Data Definition Sepcifications

Analysis

ADaM-IG N/A

Study mRNA-1273-P301 - BIMO

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

Version: 2021-08-06

Analysis Datasets

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
CLINSITE	Clnical Site Data Elements Summary	BIMO	One record per study per site per endpoint per treatment arm	Analysis	STUDYID, SITEID, ENDPOINT, ARM	clinsite.xpt	

Go to the top of the Define
Date of document generation 2021-08-06T03:59:58

Clnical Site Data Elements Summary (clinsite.xpt)

Variable	Label	Type	Length / Display Format	Controlled Terms or Formats	Source/Derivation/Comments
STUDYID	Study Identifier	text	14		Predecessor: ADaM.ADSL.STUDYID
TITLE	Study Title	text	200		Assigned: Assigned "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".
SPONCNT	Sponsor Count	integer	8		Assigned: 1
SPONSOR	Sponsor Name	text	100		Assigned: Assigned "ModernaTX Inc.".
IND	IND Number	integer	z6.		Assigned: Assigned 19745.
UNDERIND	Under IND	text	1	NY	Assigned: Assigned "Y".
NDA	NDA Number	integer	6		Assigned: Null, not applicable.
BLA	BLA Number	integer	6		Assigned: Assigned 125752.
SUPPNUM	Supplement Number	integer	8		Assigned: Null, not applicable.
SITEID	Study Site Identifier	text	10		Predecessor: ADaM.ADSL.SITEID
ARM	Description of Planned Treatment Arm	text	50		Predecessor: ADaM.ADSL.ARM
COHORT	Description of Planned Cohort	text	50		Assigned: Null, not applicable.
SAFPOP	Number of Subjects in Safety Population	integer	8		Derived: Number of subjects within each site and each arm where ADaM.ADSL.SAFFL="Y"
SCREEN	Number of Subjects Screened	integer	8		Derived: Number of screened subjects within each site in ADaM.ADSL (non-screen failures) and ADaM.ADSLSF (screen failures).
DISCSTUD	Number Subjects Discont. Study	integer	8		Derived: Number of subjects within each site and each arm where ADaM.ADSL.SAFFL="Y" and ADaM.ADSL.EOSSTT="DISCONTINUED".
DISCTRT	Number Subjects Discont. Study Treatment	integer	8		Derived: Number of subjects within each site and each arm where ADaM.ADSL.SAFFL="Y" and (ADaM.ADSL.EOT01STT="DISCONTINUED" or ADaM.ADSL.EOT02STT="DISCONTINUED").
ENDPOINT	Primary Endpoint	text	200		Assigned: Assigned "Vaccine Efficacy of mRNA-1273 to prevent the first occurrence of COVID-19 starting 14 days after the second injection of IP".
ENDPTYPE	Primary Endpoint Type	text	20	ENDPTYPE	Assigned: Assigned "time to event".
TRTEFFR	Treatment Efficacy Result	float	12.3		Derived: Equal to n / SAFPOP; where n=number of subjects in ADaM.ADTTEA where PARAMCD="TTCVDC1" and CNSR=0 and SAFFL="Y".
TRTEFFS	Treatment Efficacy Result Standard Deviation	float	6.4		Derived: Equal to square root of TRTEFFR * (1-TRTEFFR)/SAFPOP.

Variable	Label	Type	Length / Display Format	Controlled Terms or Formats	Source/Derivation/Comments
CENSOR	Number of Censored Observations	integer	8		Derived: Number of subjects in ADaM.ADTTEA where PARAMCD="TTCVDC1" and CNSR=1 and SAFFL="Y".
NSAE	Number of Non-Serious Adverse Events	integer	8		Derived: Number of records in ADaM.ADAE where AESER="N" and SAFFL="Y" within each site and each arm.
SAE	Number of Serious Adverse Events	integer	8		Derived: Number of records in ADaM.ADAE where (AESER="Y" or AESER is missing) and AEOUT^="FATAL" and SAFFL="Y" within each site and each arm.
DEATH	Number of Deaths	integer	8		Derived: Number of records in ADaM.ADSL where DTHDT is not missing and SAFFL="Y" within each site and each arm.
IMPDEV	Number of Important Protocol Deviations	integer	8		Derived: Number of records in ADaM.ADDV where SAFFL="Y" and DVSIG="SIGNIFICANT".
NOIMPDEV	Number of Non-Important Protocol Deviations	integer	8		Derived: Number of records in ADaM.ADDV where SAFFL="Y" and DVSIG^="SIGNIFICANT".
FINLDISC	Financial Disclosure Amount	text	8		Assigned: Sum of disclosures for the clinical investigator and all sub-investigators to include all required parities under the applicable regulations (21 CFR Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860).
LASTNAME	Investigator Last Name	text	20		Assigned: Last name of the clinical investigator
FRSTNAME	Investigator First Name	text	20		Assigned: First name of the clinical investigator
MINITIAL	Investigator Middle Initial	text	1		Assigned: Middle initial of the clinical investigator
PHONE	Investigator Phone Number	text	35		Assigned: Phone number of the clinical investigator
FAX	Investigator Fax Number	text	25		Assigned: Fax number of the clinical investigator
EMAIL	Investigator Email Address	text	100		Assigned: Email address of the clinical investigator
COUNTRY	Country	text	3	COUNTRY	Predecessor: ADaM.ADSL.COUNTRY
STATE	State	text	50		Assigned: Unabbreviated state or province in which the site is located. Assigned "NA" when not appliable.
CITY	City	text	50		Assigned: Unabbreviated city, county, or village in which the site is located.
POSTAL	Postal Code	text	10		Assigned: Postal code in which the site is located.
STREET	Street Address	text	200		Assigned: Street address and office number at which the site is located.

Go to the top of the Define
Date of document generation 2021-08-06T03:59:58

Controlled Terminology

Controlled Terms

Country [CL.COUNTRY]

Permitted Value (Code)	Display Value (Decode)
USA [C17234]	United States

ENDPTYPE [CL.ENDPTYPE]

Permitted Value (Code)
Continuous
Binary
Time to event
Other

No Yes Response [CL.NY]

Permitted Value (Code)	Display Value (Decode)
Y [C49488]	Yes
N [C49487]	No

Go to the top of the Define
Date of document generation 2021-08-06T03:59:58

Analysis Derivations

Method	Type	Description
MT.CLINSITE.SAFPOP	Computation	Number of subjects within each site and each arm where ADaM.ADSL.SAFFL="Y"
MT.CLINSITE.SCREEN	Computation	Number of screened subjects within each site in ADaM.ADSL (non-screen failures) and ADaM.ADSLSF (screen failures).
MT.CLINSITE.DISCSTUD	Computation	Number of subjects within each site and each arm where ADaM.ADSL.SAFFL="Y" and ADaM.ADSL.EOSSTT="DISCONTINUED".
MT.CLINSITE.DISCTRT	Computation	Number of subjects within each site and each arm where ADaM.ADSL.SAFFL="Y" and (ADaM.ADSL.EOT01STT="DISCONTINUED" or ADaM.ADSL.EOT02STT="DISCONTINUED").
MT.CLINSITE.TRTEFFR	Computation	Equal to n / SAFPOP; where n=number of subjects in ADaM.ADTTEA where PARAMCD="TTCVDC1" and CNSR=0 and SAFFL="Y".
MT.CLINSITE.TRTEFFS	Computation	Equal to square root of TRTEFFR * (1-TRTEFFR)/SAFPOP.
MT.CLINSITE.CENSOR	Computation	Number of subjects in ADaM.ADTTEA where PARAMCD="TTCVDC1" and CNSR=1 and SAFFL="Y".
MT.CLINSITE.NSAE	Computation	Number of records in ADaM.ADAE where AESER="N" and SAFFL="Y" within each site and each arm.
MT.CLINSITE.SAE	Computation	Number of records in ADaM.ADAE where (AESER="Y" or AESER is missing) and AEOUT^="FATAL" and SAFFL="Y" within each site and each arm.
MT.CLINSITE.DEATH	Computation	Number of records in ADaM.ADSL where DTHDT is not missing and SAFFL="Y" within each site and each arm.
MT.CLINSITE.IMPDEV	Computation	Number of records in ADaM.ADDV where SAFFL="Y" and DVSIG="SIGNIFICANT".
MT.CLINSITE.NOIMPDEV	Computation	Number of records in ADaM.ADDV where SAFFL="Y" and DVSIG^="SIGNIFICANT".

Go to the top of the Define
Date of document generation 2021-08-06T03:59:58

Comments

CommentOID	Description
COM.CLINSITE.TITLE	Assigned "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".
COM.CLINSITE.SPONCNT	1
COM.CLINSITE.SPONSOR	Assigned "ModernaTX Inc.".
COM.CLINSITE.IND	Assigned 19745.
COM.CLINSITE.UNDERIND	Assigned "Y".
COM.CLINSITE.NDA	Null, not applicable.
COM.CLINSITE.BLA	Assigned 125752.
COM.CLINSITE.SUPPNUM	Null, not applicable.
COM.CLINSITE.COHORT	Null, not applicable.
COM.CLINSITE.ENDPOINT	Assigned "Vaccine Efficacy of mRNA-1273 to prevent the first occurrence of COVID-19 starting 14 days after the second injection of IP".
COM.CLINSITE.ENDPTYPE	Assigned "time to event".
COM.CLINSITE.FINLDISC	Sum of disclosures for the clinical investigator and all sub-investigators to include all required parities under the applicable regulations (21 CFR Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860).
COM.CLINSITE.LASTNAME	Last name of the clinical investigator
COM.CLINSITE.FRSTNAME	First name of the clinical investigator
COM.CLINSITE.MINITIAL	Middle initial of the clinical investigator
COM.CLINSITE.PHONE	Phone number of the clinical investigator
COM.CLINSITE.FAX	Fax number of the clinical investigator
COM.CLINSITE.EMAIL	Email address of the clinical investigator
COM.CLINSITE.STATE	Unabbreviated state or province in which the site is located. Assigned "NA" when not appliable.
COM.CLINSITE.CITY	Unabbreviated city, county, or village in which the site is located.
COM.CLINSITE.POSTAL	Postal code in which the site is located.
COM.CLINSITE.STREET	Street address and office number at which the site is located.

Go to the top of the Define
Date of document generation 2021-08-06T03:59:58