

# Retrospective Multicenter Study Describing Baseline Clinical Characteristics and Outcomes in BLINCYTO® Treated Adult Patients With Relapsed or Refractory B-cell Precursor ALL Stratified by Baseline Disease Burden and Cytoreductive Therapy (20200012)

**First published:** 12/10/2020

**Last updated:** 22/01/2025

Study

Planned

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/49266>

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### **EU PAS number**

EUPAS37395

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### **Study ID**

49266

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## DARWIN EU® study

No

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### Study countries

United States

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### Study description

This observational retrospective study will be conducted at 5 sites. Around 200 subjects with relapsed or refractory B-cell precursor acute lymphoblastic leukemia who have initiated treatment with blinatumomab are planned to be included in this study. The planned study period is approximately 5 and a half years. Information will be collected to describe the baseline and clinical characteristics among the subjects. The study was cancelled on July 31, 2022

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### Study status

Planned

## Research institutions and networks

### Institutions

Amgen

United States

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

**Last updated:** 21/02/2024

Institution

## University of California

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

**Last updated:** 01/02/2024

Institution

Memorial Sloan Kettering Cancer Center New York, USA, City of Hope California, USA, Cleveland Clinic Ohio, USA, University of California San Francisco California, USA, Fred Hutchinson Cancer Center Washington, USA

## 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: 01/11/2020

Actual: 07/10/2020

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**Study start date**

Planned: 03/10/2022

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**Data analysis start date**

Planned: 02/01/2023

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**Date of final study report**

Planned: 30/09/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[Protocol-Published Original blinatumomab 20200012 .pdf\(3.35 MB\)](#)

## 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

## Other study registration identification numbers and links

Protocol number - 20200012

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

**Main study objective:**

The main objective of this study is to describe outcomes of blinatumomab treatment among four groups of subjects.

## Study Design

## **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Medical condition to be studied**

Acute lymphocytic leukaemia

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### **Additional medical condition(s)**

Relapsed or refractory B-cell precursor acute lymphoblastic leukemia

## Population studied

### **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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### **Estimated number of subjects**

200

## Study design details

### **Outcomes**

Estimate proportion of patients receiving complete remission (CR) following blinatumomab treatment for relapsed or refractory acute lymphoblastic

leukemia (R/R ALL) by baseline disease burden and cytoreductive therapy patient subgroups. Estimate disease-related patient outcomes and adverse events by baseline disease burden and cytoreductive therapy patient subgroups.

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### **Data analysis plan**

This study is a retrospective analysis of treatment outcomes among subject with relapsed or refractory B-cell precursor treated with blinatumomab.

Descriptive summaries of subject characteristics among all subjects and among four groups (Groups 1-4) will be generated from all covariates. Counts and proportions with 95% confidence intervals (CIs) will be estimated for binary/categorical endpoints. Continuous endpoints will be described using means, standard deviations, medians and interquartile ranges, minima, and maxima. Time-to-event endpoints will be estimated with Kaplan-Meier (KM) curves and medians with associated 95% CIs, 6-month and 12-month survival proportions with associated 95% CIs will also be estimated.

## Data management

### Data sources

#### **Data sources (types)**

[Other](#)

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

Institutional databases

### 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