

# Monitoring the safety of alirocumab in HIV patients: A Post-Authorization Safety Study Using Healthcare Databases

**First published:** 17/01/2017

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS17314

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### Study ID

49411

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### DARWIN EU® study

No

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### Study countries



United States

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### Study description

This study is a retrospective cohort study using existing healthcare databases. The objective of this post-marketing study is to monitor muscle events, and liver function and creatine kinase abnormalities in HIV patients treated with alirocumab by quantifying the incidences of these safety outcomes using existing healthcare databases. Two databases, the Clinformatics DataMart and the MarketScan databases in the US, will be used in this study. The study period will be from July 25, 2015 to September 30, 2020. The main study cohort will consist of new users of alirocumab with HIV infection during the study period. The comparison cohort will consist of new users of a statin or ezetimibe with HIV infection. Patients will be followed till the occurrence of outcomes of interest, which are -Serious muscle events, abnormal liver function and abnormal creatine kinase values, end of index treatment episode, end of eligibility in the database, or end of the study period. For each outcome of interest, the incidence rate (cases per 1,000 person-years) and their 95% confidence intervals (CI) will be calculated for the matched cohorts.

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## Study status

Finalised

## Research institutions and networks

### Institutions

Sanofi

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Institution

## Contact details

### Study institution contact

Trial Transparency Team Trial Transparency Team contact-us@sanofi.com

Study contact

[contact-us@sanofi.com](mailto:contact-us@sanofi.com)

### Primary lead investigator

Trial Transparency Team Trial Transparency Team

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 21/12/2015

Actual: 21/12/2015

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### Study start date

Planned: 30/09/2017

Actual: 30/09/2017

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### Date of final study report

Planned: 30/09/2022

Actual: 29/09/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Sanofi and Regeneron

## Study protocol

[rdct-aliroc07997-protocol-pdfa.pdf](#) (499.31 KB)

## 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

ALIROC07997

## 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:**

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The objective of this post-authorization safety study is to monitor muscle events, and liver function and creatine kinase abnormalities in HIV patients treated with alirocumab by assessing the incidences of these safety outcomes using existing healthcare databases.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

## **Medical condition to be studied**

HIV infection

## **Population studied**

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

Adult patients with HIV infection receiving alirocumab and other lipid-lowering treatments identified from the study period of 25 July 2015, utilizing data source from the Optum Clinformatics DataMart (Optum CDM) and the Truven Health MarketScan (MarketScan).

Inclusion criteria:

- A new prescription of a statin or ezetimibe in the study period
- HIV infection confirmed by the presence of relevant diagnosis codes (Appendix 1) prior to the index date

Exclusion criteria:

- Age < 18 years
- No continuous enrollment with prescription and medical coverage in the database for the 180-day period prior to the index date
- Use of the same index drug prior to the index date
- Use of any PCSK-9 inhibitors prior to the index date

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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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### **Special population of interest**

Immunocompromised

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### **Estimated number of subjects**

765

## Study design details

### **Outcomes**

Serious muscle events: rhabdomyolysis, myositis and myopathy  
Abnormal liver function: ALT and AST elevation > 5 times above the upper limit of normal value, total bilirubin and alkaline phosphatase elevation > 2 and > 1.5 times above the upper limits of normal value, respectively  
Abnormal creatine kinase: elevation > 10 times above the upper limit of normal value

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### **Data analysis plan**

Patients in the alirocumab cohort and those in the other lipid-lowering drug cohort will be matched on the propensity of being treated with alirocumab at a 1:1 ratio using greedy matching. Proportion and means will be used to summarize the categorical and continuous variables (demographic and baseline characteristics), respectively, for the alirocumab and the other drug cohorts both prior to and after the propensity matching. For each outcome of interest, the overall incidence rate (cases per 1,000 person-years) and its 95% confidence interval (CI) in each database will be calculated using the data of the matched cohorts. Kaplan-Meier curves will be used to display the risk of each outcome over time.

## Documents

## Study results

[rdct-aliroc07997-csr abstract-pdfa.pdf](#) (235.35 KB)

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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)

[Administrative healthcare records \(e.g., claims\)](#)

## 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