

# Observational Serial Chart Review of Repatha® Use in European Subjects with Hyperlipidaemia (20130296)

**First published:** 28/04/2016

**Last updated:** 22/02/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/47822>

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### EU PAS number

EUPAS13328

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### Study ID

47822

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### DARWIN EU® study

No

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### Study countries

Austria

- Belgium
  - Bulgaria
  - Germany
  - Greece
  - Italy
  - Poland
  - Portugal
  - Slovakia
  - Spain
  - Sweden
  - Switzerland
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### **Study description**

Review of clinical characteristics of patients who are prescribed Repatha and how their treatment is managed.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

#### Amgen

- United States

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

**Last updated:** 21/02/2024

Multiple centres: 250 centres are involved in the study

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.

Study contact

[medinfo@amgen.com](mailto:medinfo@amgen.com)

### Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 18/12/2015

Actual: 18/12/2015

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### Study start date

Planned: 29/04/2016

Actual: 04/05/2016

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### **Data analysis start date**

Planned: 26/07/2021

Actual: 13/09/2021

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

Planned: 30/05/2022

Actual: 24/05/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen Inc

## Study protocol

[01.20.01 Protocol Ver 1.0 2015-11-19 English.pdf](#)(1.11 MB)

[20130296\\_01.02.06 Public Redacted Protocol Ver 1.0 2018-12-20 English.pdf](#)  
(1.4 MB)

## 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 topic:**

Disease /health condition

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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**

To describe clinical characteristics of subjects using Repatha

**Data collection methods:**

Primary data collection

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**Main study objective:**

To ascertain the clinical characteristics of patients who are prescribed Repatha® in the post-launch period, and how their treatment is managed

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Multicountry, observational, serial chart review

## Study drug and medical condition

## **Medical condition to be studied**

Hyperlipidaemia

## **Population studied**

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

Patients receiving Repatha® as part of routine clinical management of their hyperlipidaemia.

All inclusion criteria need to be met, as follows:

- Adults ( $\geq 18$  years)
- Provided informed consent if applicable according to local requirements
- Initiated on Repatha® at physician's discretion, after 1st August 2015
- Received at least one dose of Repatha®

### **Exclusion Criteria**

If at least one exclusion criterion is met, subject is not eligible for participation in the study, as follows:

- Enrolled in an interventional study of PCSK9 inhibitor within 12 weeks prior to initiation of Repatha®
  - Received commercially available PCSK9 inhibitor within 12 weeks prior to initiation of Repatha®
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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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### **Estimated number of subjects**

2000

## Study design details

### **Outcomes**

To describe the clinical characteristic of subjects at initiation of Repatha®, To describe LDL-C and other cholesterol concentrations over time To described treatment patterns of use of Repatha® over time To describe treatment patterns of use of other lipid modifying therapies over time To describe Health Resource Utilisation components, including hospitalisations and physician visits

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### **Data analysis plan**

All summaries of the data will be descriptive in nature. For categorical variables the frequency and percentage, with 95% confidence interval, will be given. Summary statistics for continuous variables will include the number of subjects, mean, median, standard deviation or standard error, 25th percentile (Q1), 75th percentile (Q3), minimum, and maximum. Regarding the primary endpoints, summaries displaying frequency and percentage, with 95% confidence intervals will be presented for FH status, CV history and diabetic status at the time of initiation of Repatha®, while summary statistics displaying the number of subjects, mean, median, standard deviation, 25th percentile (Q1), 75th percentile (Q3), minimum, and maximum will be presented for LDL-C at the time of initiation of Repatha®. The primary intention is to analyse data for each country separately, but the final analysis will also be conducted for all countries pooled.

## Documents

## Study results

[Observational Research Study Report 20130296\\_Redacted.pdf](#)(147.65 KB)

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## Data management

### Data sources

#### 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

## Data characterisation

**Data characterisation conducted**

No