

# Rates of Suspected Hypersensitivity Reaction to Abacavir and Associated Rates of HLA-B\*5701 Testing (206206)

**First published:** 21/07/2016

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS14290

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### Study ID

42114

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study description

Rates of suspected hypersensitivity reaction (HSR) associated with the use of abacavir (ABC) and associated rates of HLA-B\*5701 testing in HIV positive patients living in the U.S. who have been exposed to ABC as part of an antiretroviral therapy (ART) regimen will be evaluated utilizing prospectively-collected electronic medical record (EMR) data obtained from the Observational Pharmaco-Epidemiology Research & Analysis (OPERA®) Observational Database

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### ViiV Healthcare

**First published:** 01/02/2024

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Institution

## Contact details

### Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure  
Advisor Pharma.CDR@gsk.com

Study contact

**Primary lead investigator**

GSK Clinical Disclosure Advisor GSK Clinical Disclosure  
Advisor

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 14/06/2016

Actual: 14/06/2016

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**Study start date**

Planned: 29/07/2016

Actual: 23/07/2016

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**Data analysis start date**

Planned: 29/07/2016

Actual: 23/07/2016

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**Date of final study report**

Planned: 30/03/2018

Actual: 30/05/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

ViiV Healthcare

## Study protocol

[viiv-206206-protocol-redact.pdf](#) (141.35 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 the baseline demographic and clinical characteristics of HIV+ patients initiating an abacavir-based ART regimen, the annual incidence rates and cumulative frequencies of HLA-B\*5701 testing, and the annual incidence rates and cumulative frequencies of suspected hypersensitivity reaction among abacavir-exposed patients before and after June 15, 2008.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Descriptive analysis

## Study drug and medical condition

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

ABACAVIR

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### **Medical condition to be studied**

Human immunodeficiency virus transmission

## **Population studied**

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

The study sample will be identified from the OPERA Observational Database for analysis. HIV-1 positive patients initiating abacavir-containing treatment for the first time between 1/1/1999 and 1/1/2016 will be included in the study sample if they meet the following inclusion criteria:

- 1) At least 13 years of age at the index date.
  - 2) Continuous clinical activity in the year prior to abacavir initiation, defined as at least one clinic visit.
  - 3) Continuous clinical activity in the year following abacavir initiation, defined as at least one clinical contact (visit or telephone contact).
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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**

### **Estimated number of subjects**

16000

## Study design details

### **Outcomes**

- Diagnosis of suspected hypersensitivity reaction to abacavir (HSR) • Documentation of HLA-B\*5701 testing and timing of the test (before or after starting ABC containing regimen) • Exposure to abacavir post positive HLA testing
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### **Data analysis plan**

Descriptive analyses will be performed for demographic and clinical variables of interest. Multivariable analyses will be used to produce rates of suspected HSR diagnoses by HLA time period.

## Documents

### **Study results**

[viiv-206206-clinical-study-report-redact.pdf](#) (5.94 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)

[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