Safety Profile of the NVX-CoV2373 Vaccine in Individuals ≥ 12 Years of Age in the United States

First published: 02/05/2023

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Study Ongoing

Administrative details

EU PAS number

EUPAS104622

Study ID

104623

DARWIN EU® study

No

Study countries

United States

Study status

Ongoing

Research institutions and networks

Institutions

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Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jessica Citronberg

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/12/2021

Actual: 18/12/2021

Study start date

Planned: 31/03/2023

Actual: 31/03/2023

Date of final study report

Planned: 30/09/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novavax, 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

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To Evaluate the Risk of Select AESIs Following Vaccination with at Least One Dose of NVX-CoV2373 Using a Self-Controlled Design

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Self-controlled case series

Study drug and medical condition

Medicinal product name, other

COVID-19 VACCINE (RECOMBINANT, ADJUVANTED)

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

COVID-19 VACCINE (RECOMBINANT, ADJUVANTED)

Medical condition to be studied

Immunodeficiency

Stem cell transplant

Additional medical condition(s)

Immunocompromised

Population studied

Age groups

- 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)

Special population of interest

Immunocompromised

Estimated number of subjects

24.264.457

Study design details

Outcomes

To Evaluate the Risk of Select AESIs Following Vaccination with at Least One Dose of NVX-CoV2373 Using a Self-Controlled Design, To Evaluate the Risk of Select AESIs Following Receipt of the First Dose of Homologous NVX-CoV2373 Primary Series Using a Self-Controlled Design To Evaluate the Risk of Select AESIs Following Completion of a Homologous NVX-CoV2373 Two-Dose Primary Series (Receipt of the Second Dose) Using a Self-Controlled Design

Data analysis plan

All study objectives (primary, secondary, and exploratory) will only utilize closed claims data to ensure we fully capture the individual's interactions with the healthcare system. Furthermore, for each AESI, if the number of outcome events are not large enough for analysis to be adequately powered, only descriptive analysis will be performed.

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)

Ambulatory EMR - OMOP

Data source(s), other

HealthVerity’s RTAEP3 United States, Hospital CDM-US

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