CABFIDENCE: Global Real-World Evidence Cohort Study to evaluate Utilization, Clinical and Patient-Reported Outcomes among CAB+RPV LA users (224047)

First published: 12/06/2025

Last updated: 08/10/2025

Study Planned

Administrative details

EU PAS number

EUPAS1000000616

Study ID

1000000616

DARWIN EU® study

No

Study countries

- ☐ Australia
- ☐ France
- ☐ Germany

- [ ] Italy
- [ ] Portugal
- [ ] Spain
- [ ] United Kingdom
- [ ] United States

Study status

Planned

Research institutions and networks

Institutions

ViiV Healthcare

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Institution

Contact details

Study institution contact

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

Study contact

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: 31/12/2024

Actual: 06/12/2024

Study start date
Planned: 30/11/2025

Date of final study report
Planned: 31/10/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

CABFIDENCE CAB+RPV LA Global RWE Study_Final Protocol Disclosure Anonymised 30 May 2025.pdf (593.31 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:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Evaluation of patient-reported outcomes

Other

Safety study (incl. comparative)

If ‘other’, further details on the scope of the study

Persistence, Adherence

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

This observational study will assess the utilization patterns, adherence, persistence, discontinuation, virologic effectiveness, and patient-reported outcomes of CAB+RPV LA in a real-world clinical setting.

Main study objective:

• To describe baseline demographics, clinical characteristics and patterns of use among individuals receiving CAB+RPV LA

• To assess the persistence, discontinuation, and adherence among individuals receiving CAB+RPV LA

• To assess virologic effectiveness among individuals receiving CAB+RPV LA

• To assess factors associated with confirmed virologic failure (CVF) among individuals receiving CAB+RPV LA regimen

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

VOCABRIA

EDURANT

Name of medicine, other

Cabenuva

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

CABOTEGRAVIR

RILPIVIRINE

Anatomical Therapeutic Chemical (ATC) code

(J05AJ04) cabotegravir

cabotegravir

(J05AG05) rilpivirine

rilpivirine

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

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)

Estimated number of subjects

1000

Study design details

Outcomes

• Persistence

• Discontinuation

• Adherence

• Virologic effectiveness

• Resistance

• ART regimen after discontinuation /CVF

• Safety outcomes (ISR and HSR)

• Health-related quality of life

• Treatment-related stigma, and benefits

• Reasons for initiating CAB+RPV LA

• Reasons for discontinuing CAB+RPV LA

• Reasons for missed injection(s)

Data analysis plan

Baseline characteristics and outcomes will be described using counts and relative frequencies for categorical variables. Continuous variables will be summarized using summary statistics (means, standard deviations, medians, minimums, maximums, and quartiles 1 and 3).

For event outcomes assessed at any point during follow-up, incidence rates will be estimated using unadjusted Poisson regression, accounting for person-time since index (i.e., first CAB+RPV LA injection).

Additional analytic approaches may also be considered (e.g., Kaplan-Meir estimator/curve). Analyses will be stratified by BMI (< 30 kg/m^2 vs. ≥ 30 kg/m^2), age (18-50, 50-64, ≥ 65 years), sex assigned at birth (female, male) and race and ethnicity, and country, if sample sizes allow, at initiation of CAB+RPV LA regimen.
Factors associated with CVF will be assessed using a logistic regression model.
Participant surveys will be summarized descriptively for item and summary score (where applicable).
The World Health Organization Quality of Life-Human Immunodeficiency Virus BREF (WHOQOL-HIV BREF) will be scored according to instrument scoring guidelines and derived scores will be summarized descriptively.

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

Participant surveys

Participant medical information via site-completed electronic case report form (eCRF)

Data sources (types)

Electronic healthcare records (EHR)

Patient surveys

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes