

# VIMKUNYA® Pregnancy registry: An Observational Prospective Study of the Safety of VIMKUNYA® Vaccine Exposure in Pregnant Women and their Offspring

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Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000001126

### Study ID

1000001126

### DARWIN EU® study

No

### Study countries



Germany



United Kingdom



United States

## **Study description**

This study is a Phase 4, non-interventional, prospective pregnancy registry designed to evaluate the safety of VIMKUNYA® (chikungunya virus-like particle vaccine) when administered up to 28 days prior to conception or at any time during pregnancy. As pregnant women were not included in pre-authorization clinical trials, there is limited information available on the safety of VIMKUNYA in this population. This registry aims to address this gap by collecting real-world data on maternal, pregnancy, and infant outcomes following vaccine exposure.

The study population includes pregnant women in the United States, Europe, and other countries where VIMKUNYA is available, along with their offspring. Participants will be enrolled prospectively after vaccine exposure and followed through pregnancy and up to one year after delivery. Data will be collected via structured questionnaires at predefined timepoints, including enrolment, delivery, neonatal period, and infant follow-up visits.

The primary objective is to describe pregnancy outcomes, including full-term birth, preterm birth, spontaneous abortion, stillbirth, and congenital anomalies. Secondary objectives include characterization of neonatal and infant outcomes such as birth weight, gestational age, neonatal complications, growth, neurodevelopment, and survival up to one year of age.

Data will be analyzed descriptively, focusing on frequencies and proportions of outcomes among exposed pregnancies. As this is an observational registry without an internal comparator group, findings will be interpreted in the context of available background rates from external sources. The study is expected to run for approximately five years and will support postmarketing safety evaluation for regulatory authorities.

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## **Study status**

Ongoing

## Contact details

### Study institution contact

Suzanne Scheele SUZS@bavarian-nordic.com

Study contact

[SUZS@bavarian-nordic.com](mailto:SUZS@bavarian-nordic.com)

### Primary lead investigator

Marc Hoffmann

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 04/12/2025

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### Study start date

Planned: 29/05/2026

Actual: 29/05/2026

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### Date of final study report

Planned: 30/11/2031

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

## 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)

## Other study registration identification numbers and links

<https://www.bnpregnancyregistry.com>

## 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:**

Evaluation of patient-reported outcomes

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Study design:**

Phase 4, noninterventional pregnancy registry with primary data collection over 5 years. Women are enrolled prospectively after VIMKUNYA exposure and before pregnancy outcome; retrospective reports are also collected. Pregnancy and infant outcomes are followed from enrolment to 1 year of age.

**Main study objective:**

- To describe pregnancy outcomes among pregnant women who received CHKV VLP vaccine up to 28 days before conception or at any time during pregnancy.
- To describe neonatal/infant outcomes until 1 year of age among the offspring of pregnant women who received CHKV VLP vaccine up to 28 days before conception or at any time during pregnancy.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Prospective pregnancy exposure registry with primary data collection. This is a Phase 4, non-interventional, product-exposure registry designed to actively collect pregnancy and infant outcome data among women exposed to

VIMKUNYA up to 28 days before conception or during pregnancy

## Study drug and medical condition

### Medicinal product name

VIMKUNYA

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### Anatomical Therapeutic Chemical (ATC) code

(J07BP02) chikungunya, virus-like particles

chikungunya, virus-like particles

## Population studied

### Short description of the study population

The study population will include women who received VIMKUNYA up to 28 days before conception or at any time during pregnancy and their offspring.

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### 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)
  - Adults (18 to < 46 years)
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### Special population of interest

Pregnant women

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## Estimated number of subjects

46

## Study design details

### Data analysis plan

Descriptive statistics will be used to summarize the characteristics of the pregnancy registry study population. Frequencies and proportions will be calculated for categorical variables and means, standard deviations, medians, minimums, and maximums will be used for continuous variables. Cohort formation and attrition details will also be presented to characterize participant discontinuation (if any) throughout the study.

Missing data will not be imputed due to the limited sample size. Instead, the extent of missingness will be reported descriptively. All analyses will be conducted using SAS version 9.4 (or above).

## 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), other**

Primary data collection, electronic patient reported outcomes (questionnaires)

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**Data sources (types)**

Other

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Yes

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**Check completeness**

Yes

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**Check stability**

Yes

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**Check logical consistency**

Yes

## Data characterisation

**Data characterisation conducted**

Yes

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### **Data characterisation moment**

after data extraction

after creation of study variables

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### **Data characterisation details**

Data characterization and quality review activities are conducted periodically throughout the study to assess data completeness, consistency, plausibility, and fitness for purpose.

Reviews include assessment of enrolled pregnancies, availability of exposure information, completeness of maternal, pregnancy, and infant outcome data, and evaluation of loss-to-follow-up and missing data patterns. Data are reviewed for conformance with study specifications, including expected formats and permissible values.

Logical consistency checks assess relationships between key data elements, including chronology of exposure, pregnancy, delivery, and infant follow-up, and consistency between linked maternal and infant records. Plausibility assessments evaluate key variables for unexpected, implausible, or inconsistent values. Pharmacovigilance personnel also perform case-level reviews and follow up on missing or inconsistent data when appropriate.