

# Drug Utilization, Adherence, Effectiveness and Resistance: A Prospective Observational Cohort Study in People living with HIV (PLWH) initiating ARV regimen CAB+RPV LA in Collaboration with EuroSIDA (215161)

**First published:** 26/08/2021

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

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS42556

---

### Study ID

46179

---

### DARWIN EU® study

No

---

### Study countries

- Albania
- Argentina
- Austria
- Belarus
- Belgium
- Bosnia and Herzegovina
- Croatia
- Czechia
- Denmark
- Estonia
- Finland
- France
- Georgia
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Israel
- Italy
- Lithuania
- Luxembourg
- Netherlands
- North Macedonia
- Norway
- Poland
- Portugal
- Romania
- Russian Federation
- Serbia

- Slovenia
  - Spain
  - Sweden
  - Switzerland
  - Ukraine
  - United Kingdom
- 

### **Study description**

This prospective cohort study will aim to better understand the population receiving CAB and/or RPV LA containing regimens in a real-world clinical setting. The study will assess usage patterns, adherence, clinical effectiveness and monitor for resistance among virologic failures for whom data on resistance testing are available.

---

### **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: 11/12/2020

Actual: 11/12/2020

---

### **Study start date**

Planned: 01/09/2021

Actual: 28/08/2021

---

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

Planned: 30/09/2027

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

## Study protocol

[viiv-215161-protocol-redact.pdf](#) (1.89 MB)

[EuroSIDA\\_Drug Utilization Study CAB+RPV LA\\_Protocol Amendment 1 Anonymised 16 May 2025.pdf](#) (1.93 MB)

## Regulatory

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

Yes

---

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

EU RMP category 1 (imposed as condition of marketing authorisation)

---

### **Regulatory procedure number**

Cabotegravir - EMEA/H/4976 Rilpivirine - EMEA/H/5060

## Methodological aspects

### Study type

### Study type list

### **Study topic:**

Disease /health condition

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

**Study design:**

This observational study aims to assess usage patterns, durability, discontinuation, and virologic outcomes following initiation of any antiretroviral (ARV) regimen containing CAB and/or RPV LA among PLWH in collaboration with EuroSIDA study.

**Main study objective:**

- Describe CAB LA and/or RPV LA containing regimens usage patterns
- Assess adherence, durability and discontinuation for persons starting regimen
- Assess the clinical effectiveness among PLWH who initiate regimen
- Monitor for resistance and next treatment response among individuals who switched off regimen
- Evaluate the effectiveness of routine risk minimization measures of regimen

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

EDURANT  
REKAMBYS  
REKAMBYS  
REKAMBYS  
VOCABRIA  
VOCABRIA  
VOCABRIA  
VOCABRIA

---

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

CABOTEGRAVIR  
RILPIVIRINE  
RILPIVIRINE HYDROCHLORIDE

---

**Anatomical Therapeutic Chemical (ATC) code**

(J05AG05) rilpivirine  
rilpivirine  
(J05AX) Other antivirals  
Other antivirals

---

**Medical condition to be studied**

Human immunodeficiency virus transmission

## Population studied

**Short description of the study population**

People living with HIV (PLWH) aged 18 years and older were included in the study

---

## **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)
- 

## **Estimated number of subjects**

1000

## **Study design details**

### **Outcomes**

- Regimen discontinuation
  - Durability
  - Adherence
  - Clinical effectiveness
  - Resistance testing
- 

### **Data analysis plan**

Descriptive analyses will summarize the study population exposed to CAB and/or RPV LA. Proportions and multivariable regression models will be used to assess adherence, discontinuation, virologic failure, and resistance among participants with virologic failure for whom data on resistance testing are available.

## **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**

EuroSIDA (34 European countries, and Israel and Argentina)

---

### **Data sources (types)**

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

## 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