Application: BLA125752
Study: mrna-1273-p301
EDR Sequence: 0003

Generated: 2021-09-09T15:11:09
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Data Standards Training
EDR Link: \\cber-fs3\m\eCTD_Submissions\BLA125752\0003\m5\datasets\mrna-1273-p301\tabulations\sdtm
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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

## Summary

### Documents

- SDTM Define.xml
- Study Data Reviewer's Guide
- ADaM Define.xml
- Analysis Data Reviewer's Guide

### Standards / Dictionaries

- SDTM-IG 3.2
- MedDRA 23.0

### Subjects / Actual Arms

- 32102 - Subjects
- 1751 (5.5%) -
- 15185 (47.3%) - A
- 2517 (7.8%) - PLA
- 12649 (39.4%) - PLAA

### Datasets

- 48 - Total SDTM Datasets
- 1 - Custom Datasets
- 18 - Suppqual Datasets
- 24 - ADaM Datasets (ADAE, ADAR1, ADAR2, ADARP7 ADARSUM, ADCM, ADDV, ADEFF, ADEFF2, ADEFF3, ADEX, ADIS, ADMB, ADMH, ADRISK, ADSL, ADSLSF, ADSYMP, ADTTE, ADTTEA, ADTTEB, ADTTRE, ADTTRE2, ADV

## Reports to Help Basic Review Activities

**Deaths**
- Death Summary
- Death Details

**Adverse Events**
- Adverse Events Coding Quality

**Disposition**
- Disposition Coding Quality

**Supplemental Info**
- Supplemental Contents

## Potential Data Quality Findings

**Demographics**
- 1,291 of 32,102 (4.0%) RACE values not found in CDISC codelist
- 1,751 of 32,102 (5.5%) values for required variable ACTARM are missing
- 6 of 32,102 (< 0.1%) values for required variable SEX are missing
- 1,679 of 32,102 (5.2%) values for required variable ARMCD are missing
- 1,679 of 32,102 (5.2%) values for required variable ARM are missing
- 1,751 of 32,102 (5.5%) values for required variable ACTARMCD are missing
- 83 of 32,102 (0.3%) subjects have a different actual arm than planned
- 76 of 32,102 (0.2%) subjects are missing important dates in demographics

**Disposition**
- 6 of 165,978 (< 0.1%) disposition events are missing Start Date/Time of Disposition Event (DSSTDTC) and Study Day of Start of Disposition Event (DSSTDY)
- 17 of 165,978 (< 0.1%) disposition statuses or protocol milestones are potential duplicates

**Exposure**
- 27 of 84,320 (< 0.1%) values for required variable EXTRT are missing
- 181 of 84,320 (0.2%) treatments have ended after the last disposition date

**Adverse Events**
- 23 of 39,215 (< 0.1%) values for required variable AEDECOD are missing
- 23 of 39,215 (< 0.1%) values for required variable AETERM are missing
- 92 of 39,215 (0.2%) events are missing start time-point
- 3,048 of 39,123 (7.8%) adverse events have started after the last disposition date
- 11 of 39,192 (< 0.1%) adverse events are potential duplicates
- 39 of 39,215 (< 0.1%) adverse events have neither severity or toxicity grade populated

**Clinical Events**
- 138,742 of 763,643 (18.2%) events are missing start time-point
- 170,374 of 763,643 (22.3%) clinical events are potential duplicates

**Laboratory**
- 3 of 44,152 (< 0.1%) laboratory test results are potential duplicates
- 10,000 of 32,102 (31.2%) subjects are either missing a lab test or a baseline value

**Vital Signs**
- 2,339 of 2,155,392 (0.1%) vital sign results are potential duplicates

**General Findings**
- Study data is missing important variables
- Study events are missing end time-points
- Study subjects are missing all baseline flags for all tests present in the dataset
- Standard Results (--STRESC) or Standard Units (--STRESU) are missing

**Traceability**
- 1,679 of 32,102 (5.2%) subjects in SDTM DM are not included in ADSL
- 1,459 of 39,215 (3.7%) Adverse Events in SDTM AE are not present in ADAE
- Treatment Emergent Flag in ADaM is inconsistent with Treatment Emergent Flag in SDTM