

# Observational Safety Data Analysis from Routine Follow-up in the EuroSIDA Study of Patients Treated with Raltegravir in a Five-Year Post Authorization Period (MK-0518-058)

**First published:** 28/04/2017

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

Study

Finalised

## Administrative details

### EU PAS number

EUPAS17912

### Study ID

18914

### DARWIN EU® study

No

### Study countries

- Argentina
- Austria

- Belarus
- Belgium
- Bulgaria
- Croatia
- Czechia
- 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 description

The purpose of this data analysis is to continue to monitor the safety of raltegravir post-licensure in accordance with the product-specific Risk Management Plan. The main objective of the study was to monitor health outcomes associated with antiretroviral drugs in a population of HIV-infected patients.

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### Study status

Finalised

## Research institutions and networks

### Institutions

#### [Merck Sharp & Dohme LLC](#)

United States

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**Institution**

**Pharmaceutical company**

[Multiple centres: 33 centres are involved in the study](#)

### Networks

# EuroSIDA Study Group

## Contact details

### **Study institution contact**

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

[ClinicalTrialsDisclosure@merck.com](mailto:ClinicalTrialsDisclosure@merck.com)

[Study contact](#)

[ClinicalTrialsDisclosure@merck.com](mailto:ClinicalTrialsDisclosure@merck.com)

### **Primary lead investigator**

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

[Primary lead investigator](#)

## Study timelines

### **Date when funding contract was signed**

Actual: 08/04/2008

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### **Study start date**

Actual: 05/05/2008

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### **Data analysis start date**

Actual: 06/03/2014

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

Actual: 06/03/2014

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## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Merck & Co., Inc

## 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 3 (required)

## Other study registration identification numbers and links

NCT01078233

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The overall objective of this analysis is to investigate the incidence of clinically important medical events following treatment with raltegravir. Incidence rates of medical events and all cause mortality will be determined for raltegravir recipients over the duration of raltegravir exposure and among both a historical and concurrent comparison group.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Retrospective analysis of prospective cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(J05AR) Antivirals for treatment of HIV infections, combinations

Antivirals for treatment of HIV infections, combinations  
(J05AX08) raltegravir  
raltegravir

## Population studied

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

All HIV-infected patients who are 16 years or older and report initiating treatment with raltegravir in the study cohort during the analysis period from 93 clinical centers in 31 European countries, Argentina and Israel.

Patients were included in the RAL patient cohort who:

- started RAL for the first time on or after the 21 December 2007 (RAL authorisation date in the European Union).
- had at least 1 month's prospective follow-up in this cohort.
- had a CD4 count and a viral load measured within 6 months prior to the start date of RAL.

Patients were included in the historical comparison cohort who:

- started a new antiretroviral drug as part of a cART regimen on or after the 1 January 2006 and before 21 December 2007. The patient must have had no previous exposure to the new drug, including as part of a different co-formulation, e.g. if zidovudine (ZDV) had been previously received as part of Combivir and the patient started Trizivir, ZDV would not be counted as a new drug.
- had at least 1 month's prospective follow-up in this cohort.
- had a CD4 count and a viral load measured within 6 months prior to the start date of the new drug.

Patients were included in the concurrent cohort not taking RAL who:

- started a new antiretroviral drug other than RAL as part of a cART regimen on or after the 21 December 2007. The patient must have had no previous exposure

to the new drug, including as part of a different co-formulation.

- had at least 1 month's prospective follow-up in this cohort.
- had a CD4 count and a viral load measured within 6 months prior to the start date of the new drug

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### **Age groups**

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

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### **Special population of interest**

Immunocompromised

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### **Estimated number of subjects**

6617

## **Study design details**

### **Outcomes**

1. Incidence of malignancy in patients treated with raltegravir2. Incidence of clinically important hepatic events in patients treated with raltegravir3. Incidence of lipodystrophy in patients treated with raltegravir4. Incidence of all-cause mortality in patients treated with raltegravir, 1. Incidence of malignancy in a post-licensure concurrent comparison cohort2. Incidence of clinically important hepatic events in a post-licensure concurrent comparison cohort3. Incidence of lipodystrophy in a post-licensure concurrent comparison cohort4.

Incidence of all-cause mortality in a post-licensure concurrent comparison cohort

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### **Data analysis plan**

Incidence rates, and 95% confidence intervals of each pre-specified medical events were tabulated. Multivariate regression was used to compare the incidence rates of raltegravir versus the historical comparison group. Rate ratios (RR) of adverse events were calculated, and regression models that incorporate propensity scores were used to adjust simultaneously for the potentially confounding effects of selected variables and comparison group characteristics using Poisson regression. Descriptive statistics will be used to describe the heterogeneity in the treatment experience and treatment failure history of raltegravir patients at initiation of therapy.

## **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 database

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## **Data sources (types)**

Other

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### **Data sources (types), other**

Prospective patient-based data collection

## 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

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## Data characterisation

### **Data characterisation conducted**

No