Post-Marketing Safety of SARS-CoV-2 mRNA-1273 Vaccine in the US: Active Surveillance, Signal Refinement and Self-Controlled Risk Interval (SCRI) Signal Evaluation in HealthVerity (COVID-19)

First published: 08/06/2021

Last updated: 14/07/2025

Study Finalised

Administrative details

EU PAS number

EUPAS41392

Study ID

42014

DARWIN EU® study

No

Study countries

- ☐ Canada
- ☐ Finland

- [ ] Germany
- [ ] Italy
- [ ] United States

Study description

The goal of this study is to add to the ongoing active and passive safety signal detection through signal refinement and, if needed, evaluation of potential safety signals related to taking the SARS-CoV-2 mRNA-1273 vaccine.

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

- [ ] United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

David Martin David.martin@modernatx.com

Study contact

David.martin@modernatx.com

Primary lead investigator

Eleonora Staines Urias

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 24/05/2021

Study start date
Actual: 07/07/2021

Date of final study report
Actual: 30/06/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Moderna

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

Scope of the study:

Other

If ‘other’, further details on the scope of the study

This study aims to augment ongoing active and passive safety signal detection through signal refinement and, where warranted, evaluation of potential safety signals associated with the introduction of SARS-CoV-2 mRNA-1273 vaccine.

Main study objective:

The goal of this study is to add to the ongoing active and passive safety signal detection through signal refinement and, if needed, evaluation of potential safety signals related to taking the SARS-CoV-2 mRNA-1273 vaccine.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ELASOMERAN

IMELASOMERAN

Anatomical Therapeutic Chemical (ATC) code

(J07BN01) covid-19, RNA-based vaccine

covid-19, RNA-based vaccine

Medical condition to be studied

Anaphylactic reaction

Liver injury

Acute disseminated encephalomyelitis

Acute kidney injury

Acute myocardial infarction

Acute respiratory distress syndrome

Anosmia

Deep vein thrombosis

Arthritis

Arrhythmia

Additional medical condition(s)

Aseptic meningitis,Bell’s palsy,Chilblain-like lesions,Chronic coronary heart disease,Coagulation disorders,Deep vein thrombosis (DVT),Disseminated intravascular coagulation (DIC),Encephalitis / Encephalomyelitis,Erythema multiforme,Gestational diabetes,Guillain-Barré Syndrome (GBS),Heart

failure,Kawasaki disease,Meningoencephalitis,Microangiopathy,Multisystem Inflammatory Syndrome in Adults

Population studied

Age groups

- 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

1400000

Study design details

Outcomes

Number of Participants With Adverse Events of Special Interests (AESIs)

Data analysis plan

Background and vaccine-exposed IRs in US adults will be stratified by age group, sex, and calendar period. when the pre-specified criteria are met for a particular AESI, the observed vs expected event ratios (O/Es) and corresponding 95% CI will be calculated, as the ratio of the number of events among those vaccinated with mRNA-1273 to the number of events expected in this population from background rates. when the pre-specified criteria are met for a particular AESI, the risk ratio (RR) of each AESI triggered in Objective 2 will be estimated using a self-controlled risk interval (SCRI) design and fitting a

conditional regression model (Poisson or negative binomial) based on model dispersion.
Each AESI will be assigned specific risk and control periods based on biologically plausible mechanisms. Sensitivity analyses may be performed by applying different risk and control periods.

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