

# Prolia® Postmarketing Active Safety Surveillance Program for Soliciting Adverse Events of Special Interest in the United States (PASP-EMR Program)

**First published:** 16/01/2017

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

Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/48699>

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### **EU PAS number**

EUPAS17198

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### **Study ID**

48699

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### **DARWIN EU® study**

No

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## Study countries

United States

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## Study description

To monitor the long-term safety of Prolia® (denosumab) and enhance the quality of data collection by proactively soliciting adverse event (AE) reporting of the 5 pre-specified AEs of special interest (AESI) from United States (US) health care providers (HCP e.g., physicians, licensed registered nurses, nurse practitioners, or physician assistants) of Prolia treated postmenopausal women and men with osteoporosis within the Postmarketing Active Safety Surveillance Program (PASP) Electronic Medical Record (EMR) (PASP-EMR program).

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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

## Contact details

## Study institution contact

Akeem Yusuf

Study contact

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

## Primary lead investigator

Akeem Yusuf

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 13/05/2016

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### Study start date

Actual: 27/05/2010

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### Data analysis start date

Planned: 01/03/2022

Actual: 01/03/2022

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### Date of final study report

Planned: 02/08/2022

Actual: 23/08/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[20090601Protocol Amend 2 2016 Fully Redacted.pdf](#)(555.62 KB)

[20090601Protocol Amend 2 2016-06-23.pdf](#)(2.84 MB)

## Regulatory

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

Yes

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

Not applicable

## Methodological aspects

### Study type

### Study type list

### **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:**

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To monitor the long-term safety of Prolia® (denosumab) and enhance the quality of data collection by proactively soliciting adverse event (AE) reporting of the 5 pre-specified AEs of special interest (AESI) from United States (US) health care providers (HCP e.g. licensed registered nurses, nurse practitioners, or physician assistants) of Prolia treated postmenopausal women and men with osteoporosis

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Postmarketing Active Safety Surveillance Program

## Study drug and medical condition

**Name of medicine**

PROLIA

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**Medical condition to be studied**

Osteoporosis

## Population studied

**Short description of the study population**

Men and postmenopausal women with osteoporosis receiving Prolia for the treatment identified from the Postmarketing Active Safety Surveillance Program (PASP) Electronic Medical Record (EMR) (PASP-EMR program).

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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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**Special population of interest**

Other

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**Special population of interest, other**

Osteoporosis patients

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**Estimated number of subjects**

5000

## Study design details

## Data analysis plan

Descriptive statistics will be used to summarize the program data. Summary data to be estimated and reported include number of Prolia-treated patients in the electronic medical record(EMR) platform, number and percentage of Prolia-treated with at least 1 AESI-soliciting questionnaire presented and completed, number and percentage of Prolia-treated patients with at least 1 AESI reported through the EMR platform, number of AESIs reported through a secure Amgen website via a link from the EMR platform and incidence rates for AESIs. Data will be computed and reported annually.

## Documents

### Study results

[denosumab 20090601 Observational Final Analysis Abstract.pdf\(216.32 KB\)](#)

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## Data management

### Data sources

#### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

### 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