Clinical Study Data Reviewer's Guide

ModernaTX, Inc.

Study mRNA-1273-P301

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.)
OVRR	Technical Specifications Document: Submitting Study Datasets for Vaccines to the Office of Vac-cines Research and Review (October 2019)

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, 2020-09-25
Data Definitions	Define-XML v2.0
Medications Dictionary	WHODD GLOBALB3Mar20, SNOMED 2020-09-01, UNII 2020-08-18, NDF-RT 2020-09-08
Medical Events Dictionary	MedDRA v23.0
Other standards (optional)	Guidance for Industry - Technical Specifications Document: Submitting Study Datasets for Vaccines to the Office of Vac-cines Research and Review (October 2019) CDISC TAUG-VAX 1.1

2. Protocol Description

2.1 Protocol Number and Title

Protocol Number: mRNA-1273-P301

Protocol Title: A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older

Protocol Versions: V8.0

Protocol Amendments do not impact analysis dataset derivation and data structure

2.2 Protocol Design

Figure 1: Study Flow Diagram: Part A, the Blinded Phase followed by Part B, the Open-Label Observational Phase

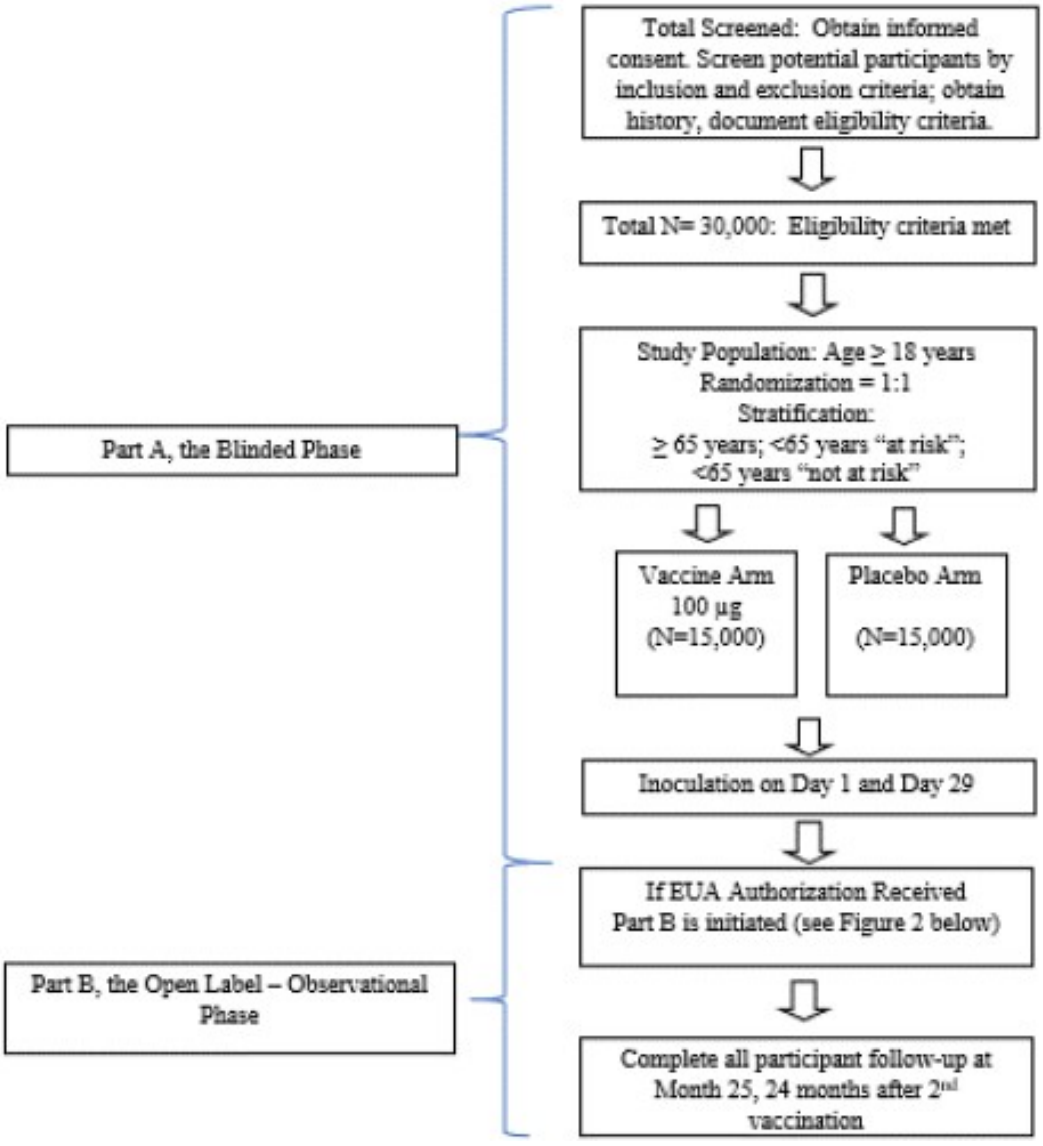
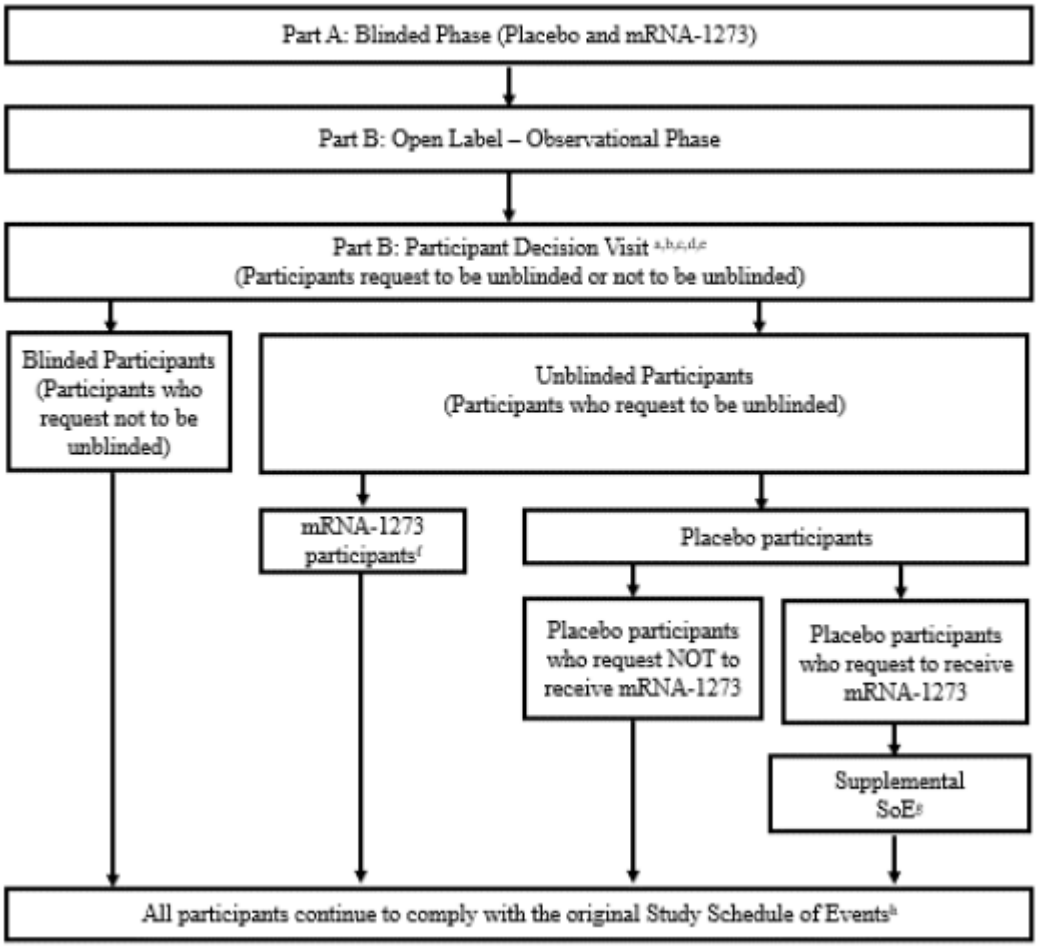


Figure 2: Part B, the Open-Label Observational Phase



[a] All participants are encouraged to remain in the study.
[b] All participants are given the option to be unblinded to treatment received in Part A: Blinded Phase.
[c] All participants are counselled about the importance of continuing other public health measures to limit the spread of disease including physical-social distancing, wearing a mask, and hand-washing.
[d] All participants sign a revised ICF.
[e] All participants consent to provide a nasopharyngeal swab and a blood sample for immunologic analysis.
[f] mRNA-1273 recipients who only received one dose of the mRNA-1273 vaccine will receive the second dose of mRNA-1273 vaccine. Additional details provided in the Supplemental Schedule of Events.
[g] Placebo recipients who request to receive mRNA-1273 and meet eligibility, will comply with a Supplemental Schedule of Events in addition to the Original Study Schedule of Events.
[h] Original Study Schedule of Events

2.3 Trial Design Datasets

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

Dataset	Dataset Label
TA	Trial Arms

Dataset	Dataset Label
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:
The data cutoff date (DCO) is defined as the date by which all data records in the clinical datasets will be included in or excluded from a prescribed set of analyses. For BLA submission, the DCO date is the date of data cutoff date (26-Mar-2021) with exceptions of data related to unblinding, death, serious adverse events (SAE), COVID-19 symptoms, and pregnancy. mRNA-1273-P301 Data Cutoff Algorithm.pdf is described in the details

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
XM	Multiple Participation
VS	Vital Signs
SV	Subject Visits
SUPPVS	Supplemental Qualifiers for VS
SUPPRP	Supplemental Qualifiers for RP
SUPPMH	Supplemental Qualifiers for MH
SUPPMB	Supplemental Qualifiers for MB
SUPPIE	Supplemental Qualifiers for IE
SUPPDV	Supplemental Qualifiers for DV
SUPPDS	Supplemental Qualifiers for DS
SUPPDM	Supplemental Qualifiers for DM

Dataset	Dataset Label
SUPPAE	Supplemental Qualifiers for AE
SE	Subject Elements
SC	Subject Characteristics
RP	Reproductive System Findings
MH	Medical History
MB	Microbiology Specimen
LB	Laboratory Test Results
IS	Immunogenicity Specimen Assessments
IE	Inclusion/Exclusion Criteria Not Met
FA	Findings About Events or Interventions
DV	Protocol Deviations
DS	Disposition
DM	Demographics
AE	Adverse Events

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? Yes

CE domain contains adjudicated COVID-19 results with CECAT="ADJUDICATION".

Only adjudicated results are mapped to SDTM.CE. The source data supporting adjudication are from clinical database and are in other SDTM domains.

Adjudicated data used vertical data structure - one record per subject and per data field.

SDTM.CE used horizontal data structure – one record per subject and per adjudication result (see Table 3.1 CE data mapping)

Table 3.1

Adjudication Data to SDTM mapping

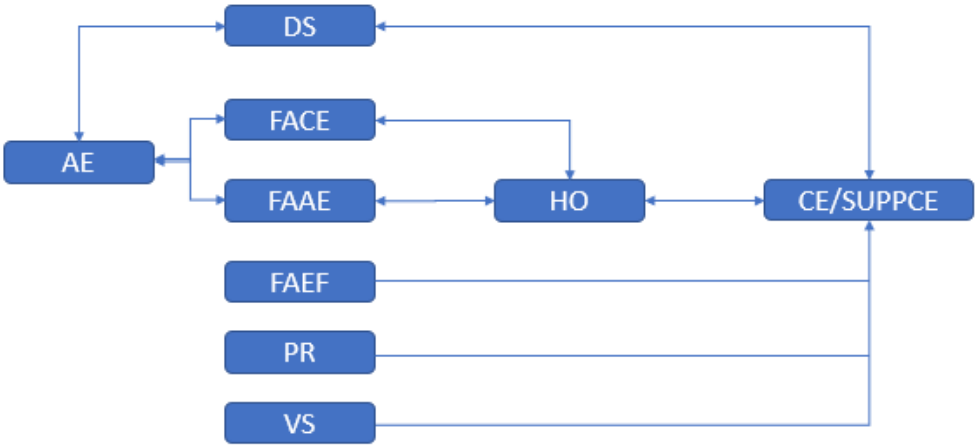
PROTOCOL	CEC_MEMBER [CE.CEEVEL]	FIELD_NAME	FIELD_DESCRIPTION	RESPONSE_DESCRIPTION	ADJUDICATION_OUTCOME [CE.CEREASOC]	SDTM.MAPPING
MRNA-1273-P301	DR. ERIC S. ROSENBERG	ADJCOMM	ADJUDICATION COMMENTS:	INSUFFICIENT DURATION OF ILLNESS TO ASSESS FOR DISEASE SEVERITY.	EVENT MEETS THE CHARTER DEFINITION OF COVID-19: 03-NOV-2020	
MRNA-1273-P301	DR. ERIC S. ROSENBERG	CLINID	EVENT NUMBER/ID:	RUS3002037	EVENT MEETS THE CHARTER DEFINITION OF COVID-19: 03-NOV-2020	**CE.CESPID**
MRNA-1273-P301	DR. ERIC S. ROSENBERG	COVIDT	COVID-19 AC-ASSESSED ONSET DATE: DD-MMM-YYYY	3-Nov-20	EVENT MEETS THE CHARTER DEFINITION OF COVID-19: 03-NOV-2020	**CE.CESTDTC**
MRNA-1273-P301	DR. ERIC S. ROSENBERG	COVIDTYP	ONE OR BOTH OPTIONS MAY BE COMPLETED:	COVID-19	EVENT MEETS THE CHARTER DEFINITION OF COVID-19: 03-NOV-2020	**CE.CESCAT**
MRNA-1273-P301	DR. ERIC S. ROSENBERG	EVENTDEF	MARK ONE ONLY:	EVENT MEETS THE CHARTER DEFINITION OF COVID-19 AND/OR SEVERE COVID-19 DIAGNOSIS	EVENT MEETS THE CHARTER DEFINITION OF COVID-19: 03-NOV-2020	**CE.CETERM**
MRNA-1273-P301	DR. ERIC S. ROSENBERG	SUBJNO	SUBJECT NUMBER:	US3002037	EVENT MEETS THE CHARTER DEFINITION OF COVID-19: 03-NOV-2020	**Derive to CE.USUBJID**

Notes: Some of SDTM datasets have been rerun after TFLs were submitted. It is to fix issues found from Pinnacle 21 SDTM validation report, but there is no impact for TFLs

3.2 Traceability Flow Diagram

Topline solicited symptoms (one record per subject per symptom per vaccination) are mapped to CE domain (FACE - if data was collected within observed period and FAAE - if data continue to be collected after observed period).

Topline efficacy results (one resod per subject and per efficacy symptom occurrence) are mapped to CE domain as well



Line connectors with double-arrows indicate there are links between the two connected boxes; and line connector between two boxes with single arrows indicate that there are mappings from one box to (arrow points toward) the other

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 2	Participant Creation form	Support data management
Page 3	Was this visit performed	This question is to support data management clean/query data only
Page 5	Participant randomization assignment Actual Dose 1 Actual Dose 2	Support Information for Site / Data Management
Page 9	Did participant meet all eligibility	This is redolently information
Page 11	Were and significant condition report	To support data management
Page 19	What was study treatment	This is redolently
Page 24	Did the participant experience any adverse event?	Support data management
Page 26	Narrative	Support data management
Page 27	Were any prior/concomitant medications and/or vaccinations taken?	Support data management
Page 30	Were any concomitant procedures performed?	Support data management
Page 34	Is the participant continuing to the next visit?	Support data management
Page 42	Was this diagnostic test performed at a lab other than the Study Central Lab?	This is redolently information
Page 50	Generate Next COVID-19 Assessment	Support data management
Page 53,54, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68	PC date Open /Close	ePRO system data
Page 70	Patient Cloud Open/Close Date & Time	Safety Follow Up Diary
Page 71	Safety Report Form	Data should be captured in the Adverse Event Form

3.4 SDTM Subject Domains

Dataset - Dataset Label	Efficacy	Safety	Other	Custom	SUPP--	Related Using RELREC
AE - Adverse Events		X			X	CE, HO, FA, VS
CE - Clinical Events	X	X			X	AE, FA, VS
CM - Concomitant Medications		X			X	
DD - Death Details		X				
DM - Demographics			X		X	
DS - Disposition			X		X	
DV - Protocol Deviations			X		X	
EC - Exposure as Collected			X		X	
EX - Exposure			X			
FAAE - Findings About Adverse Events		X			X	
FACE - Findings About Clinical Events		X			X	
FAEF - Findings About Efficacy Events	X				X	
FAOT - Findings About Events or Interventions			X		X	
HO - Healthcare Encounters	X	X			X	AE
IE - Inclusion/Exclusion Criteria Not Met			X		X	
IS - Immunogenicity Specimen Assessment	X				X	
LB - Laboratory Tests Results				X		
MB - Microbiology Specimen	X				X	
MH - Medical History			X		X	
PR - Procedures	X	XX				

Dataset - Dataset Label	Efficacy	Safety	Other	Custom	SUPP--	Related Using RELREC
RP - Reproductive System Findings			X		X	
SC - Subject Characteristics			X		X	
SE - Subject Elements			X			
SV - Subject Visits			X		X	
VS - Vital Signs	X	X			X	CE, AE, FA
XM - Multiple Participation				X		
XQ - Virus Sequencing				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: such as 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

QNAM	Description
AECVDIAG	Confirmed diagnosis Symptom Covid-19
AEDICNM	Coder Dictionary Name

QNAM	Description
AEDICVR	Coder Dictionary Version
AEHOSPEN	AE Hosp End Date
AEHOSPST	AE Hosp Start Date
AEICUSTD	Admitted to ICU? Coded Value
AEOUTSP	Recovered/Resolved with Sequelae, specif
AESEVSTD	Severity Coded Value
AESOFL	Solicited Adverse Reaction?
AESPID1	AE ID coded value
AETRTEM	Treatment Emergent Flag
DSSPIDX	DS Sponsor-Defined Identifier
HOSPIDX	HO Sponsor-Defined Identifier
MAAEFL	Medically-attended AE Flag
REMOVEFL	AR Remove Flag

DSSPIDX: Create a link between AE and DS if it indicates the event leading to discontinue treatment or study (See Table 3.4.1 Row 4 of SDTM.AE and SDTM.SUPPAE)

HOSPIDX: Create a link between AE and HO if medically attended indicates the event requires hospitalization or ICU (see Table 3.4.1 Row 1 and Row 2 of SDTM.AE and SDTM.SUPPAE)

REMOVEFL: All solicited AR captured in AE form are flagged as remove except for SAE or last beyond day 7 from vaccine reference date (see Table 3.4.1 Row 5 and 6 of SDTM.AE and SDTM.SUPPAE)

Table 3.4.1 **SDTM.AE**

	USUBJID	AESEQ	AEREFID	AESPID	AEDECOD	AESEV	AESER	AETOXGR	AESTDTC	AEENDTC
1	XXXX001	1	DOSE 2 - 2020-09-14T13:03	AE-002	Vomiting		Y	4	2020-09-15T12:00	2020-09-21
2	XXXX002	1	DOSE 2 - 2020-09-14T13:03	AE-004	Nausea		Y	4	2020-09-15T12:00	2020-09-21
3	XXXX002	2	DOSE 2 - 2020-10-12T11:10	AE-001	Myalgia	MODERATE	N	2	2021-01-09	2021-01-09T18:00
4	XXXX003	1	DOSE 1 - 2020-09-21T13:17	AE-002	Injection site swelling	MILD	N	1	2020-09-21T15:00	2020-10-06
5	XXXX003	2	DOSE 1 - 2020-09-21T16:37	AE-009	Fatigue	MILD	N	1	2020-09-22T00:03	2020-09-28T14:58
6	XXXX004	1	DOSE 1 - 2020-10-03T10:24	AE-001	Injection site pain	MILD	N	1	2020-10-08	2020-10-08
7	XXXX004	2	DOSE 1 - 2020-10-21T13:02	AE-001	Lymphadenopathy	MILD	N	1	2020-10-22T22:56	2020-11-01T01:16
8	XXXX004	3	DOSE 1 - 2020-10-21T13:02	AE-004	Myalgia	MILD	N	1	2020-10-22T21:13	2020-10-29T11:59

SDTM.SUPPAE

	USUBJID	AESEQ	MAAEFL	HOSPIDX	DSSPIDX	REMOVEFL
1	XXXX001	1	Y	HO-AE-002/AE-004		
2	XXXX002	1	Y	HO-AE-002/AE-004		
3	XXXX002	2	N			
4	XXXX003	1	N		DS-003	
5	XXXX003	2	N			Y
6	XXXX004	1	N			Y
7	XXXX004	2	Y			
8	XXXX004	3	Y			

3.4.2 CE - Clinical Events

QNAM	Description
AEFLAG	Medically-attended Flag from AE
AESEVX	AE Severity/Intensity
AESPIDX	AE Sponsor-Defined Identifier
CEREASOC	Reason Clinical Event Outcome
DSSPIDX	DS Sponsor-Defined Identifier
HOSPIDX	HO Sponsor-Defined Identifier
MAAEFL	Medically-attended AE Flag
SAEDTC	SAE Date
SAEDY	SAE Day

Three type topline records are created in CE/SUPPCE

1. CECAT = REACTOGENICITY 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).

CESDTC/CEENDTC should be identical with AESTDTC/AEENDTC if the symptom reported in AE due to symptom last beyond day 7. CEDUR covered symptom duration within 7 days and AEDUR covered symptom duration after day 7 days.

Table 3.4.2.1 illustrated data mapping and link among domains

Case 1

Subject symptom erythema data was found form both e-Diary and RAW.AE, but grade rating is different. Grade 3 from subject (CE.CESEQ=19) was mapped to CE.CETOXGR (3), grade 1 from investigator (SUPPCE.CESEQ=19) was mapped to SUPPCE.QVAL(GRADE 1/MILD) where SUPPCE.QNAM=AESEVX

Case 2

Medically-attended after Dose 2 reported by subject was mapped SUPPCE.QVAL(HO-CE-DOSE2) where SUPPCE.QNAM='HOSPIDX', and medically-attended reported by investigator was mapped to SUPPCE.QVAL(Y) where SUPPCE.QNAM='MAAEFL'.

Table 3.4.2.1

CECAT = REACTOGENICITY							
USUBJID	CESEQ	CETERM	CEOCCUR	CETOXGR	CESTDTC	CEENDTC	CETPTREF
mRNA-1273-P301-US323-2135	19	Erythema	Y	3	2020-09-30T21:00	2020-10-05T01:14	DOSE 2
mRNA-1273-P301-US323-2135	21	Pain	Y	1	2020-09-29T21:01	2020-10-06T00:45	DOSE 2
mRNA-1273-P301-US323-2135	23	Swelling	Y	2	2020-09-30T21:00	2020-10-02T21:04	DOSE 2
mRNA-1273-P301-US323-2135	25	Underarm Gland Swelling or Tenderness	N	0			DOSE 2
mRNA-1273-P301-US323-2135	27	Arthralgia	N	0			DOSE 2
mRNA-1273-P301-US323-2135	29	Chills	Y	3	2020-09-30T21:01	2020-09-30T21:01	DOSE 2
mRNA-1273-P301-US323-2135	31	Fatigue	Y	3	2020-09-30T21:01	2020-09-30T21:01	DOSE 2
mRNA-1273-P301-US323-2135	33	Fever	N	0			DOSE 2
mRNA-1273-P301-US323-2135	35	Headache	N	0			DOSE 2
mRNA-1273-P301-US323-2135	37	Myalgia	Y	2	2020-09-30T21:01	2020-09-30T21:01	DOSE 2
mRNA-1273-P301-US323-2135	39	Nausea/Vomiting	N	0			DOSE 2

SUPPCE						
USUBJID	CESEQ	AEFLAG	MAAEFL	AESEVX	AESPIDX	HOSPIDX
mRNA-1273-P301-US323-2135	19	Y	Y	GRADE 1/MILD	AE-002	HO-CE-DOSE2
mRNA-1273-P301-US323-2135	21		Y			HO-CE-DOSE2
mRNA-1273-P301-US323-2135	23	Y	Y	GRADE 1/MILD	AE-005	HO-CE-DOSE2
mRNA-1273-P301-US323-2135	29	Y	Y	GRADE 1/MILD	AE-003	HO-CE-DOSE2
mRNA-1273-P301-US323-2135	31		Y			HO-CE-DOSE2
mRNA-1273-P301-US323-2135	33	Y		GRADE 1/MILD	AE-004	
mRNA-1273-P301-US323-2135	37	Y	Y	GRADE 1/MILD	AE-006	HO-CE-DOSE2

2. CECAT = EFFICACY contains topline efficacy symptoms. It is based on one record per subject (USUBJID), per symptom (CETERM), CEDTC is based on last assessment date. CESTDTC/CEENDTC are populated only if data was

captured from Severe COVID-19 andanswer 'Does an event occur?' is 'Y'.

On the eCRF, 'Admission to an intensive care unit due to SARS-CoV-2' is not associate withany symptom, we mapped the intensive care event to HO (Healthcare Encounter) domain anduse HOSPIDX to link CE and HO (many-to-single mapping)

To get HOSPIDX from SUPPCE (See table 3.4.2.2):

Merging CE and SUPPCE domain with USUBJID and CESEQ as merging keys. In CE domain where CESCAT= 'COVID-19 SEVERITY' and CEOCCURE='Y', Three records(CE.CESEQ=23, 27, 29) are found , in SUPPCE, there are three records (CESEQ=23, 27,29) associated with SUPPCE.QNAM= HOSPIDX, SUPPCE.QVAL=HO-SCOVID-19,

Merging them and get HO-SOVID-19,

Hospital Start Date and End Data can be found from where HO.USUBJID=CE.USUBJID andHO.HOSPID=SUPPCE.QVAL where SUPPCE.QNAM=HOSPIDX.

Table 3.4.2.2

SDTM.CE where CECAT=EFFICACY

USUBJID	CESEQ	CETERM	CESCAT	CEOCCUR	CESEV	CETOXGR	CESTDTC	CEENDTC
mRNA-1273-P301-US327-2195	3	Body Aches	COVID-19	Y	SEVERE		2020-10-30	2020-11-09
mRNA-1273-P301-US327-2195	4	Chills	COVID-19	Y	SEVERE		2020-10-31	2020-11-06
mRNA-1273-P301-US327-2195	5	Cough	COVID-19	Y	SEVERE		2020-11-01	2020-11-10
mRNA-1273-P301-US327-2195	6	Diarrhea	COVID-19	Y	MODERATE		2020-11-04	2020-11-10
mRNA-1273-P301-US327-2195	7	Difficulty Breathing	COVID-19	Y	SEVERE		2020-11-03	2020-11-10
mRNA-1273-P301-US327-2195	8	Fatigue	COVID-19	Y	SEVERE		2020-10-30	2020-11-10
mRNA-1273-P301-US327-2195	9	Fever	COVID-19	Y		1	2020-11-03	2020-11-06
mRNA-1273-P301-US327-2195	10	Headache	COVID-19	Y	SEVERE		2020-11-02	2020-11-07
mRNA-1273-P301-US327-2195	11	Myalgia	COVID-19	Y	MODERATE		2020-11-03	2020-11-09
mRNA-1273-P301-US327-2195	12	Nasal Congestion	COVID-19	Y	MODERATE		2020-11-01	2020-11-10
mRNA-1273-P301-US327-2195	13	Nausea	COVID-19	Y	MODERATE		2020-11-04	2020-11-07
mRNA-1273-P301-US327-2195	14	New Loss of Smell	COVID-19	Y	SEVERE		2020-11-02	2020-11-09
mRNA-1273-P301-US327-2195	15	New Loss of Taste	COVID-19	Y	SEVERE		2020-11-01	2020-11-09
mRNA-1273-P301-US327-2195	16	Oxygen Saturation of SpO2 <=93% on room air at sea level	COVID-19	Y	ABNORMAL		2020-11-05	2020-11-09
mRNA-1273-P301-US327-2195	17	Rhinorrhea	COVID-19	Y	MILD		2020-11-10	2020-11-10
mRNA-1273-P301-US327-2195	18	Shortness of Breath	COVID-19	Y	SEVERE		2020-11-01	2020-11-10
mRNA-1273-P301-US327-2195	19	Sore Throat	COVID-19	N	NONE			
mRNA-1273-P301-US327-2195	20	Vomiting	COVID-19	N	NONE			
mRNA-1273-P301-US327-2195	21	Acute Renal Dysfunction	COVID-19 SEVERITY	N				
mRNA-1273-P301-US327-2195	22	Acute Respiratory Distress Syndrome	COVID-19 SEVERITY	N				
mRNA-1273-P301-US327-2195	23	Clinical Evidence of Pneumonia	COVID-19 SEVERITY	Y			2020-11-07	2020-11-07
mRNA-1273-P301-US327-2195	24	Evidence of Shock Requires Vasopressors	COVID-19 SEVERITY	N				
mRNA-1273-P301-US327-2195	25	Heart Rate >= 125 per Minute	COVID-19 SEVERITY	N				
mRNA-1273-P301-US327-2195	26	Neurologic Dysfunction	COVID-19 SEVERITY	N				
mRNA-1273-P301-US327-2195	27	Oxygen Saturation of SpO2 <=93% on room air at sea level	COVID-19 SEVERITY	Y			2020-11-07	2020-11-07
mRNA-1273-P301-US327-2195	28	PaO2/FIO2 Ratio < 300 mmHg	COVID-19 SEVERITY	N				
mRNA-1273-P301-US327-2195	29	Radiographical Evidence of Pneumonia	COVID-19 SEVERITY	Y			2020-11-07	2020-11-07
mRNA-1273-P301-US327-2195	30	Respiratory Failure	COVID-19 SEVERITY	N				
mRNA-1273-P301-US327-2195	31	Respiratory Rates >= 30 per Minute	COVID-19 SEVERITY	N				
mRNA-1273-P301-US327-2195	32	Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg	COVID-19 SEVERITY	N				

SDTM.SUPPCE

USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
mRNA-1273-P301-US327-2195	CESEQ	23	HOSPIDX	HO Sponsor-Defined Identifier	HO-SCOVID-19	Derived	
mRNA-1273-P301-US327-2195	CESEQ	27	HOSPIDX	HO Sponsor-Defined Identifier	HO-SCOVID-19	Derived	
mRNA-1273-P301-US327-2195	CESEQ	29	HOSPIDX	HO Sponsor-Defined Identifier	HO-SCOVID-19	Derived	

SDTM.HO

USUBJID	HOSEQ	HOSPID	HODECOD	HOCAT	HOOCCUR	HODTC	HOSTDTC
mRNA-1273-P301-US327-2195	1	HO-AE-002/AE-003	ICU	ADVERSE EVENTS	Y		
mRNA-1273-P301-US327-2195	2	HO-SCOVID-19	ICU	EFFICACY	Y	2020-11-0	2020-11-07
mRNA-1273-P301-US327-2195	3	HO-AE-001/AE-002/AE-003	HOSPITAL	ADVERSE EVENTS	Y		2020-11-07

3. CECAT= ADJUDICATION contains COVID-19 and SEVERE COVID-19 cases that are adjudicated by independent group. It is one record per subject (USUBJID), per case (CESCAT), per adjudication outcome (CEREASOC) and per case start date (CESDTC) (see Table 3.4.2.3 example)

Table 3.4.2.3

CE.CECAT=ADJUDICATION

	USUBJID	CECAT	CESCAT	CEREASOC	CESTDTC
311667	mRNA-1273-P301-US338-2152	ADJUDICATIO	COVID-19	EVENT MEETS THE CHARTER DEFINITION OF COVID-19: 02-NOV-2020	2020-11-02
311668	mRNA-1273-P301-US338-2152	ADJUDICATIO	SEVERE COVID-19	EVENT MEETS THE CHARTER DEFINITION OF SEVERE COVID-19: 03-NOV-2020	2020-11-03
322359	mRNA-1273-P301-US340-2001	ADJUDICATIO	COVID-19	EVENT MEETS THE CHARTER DEFINITION OF COVID-19: 21-OCT-2020	2020-10-21
322360	mRNA-1273-P301-US340-2001	ADJUDICATIO	COVID-19	EVENT MEETS THE CHARTER DEFINITION OF COVID-19: 21-OCT-2020	2020-10-21
323069	mRNA-1273-P301-US340-2029	ADJUDICATIO	COVID-19	EVENT MEETS THE CHARTER DEFINITION OF COVID-19: 30-SEP-2020	2020-09-30
323070	mRNA-1273-P301-US340-2029	ADJUDICATIO	SEVERE COVID-19	EVENT MEETS THE CHARTER DEFINITION OF SEVERE COVID-19: 07-OCT-2020	2020-10-07
324571	mRNA-1273-P301-US340-2094	ADJUDICATIO	COVID-19	EVENT MEETS THE CHARTER DEFINITION OF COVID-19: 02-OCT-2020	2020-10-02
329662	mRNA-1273-P301-US340-2316	ADJUDICATIO	COVID-19	EVENT MEETS THE CHARTER DEFINITION OF COVID-19: 14-OCT-2020	2020-10-14
329663	mRNA-1273-P301-US340-2316	ADJUDICATIO	COVID-19	EVENT MEETS THE CHARTER DEFINITION OF COVID-19: 14-OCT-2020	2020-10-14
338993	mRNA-1273-P301-US341-2270	ADJUDICATIO	COVID-19	EVENT MEETS THE CHARTER DEFINITION OF COVID-19: 03-NOV-2020	2020-11-03
344824	mRNA-1273-P301-US342-2149	ADJUDICATIO	COVID-19	EVENT MEETS THE CHARTER DEFINITION OF COVID-19: 26-OCT-2020	2020-10-26
344825	mRNA-1273-P301-US342-2149	ADJUDICATIO	COVID-19	EVENT MEETS THE CHARTER DEFINITION OF COVID-19: 26-OCT-2020	2020-10-26

3.4.3 CM - Concomitant Medications

QNAM	Description
ATCLEV1C	Name of MedicationATC_CODE
ATCLEV1T	Name of MedicationATC
ATCLEV3C	Name of MedicationATC3_CODE
ATCLEV3T	Name of MedicationATC3
ATCLEV4C	Name of MedicationATC4_CODE
ATCLEV4T	Name of MedicationATC4
CMDECOD1	Standardized Medication Name1
CMDECOD2	Standardized Medication Name2
CMDECOD3	Standardized Medication Name3
CMDICNM	Name of Medication_CoderDictName
CMDICVR	Name of Medication_CoderDictVersion
CMFOTHSP	Frequency Other, specify

QNAM	Description
CMONGOYN	Ongoing
CMPLX	Prophylaxis
CMPROTCD	Name of MedicationPRODUCT_CODE
CMROTHSP	If Route of Administration is Other, spe
CMSOL	Was medication taken for solicited event
CMSTUNKC	Start date completely unknown
CMTRADCD	Trade Name of Med code
CMTRTO1	Name of Medication
CMTRTTN	Name of Medication Synonym
CMTRTTN1	Name of Medication Synonym1
CMTRTTN2	Name of MedicationSYNONYM2
CMUOTHSP	Dose Unit Other, Specify

3.4.4 DD - Death Details

3.4.5 DM - Demographics

QNAM	Description
AGE_DER	Age (Derived)
COHORT	Cohort
PREVSCR	Was this participant screen previously
PROTVER	Protocol Version
RACE1	White
RACE2	Black
RACE3	Asian
RACE4	American Indian or Alaska Native
RACE5	Native Hawaiian or Other Pacific Island
RACE6	Other
RACEOTH	If race is Other, specify

QNAM	Description
SUBJID1	Previous subject number
UNBLMRNA	Will participant receive mRNA-1273
UNBLNA	NA - Unblinded Amendment 5 Discontinued
UNBLNDYN	Was the participant unblinded
UNBLPROT	Unblinded Protocol Version Coded Value

3.4.6 DS - Disposition

QNAM	Description
AESPIDX	AE Sponsor-Defined Identifier
DSEOTDT	Date of Disposition at EOT
DSTERMOX	Discontinuation reason, specify
DSTERMP1	Reason for Discont Other, specify1
DSTERMSX	Primary reason for treatment discont. St
DSTERMX	Primary reason for treatment discontinua
ENROLLYN	Was participant enrolled in the study
IRTVISDT	IRT Date of Unblinding

3.4.7 DV - Protocol Deviations

QNAM	Description
DECSRTN1	Decision Made and Rationale 1
DECSRTN2	Decision Made and Rationale 2
DECSRTN3	Decision Made and Rationale 3
DECSRTNL	Decision Made and Rationale
DVSIG	Significant
DVTERM1	Description2
SEVDES	Severity Code and Description

3.4.8 EC - Exposure as Collected

QNAM	Description
ECREASOC	Reason for Occur value
EXREASSP	Reason not given, specify
EXREASTD	Reason not given Coded Value

3.4.9 EX - Exposure

3.4.10 FAAE - Findings About Adverse Events

QNAM	Description
AESPIDX	AE Sponsor-Defined Identifier
DSSPIDX	DS Sponsor-Defined Identifier
HOSPIDX	HO Sponsor-Defined Identifier
MAAEFL	Medically-attended AE Flag
RECON	Reconstructed Data

- 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 cutoff date (03/26/2021) is used if data source is from raw.AE and symptom stop date is missing

  Table 3.4.10

  Case 1: Symptom assessment captured via e-Diary last and beyond day-7 of each vaccine will be mapped to FAAE (see Line 11-21)

  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 1 and 3, Table 3.4.10 Line 1-10 and

  Line 22)

Table 3.4.10

	SDTM.FAAE										SDTM.SUPPFAAE
Line #	USUBJID	FASEQ	FAOBJ	FACAT	FAORRES	FAEVAL	FADY	FATPT	FATPTNUM	FATPTREF	MAAEFL
1	mRNA-1273-P301-US301-2025	1	Swelling	REACTOGENICITY	GRADE 1/MILD	INVESTIGATOR	8	DAY 8	8	DOSE 1	
2	mRNA-1273-P301-US301-2025	2	Swelling	REACTOGENICITY	GRADE 1/MILD	INVESTIGATOR	9	DAY 9	9	DOSE 1	
3	mRNA-1273-P301-US301-2025	3	Swelling	REACTOGENICITY	GRADE 1/MILD	INVESTIGATOR	10	DAY 10	10	DOSE 1	
4	mRNA-1273-P301-US301-2025	4	Swelling	REACTOGENICITY	GRADE 1/MILD	INVESTIGATOR	11	DAY 11	11	DOSE 1	
5	mRNA-1273-P301-US301-2025	5	Swelling	REACTOGENICITY	GRADE 1/MILD	INVESTIGATOR	12	DAY 12	12	DOSE 1	
6	mRNA-1273-P301-US301-2025	6	Swelling	REACTOGENICITY	GRADE 1/MILD	INVESTIGATOR	13	DAY 13	13	DOSE 1	
7	mRNA-1273-P301-US301-2025	7	Swelling	REACTOGENICITY	GRADE 1/MILD	INVESTIGATOR	14	DAY 14	14	DOSE 1	
8	mRNA-1273-P301-US301-2025	8	Swelling	REACTOGENICITY	GRADE 1/MILD	INVESTIGATOR	15	DAY 15	15	DOSE 1	
9	mRNA-1273-P301-US301-2025	9	Swelling	REACTOGENICITY	GRADE 1/MILD	INVESTIGATOR	16	DAY 16	16	DOSE 1	
10	mRNA-1273-P301-US301-2025	10	Swelling	REACTOGENICITY	GRADE 1/MILD	INVESTIGATOR	17	DAY 17	17	DOSE 1	
11	mRNA-1273-P301-US301-2025	66	Swelling	REACTOGENICITY	Y	STUDY SUBJECT	8	DAY 8	8	DOSE 1	
12	mRNA-1273-P301-US301-2025	68	Swelling	REACTOGENICITY	Y	STUDY SUBJECT	9	DAY 9	9	DOSE 1	
13	mRNA-1273-P301-US301-2025	69	Swelling	REACTOGENICITY	Y	STUDY SUBJECT	10	DAY 10	10	DOSE 1	
14	mRNA-1273-P301-US301-2025	70	Swelling	REACTOGENICITY	Y	STUDY SUBJECT	11	DAY 11	11	DOSE 1	
15	mRNA-1273-P301-US301-2025	71	Swelling	REACTOGENICITY	Y	STUDY SUBJECT	12	DAY 12	12	DOSE 1	
16	mRNA-1273-P301-US301-2025	72	Swelling	REACTOGENICITY	Y	STUDY SUBJECT	13	DAY 13	13	DOSE 1	
17	mRNA-1273-P301-US301-2025	73	Swelling	REACTOGENICITY	Y	STUDY SUBJECT	14	DAY 14	14	DOSE 1	
18	mRNA-1273-P301-US301-2025	74	Swelling	REACTOGENICITY	Y	STUDY SUBJECT	15	DAY 15	15	DOSE 1	
19	mRNA-1273-P301-US301-2025	75	Swelling	REACTOGENICITY	Y	STUDY SUBJECT	16	DAY 16	16	DOSE 1	
20	mRNA-1273-P301-US301-2025	97	Swelling	REACTOGENICITY	Y	STUDY SUBJECT	44	DAY 16	16	DOSE 2	
21	mRNA-1273-P301-US301-2025	67	Swelling	REACTOGENICITY	N	STUDY SUBJECT	17	DAY 17	17	DOSE 1	
22	mRNA-1273-P301-US355-2053	1	Nausea/Vomiting	REACTOGENICITY	GRADE 4	INVESTIGATOR	36	DAY 8	8	DOSE 2	Y

3.4.11 FACE - Findings About Clinical Events

QNAM	Description
AESPIDX	AE Sponsor-Defined Identifier
DSSPIDX	DS Sponsor-Defined Identifier
HOSPIDX	HO Sponsor-Defined Identifier
MAAEFL	Medically-attended AE Flag
RECON	Reconstructed Data

- All e-Diary symptoms within 7 days are mapped to FACE with FAEVAL= STUDY SUBJECT
- All solicited AR last reported in AE Form are mapped FACE with FAEVAL=INVESTOGATORIt 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 7 -14, and Line 24-31)

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 2 to Table 3.4.11 Line 15- 17)

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 1 to Table 3.4.11 Line 1-6, and from Table 3.4.1 line 3 to Table 3.4.11 Line 18-23)

Table 3.4.11

	SDTM.FACE							SDTM.SUPPFACE
Line #	USUBJID	FASEQ	FAOBJ	FAORRES	FAEVAL	FATPT	FATPTREF	MAAEFL
1	mRNA-1273-P301-US301-2025	110	Swelling	GRADE 1/MILD	INVESTIGATOR	DAY 2	DOSE 1	
2	mRNA-1273-P301-US301-2025	111	Swelling	GRADE 1/MILD	INVESTIGATOR	DAY 3	DOSE 1	
3	mRNA-1273-P301-US301-2025	112	Swelling	GRADE 1/MILD	INVESTIGATOR	DAY 4	DOSE 1	
4	mRNA-1273-P301-US301-2025	113	Swelling	GRADE 1/MILD	INVESTIGATOR	DAY 5	DOSE 1	
5	mRNA-1273-P301-US301-2025	114	Swelling	GRADE 1/MILD	INVESTIGATOR	DAY 6	DOSE 1	
6	mRNA-1273-P301-US301-2025	115	Swelling	GRADE 1/MILD	INVESTIGATOR	DAY 7	DOSE 1	
7	mRNA-1273-P301-US301-2025	152	Swelling	N	STUDY SUBJECT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)	DOSE 1	
8	mRNA-1273-P301-US301-2025	153	Swelling	N	STUDY SUBJECT	DAY 1, AFTER VACCINATION (AT HOME)	DOSE 1	
9	mRNA-1273-P301-US301-2025	154	Swelling	Y	STUDY SUBJECT	DAY 2	DOSE 1	
10	mRNA-1273-P301-US301-2025	155	Swelling	Y	STUDY SUBJECT	DAY 3	DOSE 1	
11	mRNA-1273-P301-US301-2025	156	Swelling	Y	STUDY SUBJECT	DAY 4	DOSE 1	
12	mRNA-1273-P301-US301-2025	157	Swelling	Y	STUDY SUBJECT	DAY 5	DOSE 1	
13	mRNA-1273-P301-US301-2025	158	Swelling	Y	STUDY SUBJECT	DAY 6	DOSE 1	
14	mRNA-1273-P301-US301-2025	159	Swelling	Y	STUDY SUBJECT	DAY 7	DOSE 1	
15	mRNA-1273-P301-US301-2057	5	Fatigue	GRADE 1/MILD	INVESTIGATOR	DAY 2	DOSE 1	
16	mRNA-1273-P301-US301-2057	6	Fatigue	GRADE 1/MILD	INVESTIGATOR	DAY 3	DOSE 1	
17	mRNA-1273-P301-US301-2057	7	Fatigue	GRADE 1/MILD	INVESTIGATOR	DAY 4	DOSE 1	
18	mRNA-1273-P301-US355-2053	2	Nausea/Vomiting	GRADE 4	INVESTIGATOR	DAY 2	DOSE 2	Y
19	mRNA-1273-P301-US355-2053	3	Nausea/Vomiting	GRADE 4	INVESTIGATOR	DAY 3	DOSE 2	Y
20	mRNA-1273-P301-US355-2053	4	Nausea/Vomiting	GRADE 4	INVESTIGATOR	DAY 4	DOSE 2	Y
21	mRNA-1273-P301-US355-2053	5	Nausea/Vomiting	GRADE 4	INVESTIGATOR	DAY 5	DOSE 2	Y
22	mRNA-1273-P301-US355-2053	6	Nausea/Vomiting	GRADE 4	INVESTIGATOR	DAY 6	DOSE 2	Y
23	mRNA-1273-P301-US355-2053	7	Nausea/Vomiting	GRADE 4	INVESTIGATOR	DAY 7	DOSE 2	Y
24	mRNA-1273-P301-US355-2053	129	Nausea/Vomiting	NONE	STUDY SUBJECT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)	DOSE 2	
25	mRNA-1273-P301-US355-2053	130	Nausea/Vomiting	NONE	STUDY SUBJECT	DAY 1, AFTER VACCINATION (AT HOME)	DOSE 2	
26	mRNA-1273-P301-US355-2053	131	Nausea/Vomiting	NO INTERFERENCE WITH ACTIVITY OR 1-2 EPISODES/24 HOURS	STUDY SUBJECT	DAY 2	DOSE 2	
27	mRNA-1273-P301-US355-2053	132	Nausea/Vomiting	SOME INTERFERENCE WITH ACTIVITY OR >2 EPISODES/24 HOURS	STUDY SUBJECT	DAY 3	DOSE 2	
28	mRNA-1273-P301-US355-2053	133	Nausea/Vomiting	SOME INTERFERENCE WITH ACTIVITY OR >2 EPISODES/24 HOURS	STUDY SUBJECT	DAY 4	DOSE 2	Y
29	mRNA-1273-P301-US355-2053	134	Nausea/Vomiting	SOME INTERFERENCE WITH ACTIVITY OR >2 EPISODES/24 HOURS	STUDY SUBJECT	DAY 5	DOSE 2	Y
30	mRNA-1273-P301-US355-2053	135	Nausea/Vomiting	NO INTERFERENCE WITH ACTIVITY OR 1-2 EPISODES/24 HOURS	STUDY SUBJECT	DAY 6	DOSE 2	
31	mRNA-1273-P301-US355-2053	136	Nausea/Vomiting	NONE	STUDY SUBJECT	DAY 7	DOSE 2	

3.4.12 FAEF - Findings About Efficacy Events

QNAM	Description
HOSPIDX	HO Sponsor-Defined Identifier
FAEVDTC	Start Date/Time of Collection
FAEVDY	Study Day of Start of Observation

3.4.13 FAOT - Findings About Events or Interventions

QNAM	Description
CLIN2J	Contact your Study Clinic New Symp-confi
CLIN2	Contact your Study Clinic-confirm
CLIN4A	Contact Healthcare Provider -confirm

3.4.14 HO - Healthcare Encounters

QNAM	Description
HOEVAL	HO Evaluator

3.4.15 IE - Inclusion/Exclusion Criteria Not Met

QNAM	Description
PROTVER	Protocol Version Coded Value

3.4.16 IS - Immunogenicity Specimen Assessment

QNAM	Description
DILFAC	Dilution Factor
INITDIL	Initial Dilution
ISLOD	Limit of Detection
ISULOQ	Upper Limit of Quantitation
SAMPNOTE	Toxicity notes-Duke
TESTDT	Date of Test-Duke
TESTGDT	Date of Test-VRC
TSTCOM	Test Comment-Vaccine

3.4.17 LB - Laboratory Tests Results

3.4.18 MB - Microbiology Specimen

QNAM	Description
LBPANEL3	Lab Test
LDTCLIA	CLIA Certified
LDTTESTO	Other, Specify
LDTVISDT	COVID Test Visit Date
LOCALFL	From COVID Diag Test
RPTDTM	Reported Date
TSTCOM	Test Level Description

3.4.19 MH - Medical History

QNAM	Description
MHDICNM	Condition_CoderDictName
MHDICVR	Condition_CoderDictVersion
MHENUNKC	Stop date completely unknown
MHSTUNKC	Start date completely unknown

3.4.20 PR - Procedures

3.4.21 RP - Reproductive System Findings

QNAM	Description
CBENDTC	If Post-menopausal, date of last menstru
CBENDUNK	Date of last menstruation unknown
CBRSN	If No, what is the reason
CBSDAUNK	Date of surgery unknown
CBSDTC	If Surgically sterile, date of surgery-I
CBSP	If Partner medically sterile or Other, s

3.4.22 SC - Subject Characteristics

QNAM	Description
SCORRS1	Result or Finding 1

3.4.23 SE - Subject Elements

3.4.24 SV - Subject Visits

QNAM	Description
SVTERM1	Subject Visits Term
SVUPDES1	Description of Unplanned Visit 1
SVUPDES2	Description of Unplanned Visit 2

3.4.25 VS - Vital Signs

QNAM	Description
MEDTAK	Medication taken today for pain or fever
MEDTAKP	Prevent pain or fever
MEDTAKT	Treat Pain or Fever
VSLOCSP	Other Route of Measurement, specify

3.4.26 XM - Multiple Participation

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

For subjects with multiple screenings and no subsequent enrollment, include the primary screening in DM with additional screenings in a XM domain with a structure like DM.

3.4.27 XQ - Virus Sequencing

QNAM	Description
HAPLOTTY	Virus Haplotype

XQ contains virus sequence data that is exploratory data

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 4.2.1 Validation Engine version 2010.1**
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	245 (0.62%)	This is due to non-standard action taken term 'DOSE DELAYED' was captured from CRF.
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	AE	14734 (37.57%)	Per protocol, non-standard terms 'FOLLOW-UP BLINDED PHASE' and 'FOLLOW-UP OPEN LABEL PHASE' are defined in TE

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	CE	81257 (10.64%)	Per protocol, non-standard terms 'FOLLOW-UP BLINDED PHASE' and 'FOLLOW-UP OPEN LABEL PHASE' are defined in TE
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	CM	27138 (13.91%)	Per protocol, non-standard terms 'FOLLOW-UP BLINDED PHASE' and 'FOLLOW-UP OPEN LABEL PHASE' are defined in TE
CT2002	CMROUTE value not found in 'Route of Administration Response' extensible codelist	Warning	CM	3573 (1.83%)	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	7619 (3.91%)	Non-standard term 'OTHER' was captured from CRF. Detailed info for 'OTHER' term is provided in SUPPCM dataset.
CT2002	CMDOSU value not found in 'Unit' extensible codelist	Warning	CM	19459 (9.98%)	Non-standard term 'OTHER' was captured from CRF. Detailed info for 'OTHER' term is provided in SUPPCM dataset.
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	DD	76 (88.37%)	Per protocol, non-standard terms 'FOLLOW-UP BLINDED PHASE' and 'FOLLOW-UP OPEN LABEL PHASE' are defined in TE
CT2002	RACE value not found in 'Race' extensible codelist	Warning	DM	1289 (4.02%)	RACE="MULTIPLE" due to more than one RACE checked. RACE="OTHER" was captured from CRF
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	DS	3227 (1.94%)	Per protocol, non-standard terms 'FOLLOW-UP BLINDED PHASE' and 'FOLLOW-UP OPEN LABEL PHASE' are defined in TE

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	DV	51008 (62.13%)	Per protocol, non-standard terms 'FOLLOW-UP BLINDED PHASE' and 'FOLLOW-UP OPEN LABEL PHASE' are defined in TE
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	EC	60 (< 0.1%)	Per protocol, non-standard terms 'FOLLOW-UP BLINDED PHASE' and 'FOLLOW-UP OPEN LABEL PHASE' are defined in TE
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	EX	60 (< 0.1%)	Per protocol, non-standard terms 'FOLLOW-UP BLINDED PHASE' and 'FOLLOW-UP OPEN LABEL PHASE' are defined in TE
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	FA	1936863 (25.79%)	Per protocol, non-standard terms 'FOLLOW-UP BLINDED PHASE' and 'FOLLOW-UP OPEN LABEL PHASE' are defined in TE
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	HO	582 (12.86%)	Per protocol, non-standard terms 'FOLLOW-UP BLINDED PHASE' and 'FOLLOW-UP OPEN LABEL PHASE' are defined in TE
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	IS	96488 (44.98%)	Per protocol, non-standard terms 'FOLLOW-UP BLINDED PHASE' and 'FOLLOW-UP OPEN LABEL PHASE' are defined in TE
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	LB	2643 (5.99%)	Per protocol, non-standard terms 'FOLLOW-UP BLINDED PHASE' and 'FOLLOW-UP OPEN LABEL PHASE' are defined in TE

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	MB	114188 (39.07%)	Per protocol, non-standard terms 'FOLLOW-UP BLINDED PHASE' and 'FOLLOW-UP OPEN LABEL PHASE' are defined in TE
CT2002	MBMETHOD value not found in 'Method' extensible codelist	Warning	MB	97059 (33.21%)	Extensible value RT-PCR and MULTIPLEX have been added to code list
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	MH	2 (< 0.1%)	Per protocol, non-standard terms 'FOLLOW-UP BLINDED PHASE' and 'FOLLOW-UP OPEN LABEL PHASE' are defined in TE
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	PR	3975 (34.70%)	Per protocol, non-standard terms 'FOLLOW-UP BLINDED PHASE' and 'FOLLOW-UP OPEN LABEL PHASE' are defined in TE
CT2002	SCTESTCD value not found in 'Subject Characteristic Test Code' extensible codelist	Warning	SC	578180 (100.00%)	Extensible values have been added to code list
CT2002	SCTEST value not found in 'Subject Characteristic Test Name' extensible codelist	Warning	SC	578180 (100.00%)	Extensible values have been added to code list
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	SE	40320 (34.85%)	Per protocol, non-standard terms 'FOLLOW-UP BLINDED PHASE' and 'FOLLOW-UP OPEN LABEL PHASE' are defined in TE
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	SV	191208 (36.35%)	Per protocol, non-standard terms 'FOLLOW-UP BLINDED PHASE' and 'FOLLOW-UP OPEN LABEL PHASE' are defined in TE

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	TA	5 (38.46%)	Per protocol, non-standard terms 'FOLLOW-UP BLINDED PHASE' and 'FOLLOW-UP OPEN LABEL PHASE' are defined in TE
CT2002	VSTEST value not found in 'Vital Signs Test Name' extensible codelist	Warning	VS	830206 (38.52%)	1. Most reported records are due to a bug in CDISC SDTM CT 2020-09-25 for standard term "Temperature" 2. "Vital Signs Collections" was added to cover all "NOT DONE" Vital Signs assessments during a visit. 3. "PP Arterial O2/Fraction Inspired O2" is safety test included into Protocol.
CT2002	VSLOC value not found in 'Anatomical Location' extensible codelist	Warning	VS	30495 (1.41%)	As collected on CRF: Other, Axillary. Details for "Other" are stored in SUPPVS dataset.
CT2002	VSTESTCD value not found in 'Vital Signs Test Code' extensible codelist	Warning	VS	28709 (1.33%)	Extensible value 'VSALL' (to represent that all scheduled Vital Signs assessments were not done) and 'PAO2FIO' have been added to code list
CT2002	EPOCH value not found in 'Epoch' extensible codelist	Warning	VS	384036 (17.82%)	Per protocol, non-standard terms 'FOLLOW-UP BLINDED PHASE' and 'FOLLOW-UP OPEN LABEL PHASE' are defined in TE
CT2002	XQMETHOD value not found in 'Method' extensible codelist	Warning	XQ	790 (100.00%)	"Sequence" was added to extension list
CT2003	VSTESTCD and VSTEST values do not have the same Code in CDISC CT	Error	VS	801497 (37.19%)	False-positive message due to a bug in CDISC SDTM CT 2020-09-25 for standard term "Temperature" Please check if those tests with standard CT

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	239 (0.51%)	Study-specific terms 'COVID' and 'SERIOUS ADVERSE EVENT' captured in CRF have been added to code list
SD0002	NULL value in AEDECOD variable marked as Required	Error	AE	23 (< 0.1%)	Data collection issues due to ongoing status of the study
SD0002	NULL value in AETERM variable marked as Required	Error	AE	23 (< 0.1%)	Data collection issues due to ongoing status of the study
SD0002	NULL value in CMTRT variable marked as Required	Error	CM	1 (< 0.1%)	Data collection issues due to ongoing status of the study
SD0002	NULL value in ACTARMCD variable marked as Required	Error	DM	1751 (5.45%)	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	1751 (5.45%)	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 ARM variable marked as Required	Error	DM	1679 (5.23%)	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	1679 (5.23%)	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 SEX variable marked as Required	Error	DM	6 (< 0.1%)	Data collection issues due to ongoing status of the study
SD0002	NULL value in EXTRT variable marked as Required	Error	EX	27 (< 0.1%)	IRT Error (Missing Treatment Name)
SD0002	NULL value in IETEST variable marked as Required	Error	IE	112 (6.06%)	Unresolved issue, original INC06 is no longer existing after protocol amendment 2, but pre-created INC06 records cannot be removed.
SD0002	NULL value in IETESTCD variable marked as Required	Error	IE	2 (0.11%)	Unresolved data collection issues
SD0002	NULL value in MHTERM variable marked as Required	Error	MH	26 (< 0.1%)	Data collection issues due to ongoing status of the study
SD0006	No baseline flag record in VS for subject	Warning	DM	9 (< 0.1%)	Data collection issues due to ongoing status of the study
SD0006	No baseline flag record in LB for subject	Warning	DM	24594 (81.03%)	Per Protocol, lab tests are limited to optional Follicle Stimulating Hormone and Choriogonadotropin Beta. They do not expect to have Baseline assessments
SD0021	Missing End Time-Point value	Warning	AE	45 (0.11%)	Accepted current mapping
SD0021	Missing End Time-Point value	Warning	CE	147474 (19.31%)	Accepted current mapping
SD0021	Missing End Time-Point value	Warning	CM	28 (< 0.1%)	Accepted current mapping

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD0021	Missing End Time-Point value	Warning	EC	19 (< 0.1%)	Accepted current mapping
SD0021	Missing End Time-Point value	Warning	HO	48 (1.06%)	Accepted current mapping
SD0021	Missing End Time-Point value	Warning	MH	13227 (3.60%)	Accepted current mapping
SD0021	Missing End Time-Point value	Warning	PR	24 (0.21%)	Accepted current mapping
SD0022	Missing Start Time-Point value	Warning	AE	92 (0.23%)	Accepted current mapping
SD0022	Missing Start Time-Point value	Warning	CE	138742 (18.17%)	Accepted current mapping
SD0022	Missing Start Time-Point value	Warning	CM	5082 (2.61%)	Accepted current mapping
SD0022	Missing Start Time-Point value	Warning	DS	6 (< 0.1%)	Data collection issues (did not collecte end of study date for screen failure subjects)
SD0022	Missing Start Time-Point value	Warning	DV	28 (< 0.1%)	Data collection issues due to ongoing status of the study
SD0022	Missing Start Time-Point value	Warning	EC	19 (< 0.1%)	Data collection issues due to ongoing status of the study
SD0022	Missing Start Time-Point value	Warning	HO	104 (2.30%)	Accepted current mapping
SD0022	Missing Start Time-Point value	Warning	MH	19483 (5.31%)	Accepted current mapping

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD0022	Missing Start Time-Point value	Warning	PR	22 (0.19%)	Accepted current mapping
SD0025	FADTC is after FAENDTC	Error	FA	7 (4.29%)	Per SDTM mapping, FADTC is based on data updated date and FAENDTC is based on event stop date, It is possible FADTC is update after event stop date.
SD0026	Missing value for ISORRESU, when ISORRES is provided	Warning	IS	7445 (100.00%)	Confirmed - no unit for ISTESTCD = PSVNT50 or PSVNT80
SD0026	Missing value for VSORRESU, when VSORRES is provided	Warning	VS	1 (< 0.1%)	Data collection issues due to ongoing status of the study
SD0029	Missing value for ISSTRESU, when ISSTRESC is provided	Warning	IS	7445 (100.00%)	Accepted because ISSTRESU has to populated for ISLLQ and ISULQ
SD0031	Missing values for AESTDTC, AESTRF and AESTRTPT, when AEENDTC, AEENRF or AEENRTPT is provided	Warning	AE	59 (0.15%)	Accepted current mapping
SD0031	Missing values for CESTDTC, CESTRF and CESTRTPT, when CEENDTC, CEENRF or CEENRTPT is provided	Warning	CE	8166 (5.84%)	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 and no symptom event report during observed period

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD0031	Missing values for CMSTDTC, CMSTRF and CMSTRTPT, when CMENDTC, CMENRF or CMENRTPT is provided	Warning	CM	5056 (2.59%)	Accepted current mapping
SD0031	Missing values for MHSTDTC, MHSTRF and MHSTRTPT, when MHENDTC, MHENRF or MHENRTPT is provided	Warning	MH	6852 (3.91%)	Accepted current mapping
SD0035	Missing value for CMDOSU, when CMDOSE, CMDOSTXT or CMDOSTOT is provided	Error	CM	52 (< 0.1%)	Data collection issue. Most reported records are for unknown dose (CMDOSTXT=UNK)
SD0036	Missing value for VSSTRESC, when VSORRES is provided	Error	VS	1 (< 0.1%)	Due to missing original units for collected results and cannot convert to standard results
SD0042	CESTAT does not equal 'NOT DONE', when CEPRESP='Y' and CEOCCUR is NULL	Warning	CE	127013 (97.91%)	Data collection design issue - ePRO did not collect "NOT DONE" data.
SD0042	ECSTAT does not equal 'NOT DONE', when ECPRESP='Y' and ECOCCUR is NULL	Warning	EC	19 (100.00%)	Data collection issues due to ongoing status of the study
SD0047	Missing value for FAORRES, when FASTAT or FADRVFL is not populated	Warning	FA	7 (< 0.1%)	"NOT DONE" status was not collected

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD0047	Missing value for ISORRES, when ISSTAT or ISDRVFL is not populated	Warning	IS	6872 (60.40%)	"NOT DONE" status was not collected
SD0047	Missing value for LBORRES, when LBSTAT or LBDRVFL is not populated	Warning	LB	1818 (6.51%)	"NOT DONE" status was not collected
SD0047	Missing value for MBORRES, when MBSTAT or MBDRVFL is not populated	Warning	MB	51 (< 0.1%)	"NOT DONE" status was not collected
SD0057	SDTM Expected variable XQORRES not found	Warning	XQ	1 (100.00%)	XQ is custom domain. Accept current mapping
SD0058	Variable appears in dataset, but is not in SDTM model	Error	AE	1 (2.22%)	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	CM	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 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	DD	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	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 (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	EC	1 (4.00%)	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	IE	1 (6.25%)	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	IS	1 (3.57%)	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 (3.70%)	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	MB	1 (3.70%)	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	MH	1 (3.45%)	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	PR	1 (5.00%)	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 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	SC	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.

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 (7.69%)	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	SV	7 (35.00%)	This mapping was followed by CBER's instruction
SD0058	Variable appears in dataset, but is not in SDTM model	Error	VS	1 (3.33%)	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.
SD0064	Subject is not present in DM domain	Error	IE	3 (0.16%)	IRT errors (duplicated subjects)
SD0064	Subject is not present in DM domain	Error	SUPPIE	2 (0.11%)	IRT errors (duplicated subjects)
SD0080	AE start date is after the latest Disposition date	Error	AE	3048 (7.79%)	This is because study is still ongoing, latest date in DS is randomization date, or end of treatment date, therefore, AE start date should be after randomization date or end of treatment date.
SD0082	Exposure end date is after the latest Disposition date	Warning	EX	181 (0.21%)	This is because study is still ongoing, latest date in DS is randomization date, therefore, Exposure start date should be after randomization date

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD0087	RFSTDTC is not provided for a randomized subject	Warning	DM	72 (0.24%)	This is due to unresolved issues
SD0088	RFENDTC is not provided for a randomized subject	Warning	DM	72 (0.24%)	This is due to unresolved issue
SD1031	Value for AEENRF is populated, when RFENDTC is NULL	Warning	AE	5 (< 0.1%)	Per SDTMIG mapping standard, RFENDTC = RFXENDTC which means RFENDTC is null for a subject never dosed / screen failure
SD1043	Inconsistent value for IETESTCD within IETEST	Error	IE	2 (0.11%)	IRT errors (duplicated subjects)
SD1044	No XQBLFL variable in custom Findings domain	Warning	XQ	1 (100.00%)	XQ is custom domain. Accepted custom domain
SD1060	Duplicate VISITNUM	Warning	SV	1 (< 0.1%)	Not true duplicated by USUBJID and SUBJID. This is due to Study allow the same patient with multiple screening by assigned different screen number
SD1075	Variable not recommended for use	Warning	CE	2 (14.29%)	Per Protocol, CESHOSP variable is important and have to keep in main domain
SD1075	Variable not recommended for use	Warning	IS	2 (11.76%)	Range Low and High are included in raw data.
SD1075	Variable not recommended for use	Warning	VS	1 (12.50%)	Per Protocol, VSTOXGR variable is important information and have to keep in main domain
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.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1076	Model permissible variable added into standard domain	Notice	CE	7 (17.95%)	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, Identified Variables such as --LNKGRP, and Timing Variables are domain variables.
SD1076	Model permissible variable added into standard domain	Notice	EX	2 (6.90%)	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	FA	8 (15.09%)	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	MH	8 (19.05%)	MedDRA Coding variables. Accepted
SD1076	Model permissible variable added into standard domain	Notice	PR	1 (3.85%)	Accepted
SD1076	Model permissible variable added into standard domain	Notice	SV	1 (5.88%)	Accepted
SD1076	Model permissible variable added into standard domain	Notice	TS	2 (20.00%)	TS setting issue, and could be fixed later
SD1076	Model permissible variable added into standard domain	Notice	VS	2 (4.55%)	Per Study Date Tabulation Model Version 1.4 or above, Identified Variables such as --LNKGRP, and Timing Variables are domain variables.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1077	Regulatory Expected variable EPOCH not found	Error	XQ	1 (100.00%)	XQ is custom domain. that is no baseline data collected
SD1078	Permissible variable with missing value for all records	Notice	TS	1 (33.33%)	Variables will be removed if all of them are missing at the end of study.
SD1079	Variable is in wrong order within domain	Warning	CE	2 (6.90%)	Accepted current mapping
SD1079	Variable is in wrong order within domain	Warning	VS	1 (3.33%)	Accepted current mapping
SD1082	Variable length is too long for actual data	Error	AE	1 (2.86%)	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	CE	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	CM	1 (5.26%)	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	DD	1 (11.11%)	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	DS	1 (9.09%)	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	DV	1 (11.11%)	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	EC	2 (11.11%)	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	EX	2 (13.33%)	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	FA	2 (7.69%)	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	HO	1 (6.25%)	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	IE	2 (18.18%)	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	2 (9.52%)	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	LB	2 (10.53%)	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	2 (9.52%)	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	MH	1 (5.26%)	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	PR	1 (6.25%)	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	2 (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	SE	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	SV	2 (25.00%)	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	TA	1 (11.11%)	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	VS	2 (8.70%)	This is due to maximum length of the variable used other domains in the study
SD1096	High risk of truncated value for DSTERM variable	Warning	DS	20 (100.00%)	Checked and no issue found
SD1117	Duplicate records	Warning	FA	23470 (0.31%)	This is not true duplicated by FACAT and FASCAT within FAXX (XX: CE, AE, EF and OT). There is unique row by STUDYID, USUBJID, FASEQ, FAGRPID, FASPID, FATESTCD, FATEST, FAOBJ, FACAT, FASCAT, FAORRES, FAORRESU, FASTRESC, FASTRESU, FASTAT, FAEVAL, VISITNUM, VISIT, VISITDY, EPOCH, FADTC, FAENDTC, FADY, FATPT, FATPTNUM
SD1117	Duplicate records	Warning	IS	66 (< 0.1%)	This is not true duplicated. Missing leading validation message
SD1117	Duplicate records	Warning	LB	3 (< 0.1%)	Not true duplicated, missing leading validation message

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1117	Duplicate records	Warning	VS	2339 (0.11%)	Not true duplicated, missing leading validation message
SD1118	Neither DSSTDTC, DSDTC nor DSSTDY are populated	Warning	DS	6 (< 0.1%)	Data collection issues due to ongoing status of the study
SD1121	Neither AGE nor AGETXT values are populated	Warning	DM	1 (< 0.1%)	Data collection issues due to ongoing status of the study
SD1124	Missing value for ISREASND, when ISSTAT is 'NOT DONE'	Warning	IS	3371 (74.81%)	Reason of "Not Done" was not collected
SD1124	Missing value for MBREASND, when MBSTAT is 'NOT DONE'	Warning	MB	63081 (78.19%)	Reason of "Not Done" did not collected
SD1143	No Details info for AESMIE Adverse Event in SUPPAE domain	Warning	AE	134 (100.00%)	Data collection design issue
SD1144	MHSTDTC date is after RFSTDTC	Error	MH	2 (< 0.1%)	Data collection issues due to ongoing status of the study
SD1149	Expected variable with missing value for all records	Notice	LB	8 (53.33%)	NA! Lab test results with Negtive and Positive values only
SD1149	Expected variable with missing value for all records	Notice	RP	3 (42.86%)	Possible result is either Y or N. therefore no value to be populate for RPSTRESN, RPSTRESU, and RPORRESU
SD1201	Duplicate records in AE domain	Warning	AE	11 (< 0.1%)	Data collection issues due to ongoing status of the study

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1201	Duplicate records in CE domain	Warning	CE	170374 (22.31%)	Clinical Events were collected as pre-specified assessments of symptoms on specific time points. Therefore, actual timing information in most records is Collection Date/Time (CEDTC) rather than expected Start Date/Time of Event (CESTDTC). Rule algorithm utilizes CESTDTC and ignores CEDTC variable.
SD1201	Duplicate records in DS domain	Warning	DS	17 (< 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 DV domain	Warning	DV	2207 (2.69%)	Not true duplicated records, misleading validation message
SD1201	Duplicate records in HO domain	Warning	HO	34 (0.75%)	There are no true duplicated records per USUBJID, HOCAT, HOSCAT, HOTERM, HODTC, HOSTDTC. It is missing lead validation message
SD1201	Duplicate records in MH domain	Warning	MH	137 (< 0.1%)	Not true duplicated records. misleading validation message
SD1202	DSSTDTC date is after RFPENDTC	Error	DS	432 (0.26%)	Ongoing study issue. DSSTDTC is derived based on dose date, EOS date and data cutoff date. The data cutoff date is the cutoff of treatment period rather than RFPENDTC.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1203	CEDTC date is after RFPENDTC	Error	CE	272 (< 0.1%)	Adjudication Date has been mapped to CEDTC where CECAT = "ADJUDICATION" that is not included for RFPENDTC derivation
SD1203	FADTC date is after RFPENDTC	Error	FA	43 (< 0.1%)	Per SDTM mapping, for ongoing event will use data cutoff date that is included for RFPENDTC deviation
SD1204	MHENDTC date is after RFPENDTC	Error	MH	10 (< 0.1%)	Per SDTM Mapping, RFPENDTC should not include Medical History Date
SD1210	Missing value for RFICDTC	Warning	DM	5 (< 0.1%)	Unresolved data collection issues
SD1240	No Informed Consent Obtained record in DS domain for subject	Warning	DM	4 (< 0.1%)	Data collection issues due to ongoing status of the study
SD1272	SCTESTCD equals 'OTHER'	Warning	SC	60864 (10.53%)	Accepted as collected on CRF
SD1290	Multiple disposition events for the same EPOCH	Error	DS	211 (3.74%)	This is due to subject end of treatment and study within the same EPOCH
SD1313	Missing EPOCH value, when DSCAT is 'DISPOSITION EVENT'	Warning	DS	7 (< 0.1%)	This is due to the subject with multiple screening / enrollments. EPOCH is set to missing for previous (initial) screening
SD1318	No records for subject are found in DV domain	Warning	DS	51 (5.72%)	Data collection issues protocol deviation data was defined and reviewed study team. The reason for end of study was captured in study discontinuation form, but protocol deviation data was collected and reviewed by study team

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1319	DSSTDTC is before RFICDTC	Error	DS	186 (0.11%)	There are two reasons: 1. 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 2. The second RFICDTC is for Open Label Phase. It should be after EOT of Blinded Phase
SD1319	DVSTDTC is before RFICDTC	Error	DV	426 (0.52%)	The second RFICDTC is for Open Label Phase. DV date could be before the second RFICDTC if DV occurred in Blinded Phase
SD1320	Missing value for FASTRESC, when FASTAT is null	Warning	FA	7 (< 0.1%)	"NOT DONE" status was not collected
SD1320	Missing value for ISSTRESC, when ISSTAT is null	Warning	IS	6872 (3.27%)	"NOT DONE" status was not collected
SD1320	Missing value for LBSTRESC, when LBSTAT is null	Warning	LB	1818 (10.07%)	"NOT DONE" status was not collected
SD1320	Missing value for MBSTRESC, when MBSTAT is null	Warning	MB	51 (< 0.1%)	"NOT DONE" status was not collected
SD1320	Missing value for VSSTRESC, when VSSTAT is null	Warning	VS	1 (< 0.1%)	"NOT DONE" status was not collected
SD1330	FADY is after FAENDY	Error	FA	7 (4.29%)	FADTC is based on data collection date and FAENDTC is based on event stop date.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1332	AEOUT = NOT RECOVERED/NOT RESOLVED, but an end date is provided	Warning	AE	6 (0.15%)	Data collection issues due to ongoing status of the study
SD1333	AEOUT = RECOVERED/RESOLVED, but an end date or collected duration is not provided	Warning	AE	23 (< 0.1%)	Data collection issues due to ongoing status of the study
SD1339	Missing EPOCH value, when a start or observation date is provided	Warning	CE	196 (< 0.1%)	Per SDTM mapping, EPOCH should not be assigned for adjudicated non-EDC data
SD1339	Missing EPOCH value, when a start or observation date is provided	Warning	DV	3 (< 0.1%)	Data collection issue due to subjects without SE data
SD1339	Missing EPOCH value, when a start or observation date is provided	Warning	FA	93 (< 0.1%)	Per SDTM mapping, EPOCH is based SDTM.SE.SEENDTC, but FAAE reconstructed data from Start/End date to daily records if an event was captured in AE form. FAAE.FADTC could be beyond the date from SE if event was ongoing (cutoff date was used).
SD1339	Missing EPOCH value, when a start or observation date is provided	Warning	HO	1188 (26.87%)	Accepted - EPOCH = blank only if HOOCCUR=N
SD1339	Missing EPOCH value, when a start or observation date is provided	Warning	VS	5 (< 0.1%)	Data collection issues - no records are found from SE
SD1344	Value for CMDECOD not found in WHODrug dictionary	Error	CM	139 (< 0.1%)	Coded term is more than 200-char long and does not fit SAS XPORT v5 format

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD1352	Duplicate records in EC domain	Warning	EC	40 (< 0.1%)	Duplicated records are due ECSTDTC is missing because subject did not have dose. It is not the issue
SD1440	Inconsistent value for AEDECOD within AETERM	Warning	AE	3 (< 0.1%)	Confirmed with Coding Group, No Issue.
SD1440	Inconsistent value for MHDECOD within MHTERM	Warning	MH	4 (< 0.1%)	Confirmed with Coding Group, No Issue.
SD1441	Inconsistent value for AEHLT within AETERM	Warning	AE	2 (< 0.1%)	Confirmed with Coding Group, No Issue.
SD1441	Inconsistent value for MHHLT within MHTERM	Warning	MH	4 (< 0.1%)	Confirmed with Coding Group, No Issue.
SD1442	Inconsistent value for AEHLGT within AETERM	Warning	AE	2 (< 0.1%)	Confirmed with Coding Group, No Issue.
SD1442	Inconsistent value for MHHLGT within MHTERM	Warning	MH	4 (< 0.1%)	Confirmed with Coding Group, No Issue.
SD1443	Inconsistent value for AEBODSYS within AETERM	Warning	AE	1 (< 0.1%)	Confirmed with Coding Group, No Issue.
SD1444	Inconsistent value for AESOC within AETERM	Warning	AE	1 (< 0.1%)	Confirmed with Coding Group, No Issue.
SD2023	AGE is not provided	Error	DM	5 (< 0.1%)	Data collection issues due to ongoing status of the study

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD2236	ACTARMCD does not equal ARMCD	Warning	DM	11 (< 0.1%)	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	83 (0.26%)	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	41608 (0.58%)	This is because reference / reference date (--TPTREF and --TPTDTC) is different from each SDTM.FA--, therefore, FATPT could be different among FA-- with the same FADTC.
SD2239	Inconsistent value for MBTPT	Error	MB	5389 (2.00%)	Data collection design issue, accepted !
SD2239	Inconsistent value for VSTPT	Error	VS	878 (< 0.1%)	This is because reference / reference date (--TPTREF and --TPTDTC) is different from each SDTM.VS--, therefore, VSTPT could be different among VS-- with the same VSDTC.
SD2263	Invalid TSVAL value for PCLAS	Error	TS	1 (100.00%)	False-positive due to a bug in Pinnacle 21 validator
SD2264	Invalid TSVALCD value for PCLAS	Error	TS	1 (100.00%)	False-positive due to a bug in Pinnacle 21 validator

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD2265	TSVAL/TSVALCD value mismatch for PCLAS	Error	TS	1 (100.00%)	False-positive due to a bug in Pinnacle 21 validator
SD9999	Dataset XM class not recognized	Error	XM	1 (100.00%)	This is Special-Purpose domain with structure similar to DM domain to keep additional information about subjects with multiple enrollments into the study
TS0006	No Baseline (ALT) test results for Subject	Error	DM	30351 (100.00%)	Per protocol, safety lab data are not collected
TS0007	No Baseline (ALP) test results for Subject	Error	DM	30351 (100.00%)	Per protocol, safety lab data are not collected.
TS0008	No Baseline (AST) test results for Subject	Error	DM	30351 (100.00%)	Per protocol, safety lab data are not collected.
TS0009	No Baseline (BILI) test results for Subject	Error	DM	30351 (100.00%)	Per protocol, safety lab data are not collected.
TS0019	Both DSSTDTC and DSSTDY values are missing	Error	DS	6 (< 0.1%)	Data collection issues due to study status is still ongoing
TS0023	No (WEIGHT) results for subject	Error	DM	2 (< 0.1%)	Unresolved data collection issues
TS0024	No (HEIGHT) results for subject	Error	DM	2 (< 0.1%)	Unresolved data collection issues
TS0039	No (ALT) test results	Error	DM	30351 (100.00%)	Per protocol, safety lab data are not collected.
TS0040	No (ALP) test results	Error	DM	30351 (100.00%)	Per protocol, safety lab data are not collected.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
TS0041	No (AST) test results	Error	DM	30351 (100.00%)	Per protocol, safety lab data are not collected.
TS0042	No (BILI) test results	Error	DM	30351 (100.00%)	Per protocol, safety lab data are not collected.
TS0043	No (GGT) test results	Notice	DM	30351 (100.00%)	Per Protocol, no GGT Test results are collected
TS0050	Missing PC dataset	Warning	GLOBAL	1 (100.00%)	Per protocol, PC data is not collected
TS0051	Missing PP dataset	Warning	GLOBAL	1 (100.00%)	Per protocol, PP data is not collected
TS0053	Neither AESEV or AETOXGR is populated	Error	AE	39 (< 0.1%)	Data collection issues due to ongoing status of the study
DD0024	Invalid Term in codelist 'Action Taken with Study Treatment' for variable 'AEACN'	Warning	DEFINE	1 (100.00%)	Due to non-standard action taken term 'DOSE DELAYED' was captured from CRF
DD0050	Domain/SASDatasetName mismatch for split dataset	Error	DEFINE	4 (100.00%)	False-positive message due to a bug in Pinnacle 21 Validator which considers FAAE, FACE, FAEF and FAOT domains as split.
DD0114	Invalid usage of split datasets for non-general-observation-class datasets	Error	DEFINE	4 (100.00%)	False-positive message due to a bug in Pinnacle 21 Validator which considers FAAE, FACE, FAEF and FAOT domains as split.

Appendix I: Inclusion/Exclusion Criteria

IETESTCD	IETEST	IECAT	TIVERS	Full IE Text
EXC01	Participants who are acutely ill or febrile 72 hours prior to or at Screening may be rescheduled. Afebrile participants with minor illnesses can be enrolled at the discretion of the investigator.	EXCLUSION	Original, Amendment 1 - 8	Is acutely ill or febrile 72 hours prior to or at Screening. 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.
EXC02	Is pregnant or breastfeeding.	EXCLUSION	Original. Amendment 1 - 8	Is pregnant or breastfeeding.
EXC03	Known history of SARS-CoV-2 infection.	EXCLUSION	Original. Amendment 1 - 8	Known history of SARS-CoV-2 infection.
EXC04	Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19.	EXCLUSION	Origin l, Amendment 1 - 8	Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19.
EXC05	Demonstrated inability to comply with the study procedures.	EXCLUSION	Original, Amendment 1 - 8	Demonstrated inability to comply with the study procedures.
EXC06	An immediate family member or household member of this study's personnel.	EXCLUSION	Original, Amendment 1 - 8	An immediate family member or household member of this study's personnel.
EXC07	History of anaphylaxis, urticaria, or other significant adverse reaction requiring medical intervention after receipt of a vaccine.	EXCLUSION	Original, Amendment 1	History of anaphylaxis, urticaria, or other significant adverse reaction requiring medical intervention after receipt of a vaccine.
EXC07A	Known or suspected allergy or history of anaphylaxis, urticaria , or other significant adverse reaction to the vaccine or its excipients.	EXCLUSION	Amendment 2 - 8	Known or suspected allergy or history of anaphylaxis, urticaria , or other significant adverse reaction to the vaccine or its excipients.
EXC08	Bleeding disorder considered a contraindication to intramuscular injection or phlebotomy.	EXCLUSION	original, Amendment 1 - 8	Bleeding disorder considered a contraindication to intramuscular injection or phlebotomy.

IETESTCD	IETEST	IECAT	TIVERS	Full IE Text
EXC09	Has received or plans to receive a vaccine within 28 days prior to the first dose or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP.	EXCLUSION	original, Amendment 1	Has received or plans to receive a vaccine within 28 days prior to the first dose (Day 1) or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine, see Section 6.4.1).
EXC09A	Has received or plans to receive a non-study vaccine within 28 days before/after any dose of IP (except for seasonal influenza vaccine which not permitted within 14 days before/after any dose of IP).	EXCLUSION	Amendment 2 - 8	Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).
EXC10	Has participated in an interventional clinical study within 28 days prior to the day of enrollment.	EXCLUSION	Original, Amendment 1 - 8	Has participated in an interventional clinical study within 28 days prior to the day of enrollment.
EXC11	Current or previous diagnosis of immunocompromising condition, immune-mediated disease, or other immunosuppressive condition.	EXCLUSION	Original	Current or previous diagnosis of immunocompromising condition, immune-mediated disease, or other immunosuppressive condition.
EXC11A	Immunosuppressive or immunodeficient state, including HIV infection, asplenia, recurrent severe infections.	EXCLUSION	Amendment 1	Immunosuppressive or immunodeficient state, including HIV infection, asplenia, recurrent severe infections.
EXC11B	Immunosuppressive or immunodeficient state, asplenia, recurrent severe infections (HIV positive participants on stable antiretroviral therapy is not excluded).	EXCLUSION	Amendment 2	Immunosuppressive or immunodeficient state, asplenia, recurrent severe infections (HIV positive participants on stable antiretroviral therapy are not excluded).
EXC11C	Immunosuppressive or immunodeficient state, asplenia, recurrent severe infections (HIV positive participants with CD4 count ≥350 cells/mm3 and an undetectable HIV viral load within the past year).	EXCLUSION	Amendment 3 - 8	Immunosuppressive or immunodeficient state, asplenia, recurrent severe infections (HIV positive participants with CD4 count ≥350 cells/mm3 and an undetectable HIV viral load within the past year [low level variations from 50-500 viral copies which do not lead to changes in antiretroviral therapy [ART] are permitted]).

IETESTCD	IETEST	IECAT	TIVERS	Full IE Text
EXC12	Has received systemic immunosuppressants/immune-modifying drugs for >14 days in total within 6 months prior to Screening. Topical tacrolimus is allowed if not used within 14 days prior to Screening.	EXCLUSION	Original, Amendment 1 - 3	Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids ≥ 20 mg/day of prednisone equivalent). Topical tacrolimus is allowed if not used within 14 days prior to Screening.
EXC12A	Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids ≥ 20 mg/day of prednisone equivalent).	EXCLUSION	Amendment 3 -8	Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids ≥ 20 mg/day of prednisone equivalent).
EXC13	Has received systemic immunoglobulins or blood products within 3 months prior to the day of screening.	EXCLUSION	original, Amendment 1 - 8	Has received systemic immunoglobulins or blood products within 3 months prior to the day of screening.
EXC14	Has donated >= 450 mL of blood products within 28 days prior to Screening.	EXCLUSION	Original, Amendment 1 - 8	Has donated ≥ 450 mL of blood products within 28 days prior to Screening.
INC01	Adults, >= 18 years of age at time of consent, who are at high risk of SARS-CoV-2 infection.	INCLUSION	Original, Amendment 1 - 8	Adults, ≥ 18 years of age at time of consent, who are at high risk of SARS-CoV-2 infection, defined as adults whose locations or circumstances put them at appreciable risk of exposure to SARS-CoV-2 and COVID-19.
INC02	Understands and agrees to comply with the study procedures and provides written informed consent.	INCLUSION	Original, Amendment 1 - 8	Understands and agrees to comply with the study procedures and provides written informed consent.
INC03	Able to comply with study procedures based on the assessment of the Investigator.	INCLUSION	Original, Amendment 1 - 8	Able to comply with study procedures based on the assessment of the Investigator.

IETESTCD	IETEST	IECAT	TIVERS	Full IE Text
INC04	Female participants of nonchildbearing potential may be enrolled in the study. Nonchildbearing potential is defined as surgically sterile or postmenopausal.	INCLUSION	Original, Amendment 1-8	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 without an alternative medical cause). A follicle-stimulating hormone (FSH) level may be measured at the discretion of the investigator to confirm postmenopausal status.

INC05	Female participants of childbearing potential may be enrolled in the study if the participant fulfills all the criteria listed in the protocol.	INCLUSION	Original, Amendment 1 - 8	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 and on the day of the first dose (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 dose (Day 1). · Has agreed to continue aadequate contraception through 3months following the second dose (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 · Intra uterine device · Prescription hormonal contraceptive taken or administered via oral (pill), transdermal (pa tch), 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, hypothermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception.

IETESTCD	IETEST	IECAT	TIVERS	Full IE Text
INC06	Male participants that could result in pregnancy of sexual partners must agree to practice adequate contraception and refrain from sperm donation from the 1st dose to 3 months after the second dose.	INCLUSION	Original, Amendment 1	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 dose and through 3 months after the second dose. Adequate contraception for male participants are 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.
INC07	Healthy adults or adults with pre-existing medical conditions who are in stable condition.	INCLUSION	Original, Amendment 1 - 8	Healthy adults or adults with pre-existing medical conditions who are in stable condition. A stable medical condition is defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment.