# Osteonecrosis of the Jaw (ONJ) Case Registry

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

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





## Administrative details

EU PAS number	
EUPAS5605	
Study ID	
45163	
DARWIN EU® study	
No	
Study countries  Belgium	
Canada	
Denmark	
Finland	
France	
Germany	

Greece	
Italy	
Spain	
United Kingdom	
United States	

#### **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.

#### **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**

Global Development Leader Amgen, Inc medinfo@amgen.com

**Study contact** 

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

#### Study start date

Actual: 01/10/2012

#### Data analysis start date

Planned: 08/02/2021

Actual: 08/02/2021

#### Date of interim report, if expected

Planned: 01/09/2014

Actual: 06/11/2014

#### 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

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

Not applicable

## Methodological aspects

Study type

Study type list

#### **Study topic:**

Disease /health condition

#### Study type:

Non-interventional study

#### Scope of the study:

Disease epidemiology

Drug utilisation

Safety study (incl. comparative)

#### **Data collection methods:**

Primary data collection

#### 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

#### 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 (≥ 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

#### 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)

#### **Special population of interest**

Other

#### Special population of interest, other

Cancer patients

#### **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 yrstreatment patterns of antiresorptive therapy 5 yrs

#### 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)

### 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

Other	(types)				
Data sources	(types), othe	r			
Prospective pa	ient-based dat	a collectio	n		
Use of a (	Common	Data N	Model (	CDM)	
CDM mapping					
No					
Data qua	ity spacit	fication	2.5		
Data qua	ity specii	icatioi	15		
Check confor		icatioi	15		
•		icatioi	15		
Check confor	nance	icatioi	15		
Check confor	nance	icatioi	15		
Check conford Unknown Check comple	nance teness	icatioi	15		

## Data characterisation

### **Data characterisation conducted**

No