mRNA-1273-P920, Post-marketing safety of elasomeran/davesomeran and andusomeran vaccines in the United States

First published: 27/10/2023

Last updated: 14/07/2025

Study Finalised

Administrative details

EU PAS number

EUPAS106694

Study ID

106695

DARWIN EU® study

No

Study countries

United States

Study description

This is a retrospective cohort study of adults and children identified in US administrative claims data, a source of secondary data. The observed rates of AESI among patients who receive at least one dose of the Elasomeran/Davesomeran and Andusomeran vaccine will be compared to two concurrent comparator groups utilizing two separate cohorts.

Study status

Finalised

Contact details

Study institution contact

Clinical Trial Disclosure ModernaTX cttd@modernatx.com

Study contact

cttd@modernatx.com

Primary lead investigator

Clinical Trial Disclosure ModernaTX

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 31/01/2022

Study start date

Actual: 14/04/2023

Data analysis start date

Actual: 14/04/2023

Date of interim report, if expected
Actual: 15/09/2023

Date of final study report
Actual: 09/09/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ModernaTX Inc

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Main study objective:

The overarching aim of this study is to characterize the safety of the Omicron-containing bivalent SARS-CoV-2 mRNA-1273 booster vaccine as used in routine clinical practice.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

SPIKEVAX

Medicinal product name, other

Spikevax bivalent, Spikevax XBB.1.5

Study drug International non-proprietary name (INN) or common name

COVID-19 MRNA VACCINE (NUCLEOSIDE-MODIFIED)

Anatomical Therapeutic Chemical (ATC) code

(J07BN01) covid-19, RNA-based vaccine

covid-19, RNA-based vaccine

Population studied

Age groups

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

10.000.000

Study design details

Outcomes

Number of Participants With Adverse Events of Special Interest (AESI)

Data analysis plan

Primary Cohort Analysis For each patient, a propensity score (PS) will be calculated to estimate the probability of receiving a dose of the elasomeran/davesomeran or andusomeran vaccine conditional on measured covariates.
The PS will be calculated utilizing inverse probability of treatment weighting (IPTW).

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No