# mRNA-1273-P901, Real-World Study of the Effectiveness of Moderna COVID-19 Vaccine

**First published:** 27/10/2023

**Last updated:** 14/07/2025

Study Finalised

## Administrative details

**EU PAS number**

EUPAS106670

**Study ID**

106671

**DARWIN EU® study**

No

**Study countries**

United States

**Study description**

This is an observational cohort study to evaluate real-world vaccine effectiveness and durability of Moderna COVID-19 vaccine among a diverse population at Kaiser Permanente Southern California (KPSC).

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Kaiser Permanente Southern California (KPSC)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

# 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: 26/01/2021

**Study start date**
Actual: 18/12/2020

**Data analysis start date**
Actual: 02/07/2021

**Date of final study report**
Actual: 28/03/2025

## 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)?**

EU RMP category 3 (required)

## Other study registration identification numbers and links

NCT05933304,
https://clinicaltrials.gov/study/NCT05933304?term=NCT05933304&rank=1

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

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**Main study objective:**

The primary objective of this study is to evaluate the vaccine effectiveness (VE) of receipt of Moderna COVID-19 vaccine in preventing SARS-CoV-2 infection and severe COVID-19 disease.
SARS-CoV-2 infection will be defined as a positive antigen test result as well as a positive molecular diagnostic test among symptomatic or asymptomatic participants or a COVID-19 diagnosis code.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

ELASOMERAN

IMELASOMERAN

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**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)

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**Estimated number of subjects**

1000000

# Study design details

**Outcomes**

1. Number of Participants With SARS-CoV-2 Infection 2. Number of Participants With Severe COVID-19 Disease

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**Data analysis plan**

Primary Objectives will be analyzed at interim and final analyses.

Descriptive attributes of vaccinated and unvaccinated cohorts will be presented as absolute no. and %. χ2 test will be used to test for significant differences in the distribution of the categorical covariates among individuals between each of the vaccinated and unvaccinated cohorts at cohort entry.

Continuous variables will be presented as the mean with standard deviation and/or median with interquartile ranges, with p-values for the two-sample test or Wilcoxon rank-sum test, as appropriate.

Absolute standardized differences will be calculated to assess the balance of covariates.

Overall incidence rates of SARS-CoV-2 infection and of severe COVID-19 for the vaccinated and unvaccinated cohorts will be calculated by dividing the no. of incident events by the total no. of person-yrs. Vaccine Effectiveness will be estimated using Cox Proportional Hazards and Logistic Regression methods where appropriate.

# 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)**

Electronic healthcare records (EHR)

## 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