

# Safety of the Novavax COVID-19 vaccine in England using a self-controlled case series design: A post-authorisation safety study using data from the Clinical Practice Research Datalink (CPRD) Aurum and linked databases

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Study

Planned

## Administrative details

### EU PAS number

EUPAS103858

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### Study ID

103859

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### DARWIN EU® study

No

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### Study countries

## Study description

Novavax developed a COVID-19 vaccine (Nuvaxovid™ vaccine) which has been approved for use by the Medicines and Healthcare products Regulatory Agency (MHRA) to prevent COVID-19 caused by the SARS-CoV-2 virus in individuals 12 years of age and older. The Clinical Practice Research Datalink (CPRD) Aurum primary care and linked secondary care and mortality data will be used to assess the risk of select adverse events of interest (AESI) in patients after vaccination with the Nuvaxovid™ vaccine. A self-controlled case series (SCCS) will make within-person comparisons of the incidence of AESI in pre-specified risk windows following any dose of the Nuvaxovid™ vaccine with incidence in a post-vaccination control window. Secondary objectives will compare incidence after receipt of a first dose, completion of a two-dose primary series, receipt of a booster dose, and among subgroups of interest after any dose.

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## Study status

Planned

## Research institutions and networks

### Institutions

[Dr. Sonia Coton](#)

## Contact details

### Study institution contact

Nicole Baker nibaker@novavax.com

Study contact

nibaker@novavax.com

**Primary lead investigator**

Sonia Coton

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 26/10/2021

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**Study start date**

Planned: 31/03/2023

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**Date of final study report**

Planned: 30/06/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Novavax, Inc

## Regulatory

## Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

## Other study registration identification numbers and links

2019nCoV-402

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

#### **Main study objective:**

To evaluate the risk of select AESI following vaccination with the Nuvaxovid™ vaccine using a self-controlled case series design.

## Study Design

## Non-interventional study design

Other

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## Non-interventional study design, other

Self-controlled case series

# Study drug and medical condition

## Medicinal product name

NUVAXOVID

# 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)
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## Special population of interest

Immunocompromised

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## Estimated number of subjects

10686

# Study design details

## Outcomes

The risk of select AESI following vaccination with any dose of Nuvaxovid™ vaccine. The risk of select AESI following vaccination with Nuvaxovid™ vaccine after receipt of a first dose, completion of a two-dose primary series, receipt of a booster dose, and among subgroups of interest after any dose.

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## Data analysis plan

The primary and secondary objectives will be analyzed using Conditional Poisson regression modelling to estimate incident rate ratios for each AESI.

## 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)

Clinical Practice Research Datalink

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### Data sources (types)

[Disease registry](#)

[Electronic healthcare records \(EHR\)](#)

Other

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**Data sources (types), other**

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No