

# Bexsero® pregnancy registry: an observational study of the safety of Bexsero® exposure in pregnant women and their offspring

**First published:** 25/01/2016

**Last updated:** 02/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS12183

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### Study ID

36639

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study description

4CMenB was approved by the European Medicines Agency (EMA) in January 2013 and is indicated for active immunisation of individuals from 2 months of age and older against invasive meningococcal disease caused by *Neisseria meningitidis* group B. 4CMenB can be considered for use during pregnancy where there is a clear risk of exposure to meningococcal infection and sometimes, inadvertent exposure during pregnancy may also occur - before the woman knows she is pregnant, for example. The objective of this study is to evaluate the safety of 4CMenB during pregnancy and to help us learn more about the health of women who have been vaccinated with 4CMenB within 30 days prior to their last menstrual period (LMP) or at any time during pregnancy, and the health of their infants. The study will be conducted (with EMA approval) in the US. Pregnant women within the US who received at least 1 dose 4CMenB vaccine within 30 days prior to their last menstrual period or at any time during pregnancy are eligible to participate. A woman may self-enroll in the registry by calling the pregnancy registry telephone number directly or their healthcare provider (HCP) can, with their consent, enroll them on their behalf. Alternatively HCPs may report anonymous data on pregnancy exposures and outcomes occurring within their network/health maintenance organization (HMO). The health of the woman and her infant will be followed up until the end of the pregnancy

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

Pharmaceutical Product Development (PPD)

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**Institution**

## Contact details

### Study institution contact

Call Center EU Clinical Trials

Vx.publicdisclosureglobal@gsk.com

**Study contact**

[Vx.publicdisclosureglobal@gsk.com](mailto:Vx.publicdisclosureglobal@gsk.com)

### Primary lead investigator

Call Center EU Clinical Trials

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Actual: 24/11/2015

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### Study start date

Actual: 31/01/2016

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### Date of final study report

Actual: 02/03/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Novartis Vaccines, now a GSK company

## Study protocol

[V72\\_820B-08\\_Other\\_\(Specify\)-Redacted\\_Protocol\\_for\\_ENCePP-v1-2015-11-20-77194739.pdf](#) (1 MB)

[gsk-205533-protocol-redact.pdf](#) (791.72 KB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

### **Study topic:**

Disease /health condition  
Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Other

**If 'other', further details on the scope of the study**

Post-authorization safety study

**Data collection methods:**

Primary data collection

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**Main study objective:**

The objective of the 4CMenB Pregnancy Registry is to evaluate pregnancy outcomes among women immunized with the 4CMenB vaccine within 30 days prior to LMP or at any time during pregnancy.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Pregnancy Registry, Prospective, observational study

## Study drug and medical condition

**Medicinal product name**

BEXSERO

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

RECOMBINANT NEISSERIA MENINGITIDIS GROUP B NHBA FUSION PROTEIN

RECOMBINANT NEISSERIA MENINGITIDIS GROUP B NADA PROTEIN

RECOMBINANT NEISSERIA MENINGITIDIS GROUP B FHBP FUSION PROTEIN

PRODUCED IN E. COLI CELLS BY RECOMBINANT DNA TECHNOLOGY ADSORBED  
ON ALUMINIUM HYDROXIDE

OUTER MEMBRANE VESICLES FROM NEISSERIA MENINGITIDIS GROUP B (STRAIN  
NZ 98/254)

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**Anatomical Therapeutic Chemical (ATC) code**

(J07AH09) meningococcus B, multicomponent vaccine

meningococcus B, multicomponent vaccine

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**Medical condition to be studied**

Pregnancy

## Population studied

**Short description of the study population**

The study population will include pregnant women within the US who received at least 1 dose of Bexsero® vaccine (confirmed or possible exposure) within 30 days prior to LMP or at any time during pregnancy. Bexsero® should be used during pregnancy only if clearly needed, but inadvertent exposure during pregnancy might be expected because the age group targeted for the vaccine includes young women of reproductive potential.

The minimum criteria required for enrollment into the registry are as follows:

1. Sufficient evidence to confirm that exposure to a serogroup B meningococcal vaccine (confirmed or possible Bexsero® vaccination) occurred within 30 days prior to LMP or at any time during pregnancy
  2. Sufficient information to determine whether the pregnancy is prospectively or retrospectively registered (i.e., whether the outcome of pregnancy was known at the time of first contact with the registry)
  3. Date the pregnancy exposure is registered
  4. Full reporter (i.e., HCP) contact information to allow for follow-up (name, address, etc.)
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### **Age groups**

- Preterm newborn infants (0 - 27 days)
  - Adults (18 to < 46 years)
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### **Special population of interest**

Pregnant women

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### **Estimated number of subjects**

1

## **Study design details**

### **Outcomes**

The primary outcomes of interest include major congenital malformation (MCM), preterm birth, and low birth weight (LBW). Other pregnancy outcomes including stillbirth, spontaneous abortion (SAB), induced abortion (IAB), ectopic pregnancy, molar pregnancy.

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### **Data analysis plan**

A SAP will be completed before the study is started. Demographic and baseline characteristics will be summarized with simple descriptive statistics and data listings. The overall prevalence of MCM will be reported as well as the prevalence of preterm births and low birth weight infants. These prevalence estimates in exposed subjects will be compared with those of the Centres for Disease Control's (CDC) National Vital Statistics System (NVSS).

## Documents

### Study results

[gsk-205533-clinical-study-report-redact.pdf](#) (458.77 KB)

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## 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)

[Disease registry](#)

[Other](#)

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### Data sources (types), other

The pregnant woman and appropriate members of her health care team could serve as data reporters to the registry. The registry was strictly observational, and only data noted as part of routine care would be collected.

## 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