

# An observational study of blinatumomab safety and effectiveness, utilisation, and treatment practices (20150136)

**First published:** 17/02/2017

**Last updated:** 04/04/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS17848

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### Study ID

49944

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### DARWIN EU® study

No

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### Study countries

- Austria
- Czechia
- Finland
- France

- Germany
  - Greece
  - Italy
  - Netherlands
  - Poland
  - Portugal
  - Sweden
  - Switzerland
  - United Kingdom
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### 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: 16/06/2016

Actual: 16/06/2016

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**Study start date**

Planned: 14/03/2017

Actual: 22/03/2017

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**Data analysis start date**

Planned: 03/05/2024

Actual: 20/03/2024

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**Date of interim report, if expected**

Planned: 08/07/2018

Actual: 03/07/2018

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**Date of final study report**

Planned: 20/02/2025

Actual: 20/02/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[Protocol-Published Amendment blinatumomab 20150136 9 .pdf \(1.91 MB\)](#)

## Regulatory

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

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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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

**Main study objective:**

The first primary objective is to characterize the safety profile of Blincyto in routine clinical practice in countries in the EU by characterising specific AEs. The second primary objective is to estimate the frequency and type of medication errors identified in patient charts.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

BLINATUMOMAB

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

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

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### **Estimated number of subjects**

279

## Study design details

### **Outcomes**

Incidence of specified AEs. Time to onset of first specified AEs. Summary of duration of specified AEs. Proportion of Blincyto administrations with medication errors. Incidence of AEs collected. Incidence of specified AEs and AEs collected among patient subgroups. Proportion of patient achieving CR, CR/CRh\*/CRi, MRD within 2 cycles of Blincyto. Proportion of patients receiving allogeneic HSCT. 1 year and 100 day mortality proportion after HSCT. Relapse free survival

time. Disease free survival. Overall survival. Healthcare resource use. Blincyto Utilization.

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### **Data analysis plan**

All analyses will be descriptive. Continuous variables will be summarised by mean, median, standard deviation, 25th percentile, 75th percentile, minimum and maximum. Categorical variables will be summarised by number and percentage. For categorical outcomes, 95% confidence intervals (CIs) will also be presented where appropriate. For time-to-event endpoints, Kaplan-Meier (KM) curves and estimates (median, 1st and 3rd quartile) of the time-to-event endpoint with 95% confidence intervals will be calculated, if estimable. Six, 12- and 24-month survival proportions and 95% confidence intervals will also be estimated. Subject incidence (and 95% CIs) for adverse events will be summarised and tabulated by system organ class and preferred term. Incidence tables will also be presented with respect to time on Blincyto at the patient level (incidence rate) and event level (event rate).

## Documents

### **Study results**

[20150136 ORSR\\_Redacted.pdf](#) (2.69 MB)

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## 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

### 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