

# Abacavir Usage Patterns and Trends in Hypersensitivity Reactions (HSR) in the EuroSIDA cohort (206307)

**First published:** 22/02/2017

**Last updated:** 18/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS17919

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### Study ID

48247

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### DARWIN EU® study

No

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### Study countries

- Argentina
- Austria
- Belarus
- Belgium

- Bulgaria
  - Croatia
  - Denmark
  - Estonia
  - Finland
  - France
  - Germany
  - Greece
  - Hungary
  - Ireland
  - Israel
  - Italy
  - Latvia
  - Lithuania
  - Luxembourg
  - Netherlands
  - Norway
  - Poland
  - Portugal
  - Romania
  - Russian Federation
  - Serbia
  - Slovakia
  - Spain
  - Sweden
  - Switzerland
  - Ukraine
  - United Kingdom
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### **Study status**

Finalised

## 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 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: 28/10/2016

Actual: 28/10/2016

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**Study start date**

Planned: 24/02/2017

Actual: 23/02/2017

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**Data analysis start date**

Planned: 24/02/2017

Actual: 23/02/2017

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**Date of final study report**

Planned: 11/07/2017

Actual: 18/08/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

ViiV Healthcare

## Study protocol

[viiv-206307-protocol-redact.pdf](#) (392.93 KB)

## 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:**

Secondary use of data

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**Main study objective:**

To describe treatment utilization patterns of abacavir (ABC) and to describe the cumulative frequency, incidence and factors associated with ABC discontinuation due to any reason and due to hypersensitivity reactions (HSR) among persons initiating ABC as part of a cART regimen after 1/1/2009

### Study Design

## **Non-interventional study design**

Cohort

Other

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## **Non-interventional study design, other**

Retrospective analysis

# Study drug and medical condition

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

ABACAIVIR

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## **Medical condition to be studied**

Human immunodeficiency virus transmission

# Population studied

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

Patients aged 16 years or older living with HIV and HIV/Hepatitis C co-infection receiving combination antiretroviral therapy (cART) identified from the EuroSIDA cohort.

Inclusion criteria:

- Individuals from the EuroSIDA cohort over the age of 16 at enrolment receiving cART (at least 3 drugs from any class, excluding ritonavir) at some point after 1/1/2009 will be eligible for inclusion (Objective 1). Objective 2 will further require all individuals to have initiated ABC after 1/1/2009.
  - Drug exposure prior to EuroSIDA enrolment cannot be assessed, and will not be considered for the inclusion criteria.
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## **Age groups**

- Adolescents (12 to < 18 years)
  - 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

Other

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## **Special population of interest, other**

Patients with HIV transmission

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## **Estimated number of subjects**

20000

# Study design details

## **Outcomes**

Receipt of ABC and ABC discontinuation

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## **Data analysis plan**

- Descriptive statistics will be used to summarize outcomes of interest and risk factors as appropriate
- Baseline characteristics will be compared among patients who remain on ABC, discontinue due to any reason, and discontinue due to HSR using chi-squared tests/Fisher's exact test and Kruskal-Wallis tests as appropriate
- Factors associated with ABC initiation and HSR-related discontinuation will be investigated using Poisson models with generalized

estimating equations to control for inclusion of repeated events• Cumulative frequencies of time to discontinuation for any reason and due to HSR will be calculated using survival methods and displayed in KM plots• Sensitivity analyses will be conducted for all discontinuations of ABC occurring within the first 6 weeks and reported to be due to any toxicity

## Documents

### Study results

[viiv-206307-clinical-study-report-redact.pdf](#) (1.94 MB)

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## 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)

[Other](#)

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### Data sources (types), other

Prospective observational cohort study

## 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