

# EU-Wide Cross-Sectional Observational Study of Lipid-Modifying Therapy Use in Secondary and Primary Care DA VINCI

**First published:** 06/02/2018

**Last updated:** 19/09/2019

Study

Finalised

## Administrative details

### EU PAS number

EUPAS22075

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### Study ID

31479

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### DARWIN EU® study

No

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### Study countries

- ☐ Austria
- ☐ Belgium
- ☐ Czechia
- ☐ Denmark

- ☐ France
  - ☐ Germany
  - ☐ Greece
  - ☐ Hungary
  - ☐ Ireland
  - ☐ Italy
  - ☐ Netherlands
  - ☐ Poland
  - ☐ Romania
  - ☐ Slovakia
  - ☐ Spain
  - ☐ Sweden
  - ☐ Ukraine
  - ☐ United Kingdom
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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

Institution

Amgen

Multiple centres: 153 centres are involved in the study

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.  
medinfo@amgen.com

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: 17/11/2016

Actual: 17/11/2016

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### Study start date

Planned: 01/06/2017

Actual: 01/06/2017

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### **Data analysis start date**

Planned: 22/02/2019

Actual: 22/02/2019

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

Planned: 19/09/2019

Actual: 16/08/2019

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## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen Ltd.

## Study protocol

[EUPAS22075-23671.pdf](#)(832.58 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

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## Methodological aspects

### Study type

**Study topic:**

Human medicinal product

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**

Characterise unmet medical need

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To estimate the proportion of subjects in EU primary and secondary care, with or without established ASCVD and receiving LMT, with LDL-C above 2016 Joint ESC Guideline recommended levels

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

## **Name of medicine**

REPATHA

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## **Medical condition to be studied**

Ischaemic stroke

Myocardial infarction

Peripheral vascular disorder

Hypercholesterolaemia

## **Population studied**

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

1. Low density lipoprotein-cholesterol (LDL-C) measurement within 14 months of enrolment, obtained independently of participation in a clinical trial
  2. Use of any LMT (may include statin/ezetimibe/fibrate/PCSK9 inhibitor/bile acid absorption inhibitor/nicotinic acid/other) at time of enrolment, or any LMT prescribed within 12 months prior to date of enrolment, or any LMT prescribed at date of enrolment
  3. Age 18 years or older at enrolment
  4. Provided informed consent/notified according to local requirements
  5. Subject expected to survive for at least 1 year after enrolment
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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

6000

## Study design details

### Outcomes

LDL-C measurement most recent to enrolment, Lipid levels (total cholesterol, non-HDL-C, HDL, triglycerides, Lp(a), apo B100, apo A1) most recent to enrolment, use of Lipid-modifying therapy (type, dose, frequency), clinical characteristics at time of enrolment

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### Data analysis plan

All summaries of data will be descriptive in nature: categorical variables in frequency and percentage with 95% confidence intervals and continuous variables in mean (standard deviation) and/or median with percentiles, minimum and maximum.

## Documents

### Study results

[20150333\\_DA VINCI FINAL ORSR abstract 16AUG19 incl PI signature - 120919\\_redacted.pdf](#)(407.3 KB)

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## Data management

## Data sources

## **Data sources (types)**

Other

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

Medical notes (primary and secondary care)

## 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