

# The Cardiovascular Multi-dimensional Observational Investigation of the Use of PCSK9 Inhibitors (20180059) (cvMOBIUS)

**First published:** 10/02/2020

**Last updated:** 13/03/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS32995

### Study ID

36927

### DARWIN EU® study

No

### Study countries

- Canada
- United States

### Study description

The purpose of this registry to evaluate the effectiveness of proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors to reduce cardiovascular events among subjects presenting with a recent atherosclerotic cardiovascular disease (ASCVD) event in real-world practice. A total of 8500 patients with a recent cardiovascular event who are likely to be eligible for non-statin lipid lowering therapy will be enrolled and followed prospectively for five years. In addition, the study will assess longitudinal patterns of lipid control, clinical outcomes, and LTT including statins, ezetimibe, and PCSK9 inhibitors in adults with an ASCVD event and/or revascularization. This study will also compare the clinical characteristics and outcomes of subjects enrolled in both arms of the registry to understand the strengths and limitations of data harvested directly from electronic health record (EHR) systems as compared with prospectively collected information.

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#### **Study status**

Ongoing

## Research institutions and networks

### Institutions

[Amgen](#)

United States

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

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

[Institution](#)

# Duke Clinical Research Institute (DCRI)

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

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**Institution**

## Duke Clinical Research Institute Durham, USA

### Contact details

#### **Study institution contact**

Global Development Leader Amgen Inc.

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**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: 09/07/2018

Actual: 28/01/2019

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**Study start date**

Planned: 13/12/2019

Actual: 06/12/2019

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**Data analysis start date**

Planned: 30/10/2026

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**Date of final study report**

Planned: 05/03/2027

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## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[20180059\\_Public Redacted Protocol Amend 2 English.pdf \(2.98 MB\)](#)

[01.02.06 Public Redacted Protocol Ver 1.0 2019-12-06 English.pdf \(379.26 KB\)](#)

## 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

## **Methodological aspects**

### **Study type**

#### **Study type list**

##### **Study type:**

Non-interventional study

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##### **Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

##### **Main study objective:**

To evaluate the real-world effectiveness of PCSK9 inhibitors to reduce cardiovascular events in routine practice in a prospective cohort of adults presenting with a recent atherosclerotic cardiovascular disease (ASCVD) event and/or revascularization procedure.

## **Study Design**

### **Non-interventional study design**

Cohort

## **Study drug and medical condition**

## **Anatomical Therapeutic Chemical (ATC) code**

(C10AX13) evolocumab

evolocumab

(C10AX14) alirocumab

alirocumab

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## **Medical condition to be studied**

Myocardial infarction

Coronary artery disease

Peripheral arterial occlusive disease

Hyperlipidaemia

Ischaemic stroke

## **Population studied**

### **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**

8500

## **Study design details**

### **Outcomes**

Time to event from baseline for the first of all-cause mortality, any non-fatal myocardial infarction, any non-fatal ischemic stroke, The individual components of the primary endpoint, coronary, peripheral or carotid revascularization procedures, major adverse limb events (MALE) including amputation, cardiovascular death, transient ischemic attack (TIA), unstable angina (UA)

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## **Data analysis plan**

The primary analysis will use a marginal structural model (MSM) approach to evaluate the relative risk of the primary composite outcome (all-cause mortality, non-fatal MI, and non-fatal IS) in PCSK9i users versus non-users, while accounting for the time varying nature of PCSK9i initiation and discontinuation, and factors related to initiation and discontinuation as they change over time. Following the database lock and prior to the primary effectiveness analysis, we will implement a descriptive analysis to evaluate whether baseline characteristics are balanced between users and non-users of PCSK9is. The primary analysis will parallel an on-treatment analysis, where subjects who discontinue PCSK9i will be censored after six months off therapy. Hazard ratios will be output from a Cox proportional hazards model, weighted by inverse probability to treat weights (IPTW) and inverse probability of censoring weights (IPCW). The same approach will be used for the secondary outcomes

## **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)**

Electronic healthcare records (EHR)

Other

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

Prospective patient-based data collection, Electronic health records of enrolled subjects will be obtained from each study site and linked to the prospective registry data.

# 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