

# Frequency of HIV diagnoses among people using oral and LA PrEP (223555)

**First published:** 21/11/2024

**Last updated:** 12/06/2026

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000371

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### Study ID

1000000371

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study description

The purpose of the study is to understand patterns of PrEP use among people who acquire HIV to improve public health and clinical practice.

This study will also provide crucial real-world evidence on HIV acquisition on

PrEP, PrEP coverage, HIV testing and sexually transmitted infection (STI) screening in individuals receiving either oral or LA PrEP. Analysis is based on the OPERA cohort.

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### **Study status**

Ongoing

## Contact details

### **Study institution contact**

Call Center EU GSK Clinical Trials RD.CTT-  
globalmailbox@gsk.com

**Study contact**

[RD.CTT-globalmailbox@gsk.com](mailto:RD.CTT-globalmailbox@gsk.com)

### **Primary lead investigator**

Call Center EU GSK Clinical Trials

**Primary lead investigator**

## Study timelines

### **Date when funding contract was signed**

Planned: 28/06/2024

Actual: 28/06/2024

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### **Study start date**

Planned: 06/12/2024

Actual: 22/11/2024

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### **Date of final study report**

Planned: 31/07/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

ViiV Healthcare

## Study protocol

[OPERA\\_CAB PrEP\\_Oral and LA PrEP HIV Diagnoses\\_Final Protocol Anonymised 23 Oct 2024.pdf](#) (1.75 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)?**

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:**

Disease epidemiology  
Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Study design:**

A cohort study using secondary data from the OPERA (Observational Pharmacology Epidemiology Research & Analysis) cohort

**Main study objective:**

To assess the annual incidence of HIV diagnoses among all people without HIV in current study.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

APRETUDE

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

CABOTEGRAVIR

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**Anatomical Therapeutic Chemical (ATC) code**

(J05AJ04) cabotegravir

cabotegravir

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**Medical condition to be studied**

HIV infection

## Population studied

**Short description of the study population**

(Obj 1) People in OPERA aged  $\geq 18$  years with  $\geq 1$  clinical encounter during the calendar year of interest and no evidence of prior HIV diagnosis.

(Obj 1a) People with an incident HIV diagnosis identified in Obj 1.

(Obj 2-5) People without HIV in OPERA aged  $\geq 18$  years who initiated any new PrEP formulation during the study period with or without prior PrEP use.

(Obj 6) People without HIV in OPERA aged  $\geq 18$  years who could benefit from PrEP and are not on PrEP

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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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### **Estimated number of subjects**

23000

## Study design details

### **Setting**

OPERA is a multi-site observational database collecting data prospectively from the complete electronic health records (EHR) from clinical care throughout the US.

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### **Outcomes**

- Annual number of new HIV diagnoses
  - PrEP use, characteristics among people with an incident HIV diagnosis
  - Characteristics of people who initiate oral and LA PrEP
  - Incidence of HIV diagnoses following oral/LA PrEP initiation
  - Days with an oral PrEP prescription and LA PrEP coverage
  - Frequency of HIV testing and STI screening at oral/LA PrEP initiation
  - Characteristics among people who could benefit from PrEP
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### **Data analysis plan**

The analysis will be performed on OPERA cohort using secondary data from electronic medical records.

## 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

OPERA cohort

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### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

## 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