

# Long Term Post Marketing Drug Use Result Survey for Blinatumomab in Japan (20180238) (Blinatumomab Long Term PMS Japan)

**First published:** 09/05/2019

**Last updated:** 30/10/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS29685

---

### Study ID

33033

---

### DARWIN EU® study

No

---

### Study countries

 Japan

---

### Study description

To investigate the incidence of CTCAE grade  $\geq 3$  events of each safety specification of the Japan Risk Management Plan (neurologic events, infections, cytokine release syndrome, tumor lysis syndrome, myelosuppression and Pancreatitis) in patients receiving long term administration of blinatumomab.

---

## Study status

Finalised

## Research institutions and networks

### Institutions

Amgen

 United States

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

**Last updated:** 27/03/2026

Institution

### Contact details

#### Study institution contact

Global Development Leader Amgen Inc.

medinfo@amgen.com

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: 27/11/2018

Actual: 18/12/2018

---

### **Study start date**

Planned: 20/12/2019

Actual: 08/01/2020

---

### **Data analysis start date**

Planned: 30/09/2024

Actual: 23/01/2025

---

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

Planned: 23/01/2026

Actual: 15/08/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen Inc.

# Study protocol

[Protocol-Published Original blinatumomab 20180238 .pdf](#) (1.03 MB)

[blinatumomab\\_20180238\\_abstract ORSR\\_Redacted.pdf](#) (51.52 KB)

## Regulatory

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

Yes

---

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

Non-EU RMP only

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Human medicinal product

---

#### **Study type:**

Non-interventional study

---

#### **Scope of the study:**

Drug utilisation

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

To investigate the incidence of CTCAE grade  $\geq 3$  events of each safety specification of the Japan Risk Management Plan (neurologic events, infections, cytokine release syndrome, tumor lysis syndrome, myelosuppression and Pancreatitis) in patients receiving long term administration of blinatumomab.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

BLINCYTO

---

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

BLINATUMOMAB

---

**Anatomical Therapeutic Chemical (ATC) code**

(L01FX07) blinatumomab

blinatumomab

---

**Medical condition to be studied**

## Population studied

### Age groups

- Preterm newborn infants (0 – 27 days)
  - Term newborn infants (0 – 27 days)
  - Infants and toddlers (28 days – 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - 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)
- 

### Estimated number of subjects

40

## Study design details

### Outcomes

The incidence of CTCAE grade  $\geq 3$  events of each safety specification

---

### Data analysis plan

The number of patients and the incidence rates of CTCAE grade  $\geq 3$  events are tabulated for each safety specifications and other adverse drug reactions during the survey.

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)

[Non-interventional study](#)

## 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