

# Prenatal Exposure to Dolutegravir and Pregnancy and Neonatal Outcomes: Data from Antiretroviral Pregnancy Registry (206242)

**First published:** 21/06/2016

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

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS13840

---

### Study ID

47350

---


### DARWIN EU® study


No


---


### Study countries


 Argentina


 Australia


 Brazil


 Canada

 Ethiopia

 Israel

 Puerto Rico

 Russian Federation

 United Kingdom

 United States

---

## Study description

Descriptive analysis of prospectively collected data from the APR on prenatal exposure to dolutegravir

---

## 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

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: 13/06/2016

Actual: 13/06/2016

---

**Study start date**

Planned: 12/08/2016

Actual: 11/08/2016

---

**Date of interim report, if expected**

Planned: 01/06/2017

Actual: 09/10/2017

---

**Date of final study report**

Planned: 31/03/2031

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

ViiV Healthcare

## Study protocol

[gsk-206242-protocol-redact.pdf](#) (174.75 KB)

## Regulatory

**Was the study required by a regulatory body?**

No

---

**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Other

**If 'other', further details on the scope of the study**

Descriptive analysis

**Main study objective:**

1. To describe the demographic and clinical characteristics of pregnant women exposed to dolutegravir (DTG) (Tivicay & Triumeq)
2. To assess the frequency of birth defects among neonates, with prenatal exposure to DTG (Tivicay & Triumeq)
3. To describe non-defect pregnancy outcomes among live birth

## Study Design

**Non-interventional study design**

Other

---

**Non-interventional study design, other**

Descriptive analysis

## Study drug and medical condition

**Medicinal product name**

TIVICAY

TRIUMEQ

---

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

ABACAVIR

DOLUTEGRAVIR

LAMIVUDINE

---

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

(J05AR13) lamivudine, abacavir and dolutegravir

lamivudine, abacavir and dolutegravir

(J05AJ03) dolutegravir

dolutegravir

---

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

Human immunodeficiency virus transmission

## Population studied

### **Age groups**

- **Adult and elderly population (≥18 years)**

- Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)
- 

### **Special population of interest**

Pregnant women

---

### **Estimated number of subjects**

1

## Study design details

## Outcomes

Outcomes of interest are live births, still births, induced abortion, spontaneous abortion, birth defects, low birth weight (LBW), very low birth weight (VLBW) and preterm births.

---

## Data analysis plan

Demographic and clinical characteristics of the pregnant women will be tabulated. Frequency assessment of birth defects will be done among all live births.

## 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

Antiretroviral Pregnancy Registry (APR), United States

---

### Data sources (types)

[Other](#)

---

### Data sources (types), other

Prospective patient-based data collection, Prospective pregnancy registry

## 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**

No