Post-marketing safety of the Moderna COVID-19 vaccine following the 2024/2025 strain change in the United States

First published: 22/08/2025

Last updated: 29/09/2025

Study Finalised

Administrative details

EU PAS number

EUPAS1000000711

Study ID

1000000711

DARWIN EU® study

No

Study countries

United States

Study description

This retrospective US cohort study will actively monitor safety outcomes following administration of mRNA-1273.712 targeting the SARS-CoV-2 KP.2 variant among individuals in the US enrolled in commercial and Medicare Advantage plans.
The study will descriptively characterize the utilization of mRNA-1273.712 and inferentially assess the risk of myocarditis, pericarditis and other safety topics of interest in recipients of mRNA-1273.712.

Study status

Finalised

Research institutions and networks

Institutions

Aetion, Inc., a Datavant company

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: 16/08/2024

Study start date
Actual: 30/09/2024

Data analysis start date
Actual: 19/05/2025

Date of final study report
Planned: 31/08/2025

Actual: 29/08/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ModernaTX

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

mRNA-1273-P951

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

No individual level data collected for the purpose of the study

---

Study design:

This retrospective US cohort study will actively monitor safety outcomes following administration of mRNA-1273.712 targeting the SARS-CoV-2 KP.2 variant among individuals in the US enrolled in commercial and Medicare Advantage plans.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

SPIKEVAX

Medicinal product name, other

mRNA-1273.712

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

Study design details

Data analysis plan

Analyses will be conducted within each database, and results will be pooled through a meta-analysis when appropriate.

Analyses for <65 years old and ≥65 years old population will be conducted separately, given differences in the insurance coverage.

Covariates will be described via summary statistics and for continuous variables will include mean, standard deviation, median, interquartile range; for categorical variables, counts and proportions.

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 source(s), other

Optum de-identified Clinformatics® Data Mart Database (Optum® CDM)Humana Healthcare Research Standard De-Identified Dataset

---

Data sources (types)

Drug prescriptions

Electronic healthcare records (EHR)

Non-interventional study

Other

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after data extraction