

# DOLOMITE NEAT ID Network Study: A prospective, multi-site observational study to define the safety and effectiveness of Dolutegravir use in HIV positive pregnant women (208759)

**First published:** 30/05/2018

**Last updated:** 17/09/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS24237

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### Study ID

41940

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### DARWIN EU® study

No

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### Study countries

 Belgium

 France

-  Italy
  -  Poland
  -  Portugal
  -  Spain
  -  Ukraine
  -  United Kingdom
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## Study status

Ongoing

## Research institutions and networks

### Institutions

#### ViiV Healthcare

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

**Last updated:** 01/02/2024

Institution

## Contact details

### Study institution contact

GSK Clinical Disclosure Advisor [Pharma.CDR@gsk.com](mailto:Pharma.CDR@gsk.com)

Study contact

[Pharma.CDR@gsk.com](mailto:Pharma.CDR@gsk.com)

### Primary lead investigator

# GSK Clinical Disclosure Advisor

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 20/11/2017

Actual: 20/11/2017

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### Study start date

Planned: 18/11/2019

Actual: 18/11/2019

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### Date of final study report

Planned: 30/09/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Viiv Healthcare

## Study protocol

[viiv-208759-protocol-redact.pdf](#) (249.71 KB)

[viiv-208759-protocol1-redact.pdf](#) (1.55 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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#### **Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

#### **Data collection methods:**

Primary data collection

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

To describe pregnancy and birth outcomes of pregnant women taking dolutegravir.

## Study Design

## **Non-interventional study design**

Cohort

Other

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

Prospective patient-based data collection

# Study drug and medical condition

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

ABACAVIR

DOLUTEGRAVIR

LAMIVUDINE

RILPIVIRINE

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## **Medical condition to be studied**

Human immunodeficiency virus transmission

# Population studied

## **Age groups**

- 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**

### **Estimated number of subjects**

250

## **Study design details**

### **Outcomes**

Pregnancy outcomes include spontaneous abortion, induced abortion, still births, multiple births, type of delivery and maternal viral load (VL) at delivery. Birth outcomes include birth defects and other routinely collected data at birth such as gestational age, birth weight, APGAR score and infant's HIV status. To provide descriptive analysis of all drug related AEs and SAEs related with the regimen used. To describe rate of DTG discontinuation in pregnant women, including reasons and VL at discontinuation and viral suppression during each of the trimesters where possible.

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### **Data analysis plan**

Descriptive statistics will be generated for the following:

- Characteristics
- ARV history and concomitant medication
- Comorbidities
- Trimester of DTG initiation and exposure
- Drug related AEs and SAEs
- Incidence of DTG discontinuation
- VL in each trimester, at delivery and at DTG discontinuation
- Maternal and child outcomes

Analyses will be conducted to assess if there are any associations between DTG

exposure and outcomes for pregnancy and birth using Logistic regression and Cox proportional-hazards models. Potential confounding factors will be included to determine whether they change the odds ratio (OR) or the hazard ratio (HR) for DTG exposure by at least 10% in any of the models.

## 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

NEAT-ID Network

## 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