

# Incidence of new Primary Malignancies Among Patients With Bone Metastases From Breast, Prostate, or Lung Cancer Treated With XGEVA or Intravenous Zoledronic Acid: a Retrospective Cohort Study (20170728)

**First published:** 26/09/2018

**Last updated:** 28/02/2020

Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/33874>

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### **EU PAS number**

EUPAS25381

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### **Study ID**

33874

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## DARWIN EU® study

No

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### Study countries

United States

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### Study description

The purpose of this study is to estimate the incidence of any new primary malignancy (any haematologic or non-haematologic tumour, excluding non-melanoma skin cancer subsequent to the first primary malignancy) among patients with breast, prostate, or lung cancer and bone metastases following initiation of either XGEVA or zoledronic acid, and to describe the types of new primary malignancies that patients experience, as well as the characteristics of the patients who develop new primary malignancies. The study employs a retrospective cohort design and data from the SEER-Medicare linked datasets.

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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: 13/03/2018

Actual: 13/03/2018

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### Study start date

Planned: 14/12/2018

Actual: 11/12/2018

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### Data analysis start date

Planned: 01/03/2019

Actual: 01/03/2019

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### Date of final study report

Planned: 01/03/2020

Actual: 28/02/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen, Inc.

## Study protocol

[20170728\\_01.02.06 Public Redacted Protocol Ver 1.0 English.pdf\(703.48 KB\)](#)

## Regulatory

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

No

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

EU RMP category 3 (required)

## 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:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To estimate, overall and by primary malignancy site, incidence (rate, cumulative incidence proportion) of any subsequent new primary malignancy (any haematologic or non-haematologic tumours, excluding non-melanoma skin cancer after the first primary malignancy) among patients with breast, prostate, or lung cancer and bone metastases who were newly treated with either XGEVA or IV zoledronic acid

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

XGEVA

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## **Medical condition to be studied**

Breast cancer stage IV

Prostate cancer stage IV

Non-small cell lung cancer stage IV

## **Population studied**

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

Patients aged 18 years or older who were diagnosed with a first primary, microscopically confirmed breast, prostate, or lung cancer in SEER between 2000 and 2014. Patients must have received their first record for XGEVA or ZA between 2011 and 2014, and had a record of bone metastases within 30 days before or after this date in the Medicare claims data (ICD-9-CM code 198.5 or ICD-10-CM code C79.5) or had a record of bone metastases in the SEER data at diagnosis.

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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**

Breast, prostate, or lung cancer patients

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## **Estimated number of subjects**

15000

## Study design details

### **Outcomes**

New primary malignancy (any haematologic or non-haematologic tumours, excluding non-melanoma skin cancer subsequent to the first primary malignancy)

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### **Data analysis plan**

This is a descriptive study and will focus on exposure cohort-specific analyses (XGEVA, intravenous zoledronic acid). No formal statistical comparisons or significance testing are planned. The primary analyses estimate the incidence rate and cumulative incidence proportion of new primary malignancy in each exposure cohort using 95% confidence interval as a measure of the uncertainty of the estimates. Cumulative incidence proportions will account for the competing risk of death. Analyses will be conducted both for index malignancy types combined and individually (breast, prostate, lung).

## Documents

### **Study results**

[01.09.01 Clinical Study Report ORSR Abstract 2020-01-29 20170728 Final Analysis.pdf](#)(85.58 KB)

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## Data management

## Data sources

## **Data sources (types)**

Administrative healthcare records (e.g., claims)

Disease registry

Other

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

Disease registry data linked with administrative claims

# 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