

# A drug utilization study (DUS) of alirocumab in Europe to assess the effectiveness of the dosing recommendation to avoid very low LDL-C levels

**First published:** 17/10/2017

**Last updated:** 14/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS21314

---

### Study ID

43665


---

### DARWIN EU® study

No

---

### Study countries

 Austria


 Belgium

 Germany

 Italy

 Netherlands

 Spain

 United Kingdom

---

## Study description

This is a drug utilization study to evaluate the effectiveness of the alirocumab dosing recommendations for the 3 approved dosage regimens to date, ie, 75 mg every two weeks, 150 mg every two weeks, and 300 mg once every 4 weeks (monthly) to avoid very low LDL C levels. The secondary objective is to describe the pattern of alirocumab utilization in real-world clinical practice with respect to the dosing recommendations in the labelling of the 3 approved dosage regimens to date, ie, 75 mg every two weeks, 150 mg every two weeks, and 300 mg once every 4 weeks (monthly) to avoid very low LDL-C levels.

---

## Study status

Finalised

# Research institutions and networks

## Institutions


**Sanofi**

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

**Last updated:** 01/02/2024

**Institution**

**IQVIA**

 United Kingdom

**First published:** 12/11/2021

**Last updated:** 22/04/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## 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: 06/11/2017

Actual: 06/11/2017

---

### Study start date

Planned: 30/03/2018

Actual: 20/08/2019

---

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

Planned: 30/09/2021

Actual: 10/08/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Sanofi/Regeneron

## Study protocol

[rdct-obs14697-16-1-1-pass-amended-protocol02-PDFA.pdf](#) (839.92 KB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

---

### **Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

## Other study registration identification numbers and links

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Drug utilisation

**Data collection methods:**

Primary data collection

---

**Main study objective:**

The primary objective of this study is to assess the effectiveness of the dosing recommendations for the 3 approved dosage regimens to date. The secondary objective is to describe the pattern of alirocumab utilization in real-world clinical practice

### Study Design

## **Non-interventional study design**

Cohort

# Study drug and medical condition

## **Medicinal product name**

PRALUENT

# Population studied

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

Patients who were initiated with Praluent (brand name of alirocumab), 75 mg once every two weeks, 150 mg once every two weeks, or 300 mg once every 4 weeks (monthly).

### Inclusion criteria

Physicians who meet the following inclusion criterion will be eligible to participate in this study:

I 01. At least one initial prescription of Praluent during the eligibility period.

Eligible patients for retrospective data collection will be those meeting the following criteria:

I 02. Initiated with Praluent following a first prescription during the eligibility period.

I 03. Signed written informed consent, if it is required by the country.

### Exclusion criteria

Physicians who meet one or more of the following exclusion criteria will be excluded from this study:

E 01. Have participated in any randomized clinical trials with Praluent (alirocumab).

E 02. Have participated in a previous wave of this study.

Patients who meet one or more of the following exclusion criteria will be excluded from this study:

E 03. Have participated in any randomized clinical trials with Praluent (alirocumab).

E 04. Medical chart not retrievable, empty or missing

---

### **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)
- 

### **Estimated number of subjects**

890

## **Study design details**

### **Outcomes**

- Occurrence of very low LDL-C levels (both definitions of very low LDL-C <25 mg/dL 0.65 mmol/L and <15 mg/dL 0.39 mmol/L will be presented), - Evolution of LDL-C level after the occurrence of very low LDL-C level, - Change in treatment after the occurrence of very low LDL-C level. - The starting dose of Praluent, - The dosage regimen modification of Praluent, - Timing of LDL-C tests, - Discontinuation of Praluent: reasons will be described, if available, - Reason for Praluent prescription, - Adverse events.

---

### **Data analysis plan**

The following descriptive analyses will be presented on the eligible population:

A. Occurrence of very low LDL-C level A LDL-C level <25 mg/dL (0.65 mmol/L) is defined as very low, and an alternative definition with a cut-off at 15 mg/dL (0.39 mmol/L) will also be used.

B. Evolution of LDL-C level after the occurrence of very low LDL-C level

C. Change in treatment after the occurrence of very low LDL-C level

## Documents

### Study results

[rdct-obs14697-CSR synopsis-PDFA.pdf](#) (331.56 KB)

---

## 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](#)

---

### Data sources (types), other

Data from medical records (either EMRs or paper source files) for each participating patient will be extracted and completed by site personnel and/or trained and authorized external abstractors using an e-CRF.

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

---

### **Check completeness**

Unknown

---

### **Check stability**

Unknown

---

### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No