

# An evaluation of weight gain in patients treated with dolutegravir and other core agents (209025)

**First published:** 05/03/2019

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS28753

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### Study ID

42179

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study status

Finalised

## Research institutions and networks

## Institutions

### ViiV Healthcare

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

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Institution

## Contact details

### Study institution contact

GSK Clinical Disclosure Advisor 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 GSK Clinical Disclosure  
Advisor

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 17/07/2018

Actual: 17/07/2018

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**Study start date**

Planned: 21/03/2019

Actual: 08/03/2019

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**Data analysis start date**

Actual: 10/04/2019

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**Date of final study report**

Planned: 31/01/2020

Actual: 30/01/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

ViiV Healthcare

## Regulatory

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

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition  
Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Other

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

Observational cohort analysis

**Data collection methods:**

Combined primary data collection and secondary use of data

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**Main study objective:**

To describe the baseline demographic and clinical characteristics of ART-naïve and ART-experienced people living with HIV (PLWH) initiating DTG vs other core ART agents, and to quantify and compare rates between ART-naïve and ART-experienced patients initiating DTG vs. other core agents including change in weight and body mass index (BMI)

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

DOLUTEGRAVIR

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## **Medical condition to be studied**

Human immunodeficiency virus transmission

## Population studied

### **Short description of the study population**

ART-naïve and ART-experienced people living with HIV (PLWH) initiating DTG vs other core ART agents.

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### **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**

Immunocompromised

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### **Estimated number of subjects**

15000

## Study design details

### **Data analysis plan**

A linear mixed models method with an unstructured or exchangeable correlation structure and robust standard errors to assess differences in BMI/weight associated with antiretroviral medications accounting for within-subject correlations between repeated measures and confounding covariates will be used

## 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)

[Administrative healthcare records \(e.g., claims\)](#)

[Other](#)

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### Data sources (types), other

Prospective patient-based data collection, CNICS - Prospectively collected electronic medical record data

## 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