTN	CRF Timepoint Number
HOSPID	HO Sponsor-Defined Identifier
LYMPHEVL	Lymphadenopathy evaluated?
MAAEFL	Medically Attended Flag
SITE1	Investigator Site
SITE2	Other Institution
SREVL	Rash evaluated?

- All e-Diary symptoms within 7 days are mapped to FACE with FAEVAL = STUDY SUBJECT. --LNKGRP variables are created to link them together.
- All solicited AR last reported in AE Form are mapped FACE with FAEVAL=INVESTOGATOR

  It contains one record per subject (USUBJID), per symptom, per timepoint and per dose reference. Last day mapped to FACE should be day 7 and map to rest of symptom days to FAAE if data source is from raw.AE and stop date is after 7 days of each dose reference or stop date is missing.

  Case 1: Symptom captured via e-Diary within day-7 of each vaccine is mapped to SDTM.FACE (see Line 3 -10, and Line 18-25)

  Case 2: Symptom reported via AE if any symptom started and ended within 7 days of each vaccine (see from Table 3.4.1 Line 1 to Table 3.4.9 Line 1-2)

  Case 3: Symptom reported via AE if any symptom started within 7 days of each vaccine and ended after 7 days of each vaccine (see from Table 3.4.1 Line 2 to Table 3.4.9 Line 11-17)

Table 3.4.9

	SDTM.FACE							SDTM.SUPPFACE
Line #	USUBJID	FASEQ	FAOBJ	FAORRES	FAEVAL	FATPT	FATPTREF	MAAEFL
1	mRNA-1273-P201-US205-1103	100103	Headache	GRADE 3/SEVERE	INVESTIGATOR	DAY 6	DOSE 1	
2	mRNA-1273-P201-US205-1103	100105	Headache	GRADE 3/SEVERE	INVESTIGATOR	DAY 7	DOSE 1	
3	mRNA-1273-P201-US205-1103	100097	Headache	NONE	STUDY SUBJECT	DAY 1, 1 HOUR AFTER VACCINATION (AT STUDY CLINIC)	DOSE 1	
4	mRNA-1273-P201-US205-1103	100098	Headache	NONE	STUDY SUBJECT	DAY 1, AFTER VACCINATION (AT HOME)	DOSE 1	
5	mRNA-1273-P201-US205-1103	100099	Headache	NONE	STUDY SUBJECT	DAY 2	DOSE 1	
6	mRNA-1273-P201-US205-1103	100100	Headache	NONE	STUDY SUBJECT	DAY 3	DOSE 1	
7	mRNA-1273-P201-US205-1103	100101	Headache	NONE	STUDY SUBJECT	DAY 4	DOSE 1	
8	mRNA-1273-P201-US205-1103	100102	Headache	NONE	STUDY SUBJECT	DAY 5	DOSE 1	
9	mRNA-1273-P201-US205-1103	100104	Headache	ANY USE OF PRESCRIPTION PAIN RELIEVER OR PREVENTS DAILY ACTIVITY	STUDY SUBJECT	DAY 6	DOSE 1	
10	mRNA-1273-P201-US205-1103	100106	Headache	ANY USE OF PRESCRIPTION PAIN RELIEVER OR PREVENTS DAILY ACTIVITY	STUDY SUBJECT	DAY 7	DOSE 1	
11	mRNA-1273-P201-US208-1092	100081	Fatigue	GRADE 1/MILD	INVESTIGATOR	DAY 1	DOSE 1	
12	mRNA-1273-P201-US208-1092	100084	Fatigue	GRADE 1/MILD	INVESTIGATOR	DAY 2	DOSE 1	
13	mRNA-1273-P201-US208-1092	100086	Fatigue	GRADE 1/MILD	INVESTIGATOR	DAY 3	DOSE 1	
14	mRNA-1273-P201-US208-1092	100088	Fatigue	GRADE 1/MILD	INVESTIGATOR	DAY 4	DOSE 1	
15	mRNA-1273-P201-US208-1092	100090	Fatigue	GRADE 1/MILD	INVESTIGATOR	DAY 5	DOSE 1	
16	mRNA-1273-P201-US208-1092	100092	Fatigue	GRADE 1/MILD	INVESTIGATOR	DAY 6	DOSE 1	
17	mRNA-1273-P201-US208-1092	100094	Fatigue	GRADE 1/MILD	INVESTIGATOR	DAY 7	DOSE 1	
18	mRNA-1273-P201-US208-1092	100082	Fatigue	NONE	STUDY SUBJECT	DAY 1, 1 HOUR AFTER VACCINATION (AT STUDY CLINIC)	DOSE 1	
19	mRNA-1273-P201-US208-1092	100083	Fatigue	NO INTERFERENCE WITH ACTIVITY	STUDY SUBJECT	DAY 1, AFTER VACCINATION (AT HOME)	DOSE 1	
20	mRNA-1273-P201-US208-1092	100085	Fatigue	NO INTERFERENCE WITH ACTIVITY	STUDY SUBJECT	DAY 2	DOSE 1	
21	mRNA-1273-P201-US208-1092	100087	Fatigue	NO INTERFERENCE WITH ACTIVITY	STUDY SUBJECT	DAY 3	DOSE 1	
22	mRNA-1273-P201-US208-1092	100089	Fatigue	NONE	STUDY SUBJECT	DAY 4	DOSE 1	
23	mRNA-1273-P201-US208-1092	100091	Fatigue	SOME INTERFERENCE WITH ACTIVITY	STUDY SUBJECT	DAY 5	DOSE 1	
24	mRNA-1273-P201-US208-1092	100093	Fatigue	NO INTERFERENCE WITH ACTIVITY	STUDY SUBJECT	DAY 6	DOSE 1	
25	mRNA-1273-P201-US208-1092	100095	Fatigue	NO INTERFERENCE WITH ACTIVITY	STUDY SUBJECT	DAY 7	DOSE 1	
26	mRNA-1273-P201-US202-1007	100124	Myalgia	SOME INTERFERENCE WITH ACTIVITY	STUDY SUBJECT	DAY 2	DOSE 2	Y

3.4.10 FAOT - Findings About Events or Interventions

QNAM	Description
CLIN2	Study clinic contact 1
CLIN4A	Study clinic contact 3
SYMPOTH	Symptoms other
SYMPTDTC	Estimated date of first symptoms

3.4.11 HO - Healthcare Encounter

QNAM	Description
HOEVAL	HO Evaluator

Case 1: Medically attended Y/N captured via AE with Hospital /ICU event is mapped to HO. Hospital Admin date is mapped to HOSTDTC and Discharge date is mapped to HOENDTC (See Table 3.4.1 Line 3 to Table 3.4.11 Line 1)

Case 2: Medically attended Y/N captured via e-Diary is mapped to HO. First Medically attended date is mapped to HOSTDTC and last medically attended is mapped to HOENDTC (See from Table 3.4.11 Line 30 to Table 3.4.11 Line 2)

Table 3.4.11

	SDTM.HO								
Line #	USUBJID	HOSEQ	HOSPID	HOTERM	HOPRESP	HOOCCUR	HOSTDY	HOENDY	HOEVAL
1	mRNA-1273-P201-US208-1123	1	HO-001	HOSPITAL			33	37	INVESTIGATOR
2	mRNA-1273-P201-US202-1007	1	HO-102	MEDICAL ATTENDED	Y	Y	30	30	STUDY SUBJECT

3.4.12 IS - Immunogenicity Specimen Assessments

QNAM	Description
LLOQ	Lower Limit of Quantitation
LOD	Limit of Detection
RANGE	Range indicator
ULOQ	Upper Limit of Quantification

3.4.13 LB - Laboratory Test Results

QNAM	Description
CNVNRHI	Conventional Reference Range High
CNVNRLO	Conventional Reference Range Low
CNVRESC	Conventional Text Result
CNVRESN	Conventional Numeric Result
CNVRESNP	Conventional Numeric Result Precision
CNVU	Conventional Units
PANELOTH	Lab Panel Other, Specify
RPTRTYP	Reported Result Type

3.4.14 MB - Microbiology Specimen

QNAM	Description
CNVNRLO	Conventional Reference Range Low
CNVRESC	Conventional Text Result
LDTTYPE	Type of Diagnostic Test
LOCALFL	Local Labs Flag
RPTRTYP	Reported Result Type

3.4.15 MH - Medical History

QNAM	Description

MHDICNM	Coder Dictionary Name
MHDICVR	Coder Dictionary Version

3.4.16 PR - Procedures

QNAM	Description
PRINDOTH	Specify Other

3.4.17 RP - Reproductive System Findings

QNAM	Description
CBENDTC	Date of Last Menstruation, Post-menop.
CBRSN	Childbearing Potential No, Reason
CBSP	Partner Medically Sterile, Other Specify
CBSTDTC	Date of Surgery, if Surgically Sterile

3.4.18 VE - Visit Events

QNAM	Description
MISSASS	Missed Assessments

3.4.19 VS - Vital Signs

QNAM	Description
MEDTAK	Medication taken today for pain or fever
MEDTAKP	Prevent Pain or Fever from Occurring
MEDTAKT	Treat Pain or Fever already Occurred

3.4.20 XM - Multiple Participations

QNAM	Description
MULRACE	Multiple Race
PREVSCR	Was this participant screened previously
PROTVER	Protocol Version

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 4.1.2 Validation Engine version 1907.1**
Were sponsor-defined validation rules used to evaluate conformance?	**No**
If yes, describe any significant sponsor-defined validation rules:	**n/a**
(Text or table here. If significant amount, include as an appendix)	
Were the SDTM datasets evaluated in relation to define.xml?	**Yes**
Was define.xml evaluated?	**Yes**
Provide any additional compliance evaluation information:	

4.2 Issues Summary

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
CT2001	AEACN value not found in 'Action Taken with Study Treatment' non-extensible codelist	Error	AE	12 (3.12%)	This is due to non-standard action taken term 'DOSE DELAYED' was captured from CRF.
CT2002	CMDOSU value not found in 'Unit' extensible codelist	Warning	CM	124 (6.35%)	Non-standard term 'OTHER' was captured from CRF. Detailed info for 'OTHER' term is provided in SUPPCM dataset.
CT2002	CMROUTE value not found in 'Route of Administration Response' extensible codelist	Warning	CM	46 (2.36%)	Non-standard term 'OTHER' was captured from CRF. Detailed info for 'OTHER' term is provided in SUPPCM dataset.
CT2002	CMDOSFRQ value not found in 'Frequency' extensible codelist	Warning	CM	84 (4.30%)	Non-standard term 'OTHER' was captured from CRF. Detailed info for 'OTHER' term is provided in SUPPCM dataset.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
CT2002	RACE value not found in 'Race' extensible codelist	Warning	DM	5 (0.46%)	RACE="MULTIPLE" due to more than one RACE checked. RACE="OTHER" was captured from CRF.
CT2002	FALOC value not found in 'Anatomical Location' extensible codelist	Warning	FA	16 (< 0.1%)	Extensible values have been added to code list as it was captured from CRF
CT2002	ISORRESU value not found in 'Unit' extensible codelist	Warning	IS	7027 (74.58%)	Extensible values have been added to code list as it was captured from CRF
CT2002	ISSTRESU value not found in 'Unit' extensible codelist	Warning	IS	7027 (74.58%)	Extensible values have been added to code list
CT2002	LBORRESU value not found in 'Unit' extensible codelist	Warning	LB	18536 (36.52%)	Extensible values have been added to code list as it was received from Lab
CT2002	LBTEST value not found in 'Laboratory Test Name' extensible codelist	Warning	LB	3113 (6.13%)	Extensible values (HCAB, HBSAG, HIV, HCVVLD and HIV12AB) have been added to code list
CT2002	LBMETHOD value not found in 'Method' extensible codelist	Warning	LB	48292 (95.14%)	Extensible values have been added to code list
CT2002	LBTESTCD value not found in 'Laboratory Test Code' extensible codelist	Warning	LB	3113 (6.13%)	Extensible values (HCAB, HBSAG, HIV, HCVVLD and HIV12AB) have been added to code list
CT2002	MBMETHOD value not found in 'Method' extensible codelist	Warning	MB	1804 (4.78%)	Extensible value RT-PCR has been added to code list
CT2002	SSTEST value not found in 'Subject Status Test Name' extensible codelist	Warning	SS	11245 (100.00%)	Extensible values 'Exposed to COVID-19' and 'Participant COVID-19 Symptomatic' have been added to code list
CT2002	SSTESTCD value not found in 'Subject Status Test Code' extensible codelist	Warning	SS	11245 (100.00%)	Extensible values have been added to code list
CT2002	VSTESTCD value not found in 'Vital Signs Test Code' extensible codelist	Warning	VS	51 (0.10%)	Extensible value 'VSALL' (to represent that all scheduled Vital Signs assessments were not done) has been added to code list
CT2002	VSTEST value not found in 'Vital Signs Test Name' extensible codelist	Warning	VS	51 (0.10%)	Extensible value 'Vital Signs Collection' (to represent that all scheduled Vital Signs assessments were not done) has been added to code list

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
CT2005	DSDECOD value not found in 'Completion/Reason for Non-Completion' extensible codelist when DSCAT == 'DISPOSITION EVENT'	Warning	DS	3 (0.26%)	Study-specific 'AE COVID' and 'WITHDRAWAL COVID' terms have been added to code list.
SD0002	NULL value in ARM variable marked as Required	Error	DM	490 (44.95%)	Per TCG, Screen failures, when provided, should be included as a record in DM with the ARM, ARMCD, ACTARM, and ACTARMCD field left blank. For subjects who are randomized in treatment group but not treated, the planned arm variables (ARM and ARMCD) should be populated, but actual treatment arm variables (ACTARM and ACTARMCD) should be left blank.
SD0002	NULL value in ARMCD variable marked as Required	Error	DM	490 (44.95%)	Per TCG, Screen failures, when provided, should be included as a record in DM with the ARM, ARMCD, ACTARM, and ACTARMCD field left blank. For subjects who are randomized in treatment group but not treated, the planned arm variables (ARM and ARMCD) should be populated, but actual treatment arm variables (ACTARM and ACTARMCD) should be left blank.
SD0002	NULL value in ACTARMCD variable marked as Required	Error	DM	490 (44.95%)	Per TCG, Screen failures, when provided, should be included as a record in DM with the ARM, ARMCD, ACTARM, and ACTARMCD field left blank. For subjects who are randomized in treatment group but not treated, the planned arm variables (ARM and ARMCD) should be populated, but actual treatment arm variables (ACTARM and ACTARMCD) should be left blank.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD0002	NULL value in ACTARM variable marked as Required	Error	DM	490 (44.95%)	Per TCG, Screen failures, when provided, should be included as a record in DM with the ARM, ARMCD, ACTARM, and ACTARMCD field left blank. For subjects who are randomized in treatment group but not treated, the planned arm variables (ARM and ARMCD) should be populated, but actual treatment arm variables (ACTARM and ACTARMCD) should be left blank.
SD0021	Missing End Time-Point value	Warning	CE	279 (1.94%)	It is due to data collection issue. Per guideline of Submitting Study Datasets for Vaccines to the Office of Vaccines Research and Review, CESTDTC and / or CEENDTC should be set to null if e-Dairy card was incomplete.
SD0022	Missing Start Time-Point value	Warning	CE	166 (1.16%)	It is due to data collection issue. Per guideline of Submitting Study Datasets for Vaccines to the Office of Vaccines Research and Review, CESTDTC and / or CEENDTC should be set to null if e-Dairy card was incomplete.
SD0022	Missing Start Time-Point value	Warning	MH	1 (< 0.1%)	Data collection issue
SD0026	Missing value for LBORRESU, when LBORRES is provided	Warning	LB	1678 (4.02%)	Urea Nitrogen/Creatinine is ratio and no unit
SD0029	Missing value for LBSTRESU, when LBSTRESC is provided	Warning	LB	1678 (4.02%)	Urea Nitrogen/Creatinine is ratio and no unit
SD0031	Missing values for CESTDTC, CESTRF and CESTRTPT, when CEENDTC, CEENRF or CEENRTPT is provided	Warning	CE	127 (6.12%)	It is due to data collection issue. Per guideline of Submitting Study Datasets for Vaccines to the Office of Vaccines Research and Review, CESTDTC and / or CEENDTC should be set to null if e-Dairy card was incomplete.
SD0031	Missing values for MHSTDTC, MHSTRF and MHSTRTPT, when MHENDTC, MHENRF or MHENRTPT is provided	Warning	MH	1 (< 0.1%)	Data collection issue

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD0058	Variable appears in dataset, but is not in SDTM model	Error	AE	1 (2.27%)	This study allows a single subject screened and/or enrolled more than once with different SUBJID, USUBJID is assigned based on primary screening that is linked to SUBJID, therefore according to FDA TCG, variable SUBJID has to be included some domains beside DM if screen failure data was included.
SD0058	Variable appears in dataset, but is not in SDTM model	Error	DS	1 (7.14%)	This study allows a single subject screened and/or enrolled more than once with different SUBJID, USUBJID is assigned based on primary screening that is linked to SUBJID, therefore according to FDA TCG, variable SUBJID has to be included some domains beside DM if screen failure data was included.
SD0058	Variable appears in dataset, but is not in SDTM model	Error	DV	1 (9.09%)	This study allows a single subject screened and/or enrolled more than once with different SUBJID, USUBJID is assigned based on primary screening that is linked to SUBJID, therefore according to FDA TCG, variable SUBJID has to be included some domains beside DM if screen failure data was included.
SD0058	Variable appears in dataset, but is not in SDTM model	Error	EC	1 (4.17%)	This study allows a single subject screened and/or enrolled more than once with different SUBJID, USUBJID is assigned based on primary screening that is linked to SUBJID, therefore variable SUBJID has to be included some domains beside DM if screen failure data was included.
SD0058	Variable appears in dataset, but is not in SDTM model	Error	FA	1 (1.32%)	This study allows a single subject screened and/or enrolled more than once with different SUBJID, USUBJID is assigned based on primary screening that is linked to SUBJID, therefore according to FDA TCG, variable SUBJID has to be included some domains beside DM if screen failure data was included.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD0058	Variable appears in dataset, but is not in SDTM model	Error	HO	1 (5.88%)	This study allows a single subject screened and/or enrolled more than once with different SUBJID, USUBJID is assigned based on primary screening that is linked to SUBJID, therefore according to FDA TCG, variable SUBJID has to be included some domains beside DM if screen failure data was included.
SD0058	Variable appears in dataset, but is not in SDTM model	Error	IE	1 (7.69%)	This study allows a single subject screened and/or enrolled more than once with different SUBJID, USUBJID is assigned based on primary screening that is linked to SUBJID, therefore according to FDA TCG, variable SUBJID has to be included some domains beside DM if screen failure data was included.
SD0058	Variable appears in dataset, but is not in SDTM model	Error	LB	1 (2.94%)	This study allows a single subject screened and/or enrolled more than once with different SUBJID, USUBJID is assigned based on primary screening that is linked to SUBJID, therefore according to FDA TCG, variable SUBJID has to be included some domains beside DM if screen failure data was included.
SD0058	Variable appears in dataset, but is not in SDTM model	Error	MH	1 (3.85%)	This study allows a single subject screened and/or enrolled more than once with different SUBJID, USUBJID is assigned based on primary screening that is linked to SUBJID, therefore according to FDA TCG, variable SUBJID has to be included some domains beside DM if screen failure data was included
SD0058	Variable appears in dataset, but is not in SDTM model	Error	RP	1 (5.56%)	This study allows a single subject screened and/or enrolled more than once with different SUBJID, USUBJID is assigned based on primary screening that is linked to SUBJID, therefore variable SUBJID has to be included some domains beside DM if screen failure data was included.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD0058	Variable appears in dataset, but is not in SDTM model	Error	SE	1 (7.14%)	This study allows a single subject screened and/or enrolled more than once with different SUBJID, USUBJID is assigned based on primary screening that is linked to SUBJID, therefore variable SUBJID has to be included some domains beside DM if screen failure data was included.
SD0058	Variable appears in dataset, but is not in SDTM model	Error	SS	1 (7.14%)	This study allows a single subject screened and/or enrolled more than once with different SUBJID, USUBJID is assigned based on primary screening that is linked to SUBJID, therefore variable SUBJID has to be included some domains beside DM if screen failure data was included.
SD0058	Variable appears in dataset, but is not in SDTM model	Error	SV	1 (7.14%)	This study allows a single subject screened and/or enrolled more than once with different SUBJID, USUBJID is assigned based on primary screening that is linked to SUBJID, therefore according to FDA TCG, variable SUBJID has to be included some domains beside DM if screen failure data was included.
SD0058	Variable appears in dataset, but is not in SDTM model	Error	VE	1 (8.33%)	This study allows a single subject screened and/or enrolled more than once with different SUBJID, USUBJID is assigned based on primary screening that is linked to SUBJID, therefore according to FDA TCG, variable SUBJID has to be included some domains beside DM if screen failure data was included.
SD0058	Variable appears in dataset, but is not in SDTM model	Error	VS	1 (3.23%)	This study allows a single subject screened and/or enrolled more than once with different SUBJID, USUBJID is assigned based on primary screening that is linked to SUBJID, therefore according to FDA TCG, variable SUBJID has to be included some domains beside DM if screen failure data was included.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD0080	AE start date is after the latest Disposition date	Error	AE	161 (41.82%)	This is because study is still ongoing, latest date in DS is end of treatment date. AE start date could be after end of treatment date.
SD1075	Variable not recommended for use	Warning	IS	2 (11.76%)	Range Low and High are included in raw data
SD1076	Model permissible variable added into standard domain	Notice	AE	1 (3.70%)	Per Study Date Tabulation Model Version 1.4 or above, --LNKGRP, and Timing Variables are Domain variables.
SD1076	Model permissible variable added into standard domain	Notice	CE	8 (20.51%)	Per Study Date Tabulation Model Version 1.4 or above, Identified Variables such as --LNKGRP, and Timing Variables are domain variables.
SD1076	Model permissible variable added into standard domain	Notice	EC	2 (9.09%)	Per Study Date Tabulation Model Version 1.4 or above, --LNKGRP, and Timing Variables are Domain variable.
SD1076	Model permissible variable added into standard domain	Notice	EX	2 (6.90%)	Per Study Date Tabulation Model Version 1.4 or above, Timing Variables (VISIT and VISITNUM) are domain variable.
SD1076	Model permissible variable added into standard domain	Notice	FA	7 (13.21%)	Per Study Date Tabulation Model Version 1.4 or above, --LNKGRP, and Timing Variables are Domain variable.
SD1076	Model permissible variable added into standard domain	Notice	MH	9 (21.43%)	Per Study Date Tabulation Model Version 1.4 or above, --LNKGRP, and Timing Variables are Domain variable
SD1076	Model permissible variable added into standard domain	Notice	SV	1 (5.88%)	Accepted
SD1076	Model permissible variable added into standard domain	Notice	TS	1 (10.00%)	Per Study Date Tabulation Model Version 1.4 or above, --LNKGRP, and Timing Variables are Domain variable
SD1076	Model permissible variable added into standard domain	Notice	VS	3 (6.82%)	Per Study Date Tabulation Model Version 1.4 or above, Identified Variables such as --LNKGRP, and Timing Variables are domain variables.
SD1078	Permissible variable with missing value for all records	Notice	HO	1 (12.50%)	Keep HODUR for traceability purpose - HODUR was mapped on aCRF page 40
SD1082	Variable length is too long for actual data	Error	CO	1 (12.50%)	This is due to maximum length of the variable used other domains in the study

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1082	Variable length is too long for actual data	Error	EC	1 (5.88%)	This is due to maximum length of the variable used other domains in the study
SD1082	Variable length is too long for actual data	Error	ER	1 (8.33%)	This is due to maximum length of the variable used other domains in the study
SD1082	Variable length is too long for actual data	Error	EX	1 (6.67%)	This is due to maximum length of the variable used other domains in the study
SD1082	Variable length is too long for actual data	Error	FA	1 (4.17%)	This is due to maximum length of the variable used other domains in the study
SD1082	Variable length is too long for actual data	Error	IS	1 (5.00%)	This is due to maximum length of the variable used other domains in the study
SD1082	Variable length is too long for actual data	Error	MB	1 (4.76%)	This is due to maximum length of the variable used other domains in the study
SD1082	Variable length is too long for actual data	Error	RP	1 (8.33%)	This is due to maximum length of the variable used other domains in the study
SD1082	Variable length is too long for actual data	Error	TV	1 (16.67%)	This is due to maximum length of the variable used other domains in the study
SD1082	Variable length is too long for actual data	Error	VE	1 (12.50%)	This is due to maximum length of the variable used other domains in the study
SD1082	Variable length is too long for actual data	Error	VS	1 (4.17%)	This is due to maximum length of the variable used other domains in the study
SD1117	Duplicate records	Warning	FA	348 (0.31%)	Raw Data Issue. The study is still ongoing. All data issues will be addressed before IA or Final
SD1117	Duplicate records	Warning	IS	4 (< 0.1%)	Raw data collection issue, but it is not true duplicated if ISREFID is considered.
SD1117	Duplicate records	Warning	LB	3 (< 0.1%)	Non-EDC data cannot be updated, but they are not true duplicated records by Finding Result per subject, per test name, per timepoint and per lab reference id
SD1117	Duplicate records	Warning	VS	30 (< 0.1%)	This is not true duplicated. There is unique row by STUDYID, USUBJID, VSTESTCD, VISITNUM, VSCAT, VSDTC, EPOCH, VSTPTNUM, VSTPTREF
SD1124	Missing value for ISREASND, when ISSTAT is 'NOT DONE'	Warning	IS	22 (78.57%)	Data collection issue

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1124	Missing value for MBREASND, when MBSTAT is 'NOT DONE'	Warning	MB	56 (48.28%)	Data collection issue - Not Done reason did not collected
SD1124	Missing value for VSREASND, when VSSTAT is 'NOT DONE'	Warning	VS	124 (24.65%)	Data collection issue
SD1201	Duplicate records in CE domain	Warning	CE	4106 (28.62%)	Duplicated Records are due to missing CESTDTC and / or CEENDTC, there are no duplicated records found if CEDTC, CESTDTC and CEENDTC are used
SD1201	Duplicate records in DS domain	Warning	DS	1 (< 0.1%)	This is due to same subject with more than one screen and/or enrolled case. The same USUBJID was assigned to different SUBJID - Duplicated by USUBJID, but not by USUBJID and SUBJID
SD1201	Duplicate records in MH domain	Warning	MH	27 (0.90%)	This is due to same subject with more than one screen and/or enrolled case. The same USUBJID was assigned to different SUBJID - Duplicated by USUBJID, but not by USUBJID and SUBJID
SD1204	CMENDTC date is after RFPENDTC	Error	CM	2 (0.39%)	Data collection issue. RFPENDTC did not include partial date
SD1290	Multiple disposition events for the same EPOCH	Error	DS	17 (3.07%)	This is due to same subject with more than one screen and/or enrolled case. The same USUBJID was assigned to different SUBJID - Duplicated by USUBJID, DSDECOD, and EPOCH but not by SUBJID, DSDECOD, and EPOCH.
SD1319	DSSTDTC is before RFICDTC	Error	DS	67 (2.33%)	This study allows a single subject screened and/or enrolled more than once with different SUBJID, USUBJID is assigned based on primary screening that is linked to SUBJID, therefore, DSSTDTC is before RFICDTC could happen by USUBJID, but not SUBJID.
SD1339	Missing EPOCH value, when a start or observation date is provided	Warning	CM	225 (29.15%)	This is due to the same subject with multiple screening/enrollment, EPOCH is set to missing for previous (initial) screen.
SD1339	Missing EPOCH value, when a start or observation date is provided	Warning	LB	107 (0.21%)	This is due to the same subject with multiple screening/enrollment, EPOCH is set to missing for previous (initial) screen

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1339	Missing EPOCH value, when a start or observation date is provided	Warning	PR	1 (3.85%)	This is due to the same subject with multiple screening/enrollment, EPOCH is set to missing for previous (initial) screen
SD2236	ACTARMCD does not equal ARMCD	Warning	DM	9 (1.50%)	ACTARMCD does not equal ARMCD because dose error occurred. Dose error data was captured and most appropriate pre-defined category for the actual dose administered included in eDT.
SD2237	ACTARM does not equal ARM	Warning	DM	9 (0.83%)	ACTARM does not equal ARM because dose error occurred. Dose error data was captured and most appropriate pre-defined category for the actual dose administered included in eDT.
SD2239	Inconsistent value for FATPT	Error	FA	31 (< 0.1%)	e-Diary raw data issue could not be resolved.
SD2263	Invalid TSVAL value for PCLAS	Error	TS	1 (100.00%)	New term is still not supported by MED-RT dictionary
SD2264	Invalid TSVALCD value for PCLAS	Error	TS	1 (100.00%)	New term is still not supported by MED-RT dictionary
SD2265	TSVAL/TSVALCD value mismatch for PCLAS	Error	TS	1 (100.00%)	New term is still not supported by MED-RT dictionary
SD9999	Dataset XM class not recognized	Error	XM	1 (100.00%)	For subjects with multiple enrollments within a single study, the primary enrollment is submitted in DM. According to FDA TCG, additional enrollments are included in custom domain (XM) with a similar structure to DM.
TS0006	No Baseline (ALT) test results for Subject	Error	DM	1 (0.17%)	Raw Data Issue and did not impact analysis.
TS0008	No Baseline (AST) test results for Subject	Error	DM	1 (0.17%)	Raw Data Issue and did not impact analysis.
TS0009	No Baseline (BILI) test results for Subject	Error	DM	1 (0.17%)	Raw Data Issue and did not impact analysis.
TS0039	No (ALT) test results	Error	DM	1 (0.17%)	Raw Data Issue and did not impact analysis.
TS0041	No (AST) test results	Error	DM	1 (0.17%)	Raw Data Issue and did not impact analysis.
TS0042	No (BILI) test results	Error	DM	1 (0.17%)	Raw Data Issue and did not impact analysis.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
TS0043	No (GGT) test results	Notice	DM	600 (100.00%)	Per Protocol, no GGT Test results are collected.
TS0050	Missing PC dataset	Warning	GLOBAL	1 (100.00%)	Per protocol, PC data collected
TS0051	Missing PP dataset	Warning	GLOBAL	1 (100.00%)	Per protocol, PP data collected
TS0057	LBSTRESN is populated but LBSTNRHI is not populated	Warning	LB	3 (< 0.1%)	Raw data
DD0024	Invalid Term in codelist 'Action Taken with Study Treatment' for variable 'AEACN'	Warning	DEFINE	1 (100.00%)	This is due to non-standard action taken term 'DOSE DELAYED' was captured from CRF
DD0050	Domain/SASDatasetName mismatch for split dataset	Error	DEFINE	3 (100.00%)	This is false-positive validation message specific for SUPPFAxx datasets which are not processed correctly by Pinnacle 21
DD0114	Invalid usage of split datasets for non-general-observation-class datasets	Error	DEFINE	3 (100.00%)	This is false-positive validation message specific for SUPPFAxx datasets which are not processed correctly by Pinnacle 21

4.3 Additional Conformance Details

Not available

Appendix I: Inclusion/Exclusion Criteria

Protocol/ Amendment Version	Category	IETESTCD	Full Text of Criterion
Original/ Amendment 1	Inclusion	INC01	Male or female, 18 years of age or older at the time of consent (Screening Visit, Day 0).
Original/ Amendment 1	Inclusion	INC02	Understands and agrees to comply with the study procedures and provides written informed consent.
Original/ Amendment 1	Inclusion	INC03	According to the assessment of the investigator, is in good general health and can comply with study procedures.
Original/ Amendment 1	Inclusion	INC04	Body mass index (BMI) of 18 kg/m2 to 30 kg/m2 (inclusive) at the Screening Visit (Day 0).
Original/ Amendment 1	Inclusion	INC05	Female participants of nonchildbearing potential may be enrolled in the study. Nonchildbearing potential is defined as surgically sterile (history of bilateral tubal ligation, bilateral oophorectomy, hysterectomy) or postmenopausal (defined as amenorrhea for ≥ 12 consecutive months prior to Screening (Day 0) without an alternative medical cause). A follicle-stimulating hormone (FSH) level may be measured at the discretion of the investigator to confirm postmenopausal status.

Protocol/ Amendment Version	Category	IETESTCD	Full Text of Criterion
Original/ Amendment 1	Inclusion	INC06	Female participants of childbearing potential may be enrolled in the study if the participant fulfills all the following criteria: • Has a negative pregnancy test at Screening (Day 0) and on the day of the first injection (Day 1). • Has practiced adequate contraception or has abstained from all activities that could result in pregnancy for at least 28 days prior to the first injection (Day 1). • Has agreed to continue adequate contraception through 3 months following the second injection (Day 29). • Is not currently breastfeeding. Adequate female contraception is defined as consistent and correct use of a Food and Drug Administration (FDA) approved contraceptive method in accordance with the product label. For example: • Barrier method (such as condoms, diaphragm, or cervical cap) used in conjunction with spermicide • Intrauterine device • Prescription hormonal contraceptive taken or administered via oral (pill), transdermal (patch), subdermal, or IM route • Sterilization of a female participant's monogamous male partner prior to entry into the study Note: periodic abstinence (eg, calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception.

Protocol/ Amendment Version	Category	IETESTCD	Full Text of Criterion
Amendment 1	Inclusion	INC07	Male participants engaging in activity that could result in pregnancy of sexual partners must agree to practice adequate contraception and refrain from sperm donation from the time of the first injection and through 3 months after the last injection. Adequate contraception for male participants is defined as: • Monogamous relationship with a female partner using an intrauterine device or hormonal contraception (described above) • Use of barrier methods and spermicide • History of surgical sterilization Male participants with partners who have become pregnant prior to Screening are eligible to participate in the study.
Original/ Amendment 1	Exclusion	EXC01	Known history of SARS-CoV-2 infection or known exposure to someone with SARS-CoV-2 infection or COVID-19.
Original/ Amendment 1	Exclusion	EXC02	Travel outside of the US in the 28 days prior to the Screening Visit (Day 0).
Original/ Amendment 1	Exclusion	EXC03	Pregnant or breastfeeding.
Original/ Amendment 1	Exclusion	EXC04	Is acutely ill or febrile 24 hours prior to or at the Screening Visit (Day 0). Fever is defined as a body temperature ≥ 38.0°C/100.4°F. Participants meeting this criterion may be rescheduled within the relevant window periods. Afebrile participants with minor illnesses can be enrolled at the discretion of the investigator.
Original/ Amendment 1	Exclusion	EXC05	Prior administration of an investigational CoV (eg, SARS-CoV-2, SARS-CoV, MERS-CoV) vaccine.
Original/ Amendment 1	Exclusion	EXC06	Current treatment with investigational agents for prophylaxis against COVID-19.

Protocol/ Amendment Version	Category	IETESTCD	Full Text of Criterion
Original/ Amendment 1	Exclusion	EXC07	Has a medical, psychiatric, or occupational condition that may pose additional risk as a result of participation, or that could interfere with safety assessments or interpretation of results according to the investigator's judgment.
Original/ Amendment 1	Exclusion	EXC08	Is a healthcare worker or a member of an emergency response team
Original/ Amendment 1	Exclusion	EXC09	Current use of any inhaled substance (eg, tobacco or cannabis smoke, nicotine vapors).
Original/ Amendment 1	Exclusion	EXC10	History of chronic smoking (≥ 1 cigarette a day) within 1 year of the Screening Visit (Day 0).
Original/ Amendment 1	Exclusion	EXC11	History of illegal substance use or alcohol abuse within the past 2 years. This exclusion does not apply to historical cannabis use that was formerly illegal in the participant's state but is legal at the time of Screening.
Original/ Amendment 1	Exclusion	EXC12	Known history of hypertension, or systolic blood pressure > 150 mm Hg in participants in Cohort 1 (≥ 18 to < 55 years old) or systolic blood pressure > 160 mm Hg in participants in Cohort 2 (≥ 55 years old) at the Screening Visit (Day 0).
Original/ Amendment 1	Exclusion	EXC13	Known history of hypotension or systolic blood pressure < 85 mm Hg at the Screening Visit (Day 0).
Original/ Amendment 1	Exclusion	EXC14	Diabetes mellitus
Original/ Amendment 1	Exclusion	EXC15	Diagnosis of chronic pulmonary disease (eg, chronic obstructive pulmonary disease, asthma)
Original/ Amendment 1	Exclusion	EXC16	Chronic cardiovascular disease
Original/ Amendment 1	Exclusion	EXC17	Resides in a nursing home

Protocol/ Amendment Version	Category	IETESTCD	Full Text of Criterion
Original/ Amendment 1	Exclusion	EXC18	Grade 1 or higher toxicity on clinical safety laboratory testing at the Screening Visit (Day 0)
Original/ Amendment 1	Exclusion	EXC19	Current or previous diagnosis of immunocompromising condition, immune-mediated disease, or other immunosuppressive condition.
Original/ Amendment 1	Exclusion	EXC20	Received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to the Screening Visit (Day 0) (for corticosteroids ≥ 20 mg/day of prednisone equivalent). Topical tacrolimus is allowed if not used within 14 days prior to the Screening Visit (Day 0).
Original/ Amendment 1	Exclusion	EXC21	Anticipating the need for immunosuppressive treatment at any time during participation in the study.
Original/ Amendment 1	Exclusion	EXC22	Positive serology for hepatitis B virus surface antigen, hepatitis C virus antibody, or human immunodeficiency virus (HIV) type 1 or 2 antibodies identified at the Screening Visit (Day 0).
Original/ Amendment 1	Exclusion	EXC23	History of anaphylaxis, urticaria, or other significant AR requiring medical intervention after receipt of a vaccine.
Original/ Amendment 1	Exclusion	EXC24	Bleeding disorder considered a contraindication to IM injection or phlebotomy.
Original/ Amendment 1	Exclusion	EXC25	Diagnosis of malignancy within previous 10 years (excluding non-melanoma skin cancer).
Original/ Amendment 1	Exclusion	EXC26	Has received or plans to receive a licensed vaccine ≤ 28 days prior to the first injection (Day 1) or plans to receive a licensed vaccine within 28 days before or after any study injection. Licensed influenza vaccines may be received more than 14 days before or after any study injection.
Original/ Amendment 1	Exclusion	EXC27	Receipt of systemic immunoglobulins or blood products within 3 months prior to the Screening Visit (Day 0) or plans for receipt during the study.

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Original/ Amendment 1	Exclusion	EXC28	Has donated ≥ 450 mL of blood products within 28 days prior to the Screening Visit (Day 0) or plans to donate blood products during the study.
Original/ Amendment 1	Exclusion	EXC29	Participated in an interventional clinical study within 28 days prior to the Screening Visit (Day 0) or plans to do so while participating in this study.
Original/ Amendment 1	Exclusion	EXC30	Is an immediate family member or household member of study personnel.