

# Pregnancy and Neonatal Outcomes following Prenatal Exposure to Cabotegravir Long Acting (CAB LA): Data from the European Pregnancy and Paediatric HIV Cohort Collaboration (EPPICC) (215163)

**First published:** 16/02/2022

**Last updated:** 05/09/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS45777

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### Study ID

47336

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### DARWIN EU® study

No

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### Study countries

Belgium

France

- Germany
  - Greece
  - Italy
  - Poland
  - Romania
  - Russian Federation
  - Spain
  - Switzerland
  - Ukraine
  - United Kingdom
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### Study status

Ongoing

## Research institutions and networks

### Institutions

ViiV Healthcare

**First published:** 01/02/2024

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Institution

## Contact details

### Study institution contact

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Study contact

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**Primary lead investigator**

GSK Clinical Disclosure Advisor

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 09/11/2020

Actual: 09/11/2020

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**Study start date**

Planned: 17/03/2022

Actual: 18/02/2022

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**Date of final study report**

Planned: 31/12/2031

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

ViiV Healthcare

# Study protocol

[viiv-215163-protocol-orig-redact.pdf](#) (1.03 MB)

## 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)

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

1. Describe maternal characteristics by timing of 1st CAB exposure in relation to estimated date of conception;
2. Est. frequency of adverse pregnancy and neonatal outcomes, by timing of 1st

CAB exposure;

3. Est. perinatal transmission rates in mother-infant pairs;

4. Assess proportion of women who achieve viral suppression by the end of pregnancy, by trimester of exposure.

## Study Design

### **Non-interventional study design**

Cohort

Other

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### **Non-interventional study design, other**

Observational clinical cohort analysis

## Study drug and medical condition

### **Medicinal product name**

VOCABRIA

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

CABOTEGRAVIR

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### **Anatomical Therapeutic Chemical (ATC) code**

(J05AX) Other antivirals

Other antivirals

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### **Medical condition to be studied**

Human immunodeficiency virus transmission

## Population studied

## **Age groups**

- Preterm newborn infants (0 – 27 days)
  - Term newborn infants (0 – 27 days)
  - 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**

Pregnant women

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## **Estimated number of subjects**

0

# Study design details

## **Outcomes**

- Demographic, clinical and immunological characteristics, co-infections, timing of CAB LA initiation, other ARVs used in the regimen;
  - No. with adverse pregnancy outcome, infants with adverse neonatal outcome, with perinatal transmission rates in mother-infant pairs, percentage achieving viral suppression.
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## **Data analysis plan**

Frequency distributions for categorical variables and summary measures for continuous variables will be used for descriptive analyses. For rates, 95% confidence intervals will be calculated. The unit of analysis will vary depending on outcome and multiple gestations will be taken into account where

appropriate.

Descriptive analyses will include the whole study population. Analyses for preterm and low birth weights will be restricted to live singleton births, birth defects will be estimated among live births, maternal viral suppression estimates will be restricted to women delivering live or stillborn infants, and vertical transmission analyses will be limited to live-born infants.

There will be four analyses: the first analyses when the number of pregnant women exposed to CAB containing regimen in the cohorts reaches 25, followed by two more analyses when the study pop reaches 100 and 200 pregnancies. A final analysis will be done 12 months after the 3rd analysis.

## 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

European Pregnancy and Paediatric HIV Cohort Collaboration (EPPICC)

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### 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