# 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





# 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 Omicroncontaining 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)</li>
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)</li>
- Adults (65 to < 75 years)</li>
- Adults (75 to < 85 years)
- Adults (85 years and over)

#### **Estimated number of subjects**

10000000

# 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