# A Pregnancy Registry Study to Evaluate the Safety of PENBRAYA™ Meningococcal Vaccine Exposure During Pregnancy

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Study | Planned

## Administrative details

**PURI**
https://redirect.ema.europa.eu/resource/1000000078

**EU PAS number**
EUPAS1000000078

**Study ID**
1000000078

**DARWIN EU® study**
No

**Study countries**
United States

**Study description**
PENBRAYA (Neisseria meningitidis Groups A, B, C, W, and Y Vaccine; MenABCWY) is a pentavalent meningococcal vaccine composed of 2 licensed meningococcal vaccines: Trumenba® (N meningitidis serogroup B bivalent recombinant lipoprotein 2086 vaccine [bivalent rLP2086, also referred to as MenB-fHbp]) and Nimenrix® (meningococcal polysaccharide groups A, C, W, and Y tetanus toxoid conjugate vaccine [MenACWY-TT]).

On 20 October 2023, the United States (US) Food and Drug Administration (FDA) approved PENBRAYA for the prevention of meningococcal disease caused by

meningococcal groups A, B, C, W, and Y in adolescents and young adults 10 through 25 years of age. As part of the PENBRAYA pharmacovigilance plan and in fulfillment of a post-marketing commitment (PMC) requested by the Center for Biologics Evaluation and Research (CBER), this noninterventional study (NIS) is being conducted to evaluate the safety of PENBRAYA exposure during pregnancy in a real-world setting.

The research question is: What is the risk of maternal, neonatal, or infant safety outcomes among individuals exposed to PENBRAYA during pregnancy?

The specific objective is: To estimate the proportion of major congenital malformation (MCM), spontaneous abortion (SAB), elective termination, stillbirth, preterm birth, and small for gestational age (SGA) among individuals exposed to PENBRAYA during pregnancy or within 30 days prior to last menstrual period (LMP).

**Study status**
Planned

# Research institution and networks

## Institutions

### Pfizer
**First published:** 01/02/2024
Last updated 01/02/2024
Institution

### Pharmaceutical Product Development (PPD)
**First published:** 01/02/2024
Last updated 01/02/2024
Institution

# Contact details

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Primary lead investigator

# Study timelines

**Date when funding contract was signed**
Planned:
28/12/2023
Actual:
28/12/2023

**Study start date**
Planned:
30/04/2024

**Date of interim report, if expected**
Planned:
30/04/2025

**Date of final study report**
Planned:
30/04/2033

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer 100%

# Study protocol

C3511007_PROTOCOL_v1_24JAN2024.pdf(1.04 MB)

# Regulatory

**Was the study required by a regulatory body?**
No

**Is the study required by a Risk Management Plan (RMP)?**
Not applicable

## Other study registration identification numbers and links

C3511007

# Methodological aspects

## Study type

### Study type list

**Study topic:**
Human medicinal product

**Study type:**
Non-interventional study

**Scope of the study:**
Safety study (incl. comparative)

**Data collection methods:**
Primary data collection

**Study design:**
This registry-based, prospective, observational cohort study will enroll and follow pregnant individuals 10-25 years of age in the US who are exposed to PENBRAYA during pregnancy. Data will be collected from enrolled pregnant individuals and the healthcare providers (HCPs) involved in their care.

**Main study objective:**
To estimate the proportion of major congenital malformation (MCM), spontaneous abortion (SAB), elective termination, stillbirth, preterm birth, and small for gestational age (SGA) among individuals exposed to PENBRAYA during pregnancy or within 30 days prior to last menstrual period (LMP).

## Study Design

**Non-interventional study design**
Cohort

## Study drug and medical condition

**Name of medicine, other**
PENBRAYA (meningococcal groups A, B, C, W and Y vaccine)

**Medical condition to be studied**
Stillbirth

**Additional medical condition(s)**
Congenital malformation (MCM), spontaneous abortion(SAB), elective termination, preterm birth, and small for gestational age (SGA)

## Population studied

**Short description of the study population**
The study population will include a single cohort of pregnant individuals in the US exposed to PRENBAYA during pregnancy.

**Age groups**
In utero
Paediatric Population (< 18 years)
Neonate
Preterm newborn infants (0 – 27 days)
Term newborn infants (0 – 27 days)
Infants and toddlers (28 days – 23 months)
Children (2 to < 12 years)
Adolescents (12 to < 18 years)
Adults (18 to < 46 years)

**Special population of interest**
Pregnant women

**Estimated number of subjects**
50

## Study design details

**Setting**
The study population will be derived from eligible individuals in the US enrolled in the pregnancy registry. The virtual registry coordinating center (VRCC) will coordinate enrollment and data collection. Pregnant individuals will be identified in the US during the study period using an active, targeted, multi-pronged recruitment campaign.

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**Outcomes**
Outcomes of interest: major congenital malformation (MCM), spontaneous abortion (SAB), elective termination, stillbirth, preterm birth, and small for gestational age (SGA). For outcomes not reported by the HCP, additional information on outcome ascertainment is provided.

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**Data analysis plan**
Demographic and baseline characteristics will be summarized with descriptive statistics for the study population.

The number of observations, median, mean, standard deviation, minimum, and maximum will be reported for each continuous variable. The frequency and percentage per category will be reported for each categorical variable. Proportion of the outcomes of interest will be calculated according to the conventions described in protocol Table 4. In general, the proportion of each outcome will be calculated by dividing the number of cases of the outcome by the appropriate denominator for that particular outcome, based on clinical knowledge. For most outcomes, the analysis population (denominator) will be the number of pregnant individuals with pregnancy outcome data, the number of live births, or the number of infants with follow-up data at the timepoint of interest, as appropriate; however, for some outcomes, the analysis population (denominator) will be restricted based on certain relevant factors (as noted in Table 4). If sample size permits, subgroup analyses will be conducted that consider timing of exposure (earliest trimester of exposure), extent of exposure (cumulative vaccine doses during pregnancy, or relevant exposure window), and maternal age group at conception (10 to <18, 18 to 25 years). Supplementary analyses will be conducted that include pregnant individuals who were excluded from the analysis population due to occurrence of the pregnancy outcome prior to enrollment (retrospectively enrolled participants) or exposure to a known teratogen or an investigational medication during or prior to pregnancy (teratogen/investigational medication-exposed participants). Sensitivity analyses of major congenital malformation that applies a stricter definition of prospective enrollment and that restricts the preconception exposure window to 28 days prior to conception rather than 30 days prior to last menstrual period will also be conducted.

# Data management

## Data sources

**Data source(s), other**
This will be a new, product-based pregnancy registry conducted by PPD (part of Thermo Fisher Scientific).

**Data sources (types)**
Other

**Data sources (types), other**
Primary data collection

## 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**
Unknown