

# EVENITY® Risk Minimisation Materials Effectiveness Measurement in Australia (20220120)

**First published:** 13/04/2023

**Last updated:** 13/05/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/106263>

---

### EU PAS number

EUPAS104308

---

### Study ID

106263

---

### DARWIN EU® study

No

---

### Study countries

☐ Australia

---

## Study description

Study to measure the effectiveness of educational materials on awareness, utilization and adequacy targeted to medical professionals in addressing the cardiovascular risks associated with the use of EVENITY.

---

## Study status

Finalised

## Research institutions and networks

### Institutions

Amgen

☐ United States

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

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

Institution

## 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: 01/12/2022

Actual: 01/12/2022

---

### Study start date

Planned: 01/03/2023

Actual: 04/04/2023

---

### Data analysis start date

Planned: 01/05/2023

Actual: 01/05/2023

---

### Date of final study report

Planned: 15/04/2024

Actual: 03/04/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

## Regulatory

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

No

---

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

---

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

Effectiveness study (incl. comparative)

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

The objective of this study is to measure the effectiveness of prescriber guide and patient alert card on awareness, utilization and adequacy targeted to HCPs in addressing the cardiovascular risks (myocardial infarction and stroke).

## Study Design

## Non-interventional study design

Other

---

### Non-interventional study design, other

Study of responses to questionnaires on educational materials by medical professionals in Australia

## Study drug and medical condition

### Name of medicine

EVENITY

---

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

ROMOSUZUMAB

---

### Anatomical Therapeutic Chemical (ATC) code

(M05BX06) romosozumab

romosozumab

## Population studied

### Age groups

Adult and elderly population ( $\geq 18$  years)

Adults (18 to  $< 65$  years)

Adults (18 to  $< 46$  years)

Adults (46 to  $< 65$  years)

Elderly ( $\geq 65$  years)

Adults (65 to  $< 75$  years)

Adults (75 to < 85 years)

Adults (85 years and over)

---

### **Estimated number of subjects**

765

## Study design details

### **Outcomes**

Measure awareness of the educational materials, identify if specialists distribute the educational materials to their patients and/or caregivers when prescribing EVENITY, determine adequacy of the content of the education materials.

---

### **Data analysis plan**

A market research vendor will conduct a survey to assess the effectiveness of the educational materials provided to Specialists. This survey will consist of a questionnaire targeted to Endocrinologists, Rheumatologists, Geriatricians and General Physicians in Australia who can prescribe EVENITY to patients. Study results will be in tabular form and aggregate analyses that omits subject identification.

## Documents

### **Study report**

[20220120\\_ORSR\\_Abstract\\_Redacted.pdf](#)(1.78 MB)

## Data management

## Data sources

## Data sources (types)

Other

---

### Data sources (types), other

Survey questionnaire targeted to Endocrinologists, Rheumatologists, Geriatricians and General Physicians in Australia who can prescribe EVENITY to patients.

## 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