

# 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

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Study

Ongoing

## Administrative details

### EU PAS number

EUPAS42556

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### Study ID

46179

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### DARWIN EU® study

No

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### **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
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### 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.

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### Study status

Ongoing

## Research institutions and networks

### Institutions

ViiV Healthcare

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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: 11/12/2020

Actual: 11/12/2020

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**Study start date**

Planned: 27/08/2021

Actual: 28/08/2021

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**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

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

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

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**Regulatory procedure number**

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

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**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

**Name of medicine**

EDURANT 25 MG - FILM-COATED TABLET

REKAMBYS

REKAMBYS 600 MG - PROLONGED-RELEASE SUSPENSION FOR INJECTION

REKAMBYS 900 MG - PROLONGED-RELEASE SUSPENSION FOR INJECTION

VOCABRIA

VOCABRIA 30 MG - FILM-COATED TABLET

VOCABRIA 400 MG - PROLONGED-RELEASE SUSPENSION FOR INJECTION

VOCABRIA 600 MG - PROLONGED-RELEASE SUSPENSION FOR INJECTION

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

CABOTEGRAVIR

RILPIVIRINE

RILPIVIRINE HYDROCHLORIDE

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**Anatomical Therapeutic Chemical (ATC) code**

(J05AG05) rilpivirine

rilpivirine

(J05AX) Other antivirals

Other antivirals

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**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

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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**

1000

# Study design details

## **Outcomes**

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

## Data sources



**Data source(s), other**

EuroSIDA (34 European countries, and Israel and Argentina)

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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