

# Osteonecrosis of the Jaw (ONJ) Case Registry

**First published:** 14/02/2014

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

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/45163>

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### EU PAS number

EUPAS5605

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### Study ID

45163

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### DARWIN EU® study

No

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### Study countries

Belgium

Canada

Denmark

- Finland
  - France
  - Germany
  - Greece
  - Italy
  - Spain
  - United Kingdom
  - United States
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### **Study description**

The purpose of the ONJ case registry is to describe the natural history of positively-adjudicated ONJ in subjects with cancer with an observation period of 5 years. Most of these subjects are expected to have received bone antiresorptive agents such as bisphosphonates or denosumab together with cancer-specific therapies (eg, chemotherapy, steroids, or anti-angiogenics). It is also possible that the registry will include subjects with cancer who developed ONJ without exposure to any antiresorptive therapy.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

**Amgen**

United States

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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

Actual: 16/07/2010

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### Study start date

Actual: 01/10/2012

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### Data analysis start date

Planned: 08/02/2021

Actual: 08/02/2021

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### Date of interim report, if expected

Planned: 01/09/2014

Actual: 06/11/2014

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### **Date of final study report**

Planned: 29/09/2021

Actual: 13/01/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[20101102\\_Protocol\\_14Feb14.pdf](#)(728.09 KB)

[20101102\\_01.02.06 Public Redacted Protocol Ver 1.0 2018-07-19 English.pdf](#)

(1.1 MB)

## Regulatory

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

No

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

Not applicable

## Methodological aspects

### Study type

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Drug utilisation

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

To describe the natural history of positively-adjudicated ONJ in subjects with cancer with a 5-yr. observation period. Most of these subjects are expected to have received bone antiresorptive agents such as bisphosphonates or denosumab together with cancer-specific therapies. The registry may also include subjects with cancer who developed ONJ without exposure to any antiresorptive therapy.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Case-series, Post-Marketing Safety Study

## Study drug and medical condition

## **Medical condition to be studied**

Osteonecrosis of jaw

## **Population studied**

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

Investigators will be expected to maintain a screening log of all potential study candidates that includes limited information about the potential candidate such as sex, age, race, screening date, and outcome of the screening process (eg, enrolled into study, reason for ineligibility [eg, ONJ not positively adjudicated], or declined to participate). The rate of nonparticipation will be monitored during the trial. Before any study-specific procedure, the appropriate written informed consent will be obtained

#### **Inclusion Criteria**

1. Adult ( $\geq 18$  years of age) with diagnosis of cancer
2. Newly diagnosed, positively-adjudicated ONJ
3. ECOG  $\leq 2$  and expected survival  $\geq 3$  months
4. Willing to provide access to previous and future medical and dental information
5. Subject or subject's legally acceptable representative has provided written informed consent

#### **Exclusion Criteria**

1. History of radiation to the jaws administered for the treatment of cancer
2. Subject will not be available for protocol-required study visits, to the best of the subject and investigator's knowledge
3. Subject has any kind of disorder that, in the opinion of the investigator, may compromise the ability of the subject to give written informed consent and/or to

comply with all required study procedures

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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**

Cancer patients

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### **Estimated number of subjects**

327

## Study design details

### **Outcomes**

Resolution rate and time to ONJ resolution Time Frame: 5 years , Explore the relationship between rate and time to ONJ resolution with the following:ONJ severity and staging at Registry enrollment 5 yrs potential risk factors 5 yrs Explore the relationship between rate and time to ONJ resolution and the following:subsequent treatment patterns for ONJ 5 yrtreatment patterns of antiresorptive therapy 5 yrs

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## Data analysis plan

The objective of this study is to describe the natural history of positively-adjudicated ONJ in subjects with cancer. The primary endpoint is ONJ resolution and time course of resolution. Secondary endpoints include the clinical features of ONJ, including severity and staging at enrolment and the frequency of risk factors for incident ONJ. Continuous parameters will be summarized using descriptive statistics, which includes mean, standard deviation, median, and/or selected percentiles, and the number of non-missing observations. Categorical parameters will be summarized using frequencies and percentages. In general, analyses will be based on available data.

## Documents

### Study results

[20101102\\_Observational\\_Research\\_Study\\_Report\\_Published\\_Report\\_Summary.pdf](#)

(288.89 KB)

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## Data management

## Data sources

### Data sources (types)

[Other](#)

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### Data sources (types), other

Prospective patient-based data collection

## 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