

Data Fitness Findings Report

BLA125752

ModernaTX, Inc., September 2021

Findings			Notes
mRNA-1273-P301 Title: <i>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</i>			
Document / Standard	Version	Notes	
annotated CRF		Seems fine	
SDTM Implementation Guide	SDTM-IG v3.2		
SDTM Controlled Terminology	2020-09-25		
SDTM define.xml	V2.0	Stylesheet has incorrect filename('define1-0-0.xml'). It has to be changed to 'define2-0-0.xml' to be able to view define.	
Medications Dictionary	WHODD GLOBALB3Mar20		
Medical Events Dictionary (MedDRA)	V23.0		
SDTM Reviewer's Guide		Seems fine	
From cSDRG: 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			

Data Issues

Inconsistent coding of the exact same adverse event term

- 1 (distinct) AETERM

aeterm	aellt	aedecod	aehlt	aehlgt	aebodsys	count_ of_aes	med drav
UPPER RESPIRATORY ILLNESS	UPPER RESPIRATORY DISORDER	RESPIRATORY DISORDER	RESPIRATORY TRACT DISORDERS NEC	RESPIRATORY DISORDERS NEC	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1	23
UPPER RESPIRATORY ILLNESS	UPPER RESPIRATORY INFECTION	UPPER RESPIRATORY TRACT INFECTION	UPPER RESPIRATORY TRACT INFECTIONS	INFECTIONS - PATHOGEN UNSPECIFIED	INFECTIONS AND INFESTATIONS	1	23

- cSDRG explanation: Confirmed with Coding Group, No Issue.

Inconsistent coding of the exact same medical history term

- 2 (distinct) MHTERMS

mhterm	mhlit	mhdecod	mhhlt	mhhlgt	mhbodsys	count_ of_mhs	med drav
BOTOX (FOREHEAD)	BOTULINUM TOXIN INJECTION	BOTULINUM TOXIN INJECTION	THERAPEUTIC PROCEDURES NEC	THERAPEUTIC PROCEDURES AND SUPPORTIVE CARE NEC	SURGICAL AND MEDICAL PROCEDURES	4	23
BOTOX (FOREHEAD)	DERMAL FILLER INJECTION	DERMAL FILLER INJECTION	SKIN AND SUBCUTANEOUS TISSUE THERAPEUTIC PROCEDURES NEC	SKIN AND SUBCUTANEOUS TISSUE THERAPEUTIC PROCEDURES	SURGICAL AND MEDICAL PROCEDURES	3	23
BOTOX INJECTIONS FOR COSMETIC PURPOSES	BOTULINUM TOXIN INJECTION	BOTULINUM TOXIN INJECTION	THERAPEUTIC PROCEDURES NEC	THERAPEUTIC PROCEDURES AND SUPPORTIVE CARE NEC	SURGICAL AND MEDICAL PROCEDURES	1	23
BOTOX INJECTIONS FOR COSMETIC PURPOSES	SKIN COSMETIC PROCEDURE	SKIN COSMETIC PROCEDURE	SKIN AND SUBCUTANEOUS TISSUE THERAPEUTIC PROCEDURES NEC	SKIN AND SUBCUTANEOUS TISSUE THERAPEUTIC PROCEDURES	SURGICAL AND MEDICAL PROCEDURES	1	23

- cSDRG explanation: Confirmed with Coding Group, No Issue.

AEOUT = NOT RECOVERED/NOT RESOLVED, but an end date is provided <ul style="list-style-type: none"> 6 records cSDRG explanation: Data collection issues due to ongoing status of the study For details, see report “BLA125752 - p301 - AEOUT vs AEENDTC.xlsx” 				
AEOUT = RECOVERED/RESOLVED or RECOVERED/RESOLVED WITH SEQUELAE, but an end date or collected duration is not provided <ul style="list-style-type: none"> 25 records Note that 8 of these records also have AEENRF = ONGOING cSDRG explanation: Data collection issues due to ongoing status of the study For details, see report “BLA125752 - p301 - AEOUT vs AEENDTC.xlsx” 				
There are adverse events marked DRUG WITHDRAWN, but the subject doesn’t have a corresponding (ADVERSE EVENT) DS record <ul style="list-style-type: none"> 17 subjects See report “BLA125752 - p301 - AEACN is DRUG WITHDRAWN but no DS ADVERSE EVENT record.xlsx” 				
Reactogenicity events lasting longer than the evaluation period (CERFTDTC + 6), but not in AE dataset <ul style="list-style-type: none"> Joining on USUBJID and –LNKGRP (according to RELREC) results in 2428 records <ul style="list-style-type: none"> See report for details: “BLA125752 – p301 - Reactogenicity missing from AE.xlsx” 				
Reactogenicity events in AE dataset but either start date or end date doesn’t equal dates in CE <ul style="list-style-type: none"> 3290 records <ul style="list-style-type: none"> See report for details: “BLA125752 – p301 - Reactogenicity date mismatch between CE and AE.xlsx” 				
Reactogenicity events in AE dataset but not in CE (using USUBJID and LNKGRP to join) <ul style="list-style-type: none"> 456 records <ul style="list-style-type: none"> Note that all of these AEs have AESPID populated, but not AELNKGRP. And there is no matching value in CE (no CESPID, etc) See report for details: “BLA125752 – p301 - Reactogenicity in AE but not CE.xlsx” 				
MHSTDTC is after RFSTDTC				
USUBJID	MHTERM	MHDECOD	MHSTDTC	RFSTDTC
mRNA-1273-P301-US325-2195	DEPRESSION	Depression	2020-11-03	2020-08-15T11:56
mRNA-1273-P301-US326-2100	NEW ONSET TYPE 2 DIABETES	Type 2 diabetes mellitus	2021-03-26	2020-08-05T13:57

<ul style="list-style-type: none">• cSDRG explanation: Data collection issues due to ongoing status of the study	
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