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

First published: 02/05/2023
Last updated: 23/04/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/104623

EU PAS number
EUPAS104622

Study ID
104623

DARWIN EU® study
No

Study countries
United States

Study status
Ongoing

Research institution and networks

Institutions

Jessica Citronberg

Contact details

Study institution contact
Jessica Citronberg
Study contact

jessica.citronberg@aetion.com
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

Name of medicine, 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
24264457

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

Data sources

Data source(s)
Ambulatory EMR - OMOP

Data source(s), other
HealthVerity’s RTAEP3 United States, Hospital CDM-US

Data sources (types)
Administrative data (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