# 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

**EU PAS number**

EUPAS17198

**Study ID**

48699

**DARWIN EU® study**

No

**Study countries**

☐ United States

**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).

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Amgen

United States

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

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**Institution**

# Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Akeem Yusuf

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**
Actual: 13/05/2016

**Study start date**
Actual: 27/05/2010

**Data analysis start date**
Planned: 01/03/2022

Actual: 01/03/2022

**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 osteoporos

## 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 perecentage 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)

# 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)

## 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