

# A Prospective, Registry-based, Observational Study to Assess Maternal, Fetal and Infant Outcomes Following Exposure to Rimegepant: The Migraine Observational Nurtec Pregnancy Registry (MONITOR)

**First published:** 26/01/2022

**Last updated:** 09/07/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS45356

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### Study ID

45357

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### DARWIN EU® study

No

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## Study countries

☐ United States

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## Study description

This observational exposure registry will compare the occurrence of major congenital malformations in the fetuses/infants of women with migraine exposed to rimegepant during pregnancy or just prior to pregnancy to those not exposure to rimegepant during or just prior to pregnancy.

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## Study status

Ongoing

# Research institutions 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

## Study institution contact

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## Primary lead investigator

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Primary lead investigator

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# Study timelines

## Date when funding contract was signed

Planned: 09/11/2020

Actual: 09/11/2020

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## Study start date

Planned: 01/07/2021

Actual: 23/09/2021

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## Data analysis start date

Planned: 01/04/2034

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## Date of interim report, if expected

Planned: 15/04/2022

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## Date of final study report

Planned: 01/04/2035

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

PFIZER 100%

## Study protocol

[C4951005\\_BHV3000-402\\_BC102842-01\\_Protocol\\_25Apr2023\\_clean\\_signed.pdf](#)  
(1.27 MB)

[C4951005\\_MONITOR PROTOCOL CLEAN\\_V2.0\\_08NOV2022.pdf](#)(745.02 KB)

[C4951005\\_MONITOR PROTOCOL CLEAN\\_V3.0\\_25APR2023.pdf](#)(1.3 MB)

[C4951005\\_MONITOR PROTOCOL CLEAN\\_V4.0\\_27FEB2024.pdf](#)(716.9 KB)

[C4951005\\_MONITOR PROTOCOL CLEAN\\_V5.0\\_18OCT2024.pdf](#)(688.86 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:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Primary data collection

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**Study design:**

This study is a prospective, observational, pregnancy exposure registry of pregnant women with migraine who were exposed to rimegepant in the US conducted using primary data collection.

**Main study objective:**

To compare the occurrence of major congenital malformations (MCMs) in the fetuses/infants of women with migraine who were exposed to rimegepant during pregnancy or just prior to pregnancy (up to 3 days prior to conception) with:

- 1) an internal cohort of women with migraine who were not exposed to rimegepant during pregnancy or just prior to pregnancy (up to 5 product half-lives prior to conception) and
- 2) an external cohort of pregnant women without migraine.

## Study Design

## Non-interventional study design

Cohort

## Study drug and medical condition

### Name of medicine, other

Nurtec ODT

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

RIMEGEPANT

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### Anatomical Therapeutic Chemical (ATC) code

(N02CD06) rimegepant

rimegepant

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### Medical condition to be studied

Migraine

## Population studied

### Short description of the study population

The study population includes pregnant women with migraine who were exposed to rimegepant in the United States.

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### Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

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### **Special population of interest**

Pregnant women

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### **Estimated number of subjects**

780

## Study design details

### **Setting**

This study is US-based. The study became open for enrollment on 23 September 2021.

The data collection process for each participant will begin at enrollment, with data collection from the participant and her HCP.

For prospectively enrolled participants, follow-up with the maternal HCP will occur at the end of the second trimester (approximately 26 gestational weeks) and/or in the month of estimated date of delivery (EDD) for pregnancy outcome (delivery or early termination).

The second trimester pregnancy follow-up may not be applicable for women who enroll late in pregnancy.

If a live birth is reported, the registry will conduct follow-up with the infant's HCP at 4 and 12 months after delivery.

At approximately 4 months after delivery, infant data at 2 and 4 months of age will be collected; at approximately 12 months after delivery, infant data at 6 and 12 months of age will be collected.

An annual interim study report, reviewed by the Scientific Advisory Committee (SAC), has been submitted to the Center for Drug Evaluation and Research (CDER) beginning April 2022. The Interim Report summarizes the status and the cumulative data that are current to the most recent annual data cutoff period. The estimated end of data collection is April 2034, and a final study report will be submitted by April 2035.

The internal study population will include pregnant women of any age within the US with migraine who were treated with rimegepant as part of routine care at any time during pregnancy or just prior to pregnancy (up to 3 days prior to conception), as well as pregnant women with migraine who were not exposed to rimegepant during pregnancy or just prior to pregnancy (up to 5 product half-lives prior to conception).

Eligible pregnant women may self-enroll or voluntarily be enrolled by their HCP. Enrollment should occur as early in pregnancy as possible.

Enrollment and data collection will be coordinated through the Registry Coordinating Center (RCC).

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## **Comparators**

The registry will include 2 comparator groups:

Pregnant women with migraine who are unexposed to rimegepant cohort: migraine diagnosis and no exposure to rimegepant before or during the pregnancy period. Women in this cohort may or may not be exposed to other migraine therapies during pregnancy.

Pregnant women without migraine cohort: 1) external published US background outcome rates among pregnant women without a diagnosis of migraine, 2) the



comparison population of the retrospective pregnancy outcomes study (NDA 212728, post-marketing requirement 3799-7, Pfizer study C4951006 [formerly BHV3000-403]) as an additional resource for non-migraine comparison group outcome rates of MCM, SAB, elective termination, stillbirth, pre-eclampsia/eclampsia, preterm birth, and SGA. Women in this cohort may or may not be exposed to medications during pregnancy.

This study will also use external published and population-based data on migraine to provide context for any events observed in the cohort of pregnant women with migraine who were exposed to rimegepant and the cohort of pregnant women with migraine who were unexposed to rimegepant.

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## **Outcomes**

The primary objective is to compare the rate of major congenital malformations in the fetuses/infants of women with migraine exposed to rimegepant (during pregnancy or just prior to pregnancy) to women with migraine not exposed to rimegepant before or during pregnancy and pregnant women without migraine. The secondary objective is to compare the rate of adverse fetal outcomes, maternal pregnancy complications, infant outcomes at birth, and infant events of interest up to 1 year post-delivery in women with migraine exposed to rimegepant during pregnancy or just prior to pregnancy, as well as in women with migraine not exposed to rimegepant before or during pregnancy and pregnant women without migraine

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## **Data analysis plan**

Descriptive analyses for the primary and secondary study objectives will be performed annually for all data; comparative analyses will be conducted for the final analysis.

Registry data will be summarized in tables and listings by study cohort, as

appropriate. These data include maternal demographic characteristics and pre-pregnancy anthropometrics, pregnancy information, maternal obstetrical history, family history of congenital malformations, disease information, maternal exposures during pregnancy, pregnancy outcome information, and infant outcome information.

For each continuous variable, the number of observations, median, mean, standard deviation, minimum, and maximum will be reported. For each categorical variable, the frequency and percentage in each category will be reported.

The frequency and percentage of participants with missing data for each data point will be presented. Results will be rounded to one decimal place; therefore, percentages may not always add up to 100.

Pair-wise comparisons of demographic characteristics, baseline characteristics, and prevalence rates of the outcomes of interest will be conducted between the study cohorts: pregnant women with migraine who were exposed to rimegepant versus pregnant women with migraine who were unexposed to rimegepant.

## 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)**

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