

# Integrated Retrospective Analysis of Metastatic-related and Non metastatic-related Fractures in Studies 20050136, 20050244, and 20050103

**First published:** 16/11/2018

**Last updated:** 27/03/2024

Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/30045>

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### **EU PAS number**

EUPAS24775

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### **Study ID**

30045

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### **DARWIN EU® study**

No

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## Study countries

United States

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## Study description

Descriptive analysis of on-study metastatic and non-metastatic fractures from studies 20050136, 20050103, and 20050244 in subjects with bone metastases from solid tumors. To describe additional risk factors associated with on-study non-metastatic fractures for subjects with on-study non-metastatic fracture(s) This study will fulfil a postmarketing commitment to the US Food and Drug Administration (FDA) (part of the approval of XGEVA® prior approval supplement which added Multiple Vertebral Fractures (MVF) Following Treatment Discontinuation to Warnings & Precautions section of XGEVA US Prescribing Information).

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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

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: 19/06/2018

Actual: 19/06/2018

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### Study start date

Planned: 01/12/2018

Actual: 07/09/2018

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### Data analysis start date

Planned: 01/03/2019

Actual: 21/11/2018

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### Date of final study report

Planned: 01/06/2019

Actual: 08/05/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[01.02.06 Public Redacted Protocol Ver 1.0 2018-06-19 English.pdf\(889.99 KB\)](#)

## 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

## Other study registration identification numbers and links

20180024

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition  
Human medicinal product

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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 characterize the on-study metastatic and non-metastatic fractures seen in studies 20050136, 20050244 and 20050103

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Retrospective analysis

## Study drug and medical condition

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

DENOSUMAB

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### **Medical condition to be studied**

Bone cancer metastatic

## Population studied

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

Subjects with bone metastases from solid tumors.

All subjects randomized on Studies 20050136, 20050103, and 20050244

(excluding 179 subjects with multiple myeloma) will be included in the analysis.

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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**

Solid tumors patients with bone metastases

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### **Estimated number of subjects**

5723

## Study design details

## Outcomes

The primary objective is to characterize the on-study metastatic and non-metastatic fractures seen in the 20050136, 20050244 and 20050103 studies. Location of non metastatic fracture (vertebral vs non-vertebral) and fracture CTCAE grades will be assessed. The secondary objective is to describe baseline medications known to reduce bone mineral density (BMD) and/or a history of osteoporosis in those patients experiencing a non-metastatic fracture.

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## Data analysis plan

The statistical analysis in this study will be descriptive in nature. Categorical outcomes will be summarized by the number and percentage of subjects or events in each category. Continuous outcomes will be summarized by the number of nonmissing values, mean, standard deviation, median, lower and upper quartiles, minimum, and maximum.

## Documents

### Study results

[20180024\\_01.47.01.01 Observational Research Study Report Published Report\\_Redacted \(002\).pdf\(159 KB\)](#)

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## Data management

## Data sources

### Data sources (types)

[Other](#)

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

Clinical trial results

## 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