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

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## 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

Ongoing

## **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

## Date of interim report, if expected

Actual: 15/09/2023

## Date of final study report

Planned: 15/09/2024

# 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

## Name of medicine SPIKEVAX

## Name of medicine, other

Spikevax bivalent, Spikevax XBB.1.5

## 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

1000000

## 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

## 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