

# Healthcare Providers' Awareness of the risks and safe use conditions associated with BLINCYTO®: A REMS Assessment Survey (20170108)

**First published:** 14/06/2017

**Last updated:** 21/12/2019

Study

Finalised

## Administrative details

### EU PAS number

EUPAS19116

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### Study ID

32897

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study description

This cross-sectional study is to evaluate the effectiveness of the BLINCYTO Risk Evaluation and Mitigation Strategy (REMS) Program among healthcare providers (HCPs) who have used BLINCYTO for patients in the treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) and B-cell precursor ALL in first or second complete remission with minimal residual disease (MRD) in the United States. Specifically, the study is to determine the level of awareness and understanding of the key risks (cytokine release syndrome, neurologic toxicities, and preparation and administration errors,) and safe use conditions associated with BLINCYTO therapy. The REMS surveys were conducted at 18 months and 3 years, and will be conducted at 5 years and 7 years after the launch of BLINCYTO. In this 5-year survey, at least 300 completed surveys will be targeted, including at least 100 prescribers, 100 nurses, and 100 hospital and/or home healthcare pharmacists. A threshold knowledge score of 80% will be used to evaluate a minimum acceptable level of understanding of the key risk messages.

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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

## 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: 29/03/2019

Actual: 29/03/2019

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### Study start date

Planned: 21/08/2019

Actual: 25/09/2019

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### Data analysis start date

Planned: 21/09/2019

Actual: 15/10/2019

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## **Date of final study report**

Planned: 06/12/2019

Actual: 14/11/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen Inc.

## Study protocol

[Protocol 2017-04-20 redaction 2017-05-23.pdf](#) (273.6 KB)

## Regulatory

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

Yes

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

Non-EU RMP only

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

To determine the level of awareness on the risks and safe use conditions associated with BLINCYTO therapy and certain aspects of the BLINCYTO REMS Program among healthcare providers (HCPs) who have used BLINCYTO for patients in the treatment of B-cell precursor acute lymphoblastic leukemia (ALL)

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Medical condition to be studied**

Philadelphia chromosome negative

Precursor B-lymphoblastic lymphoma refractory

B-cell type acute leukaemia

## Population studied

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

Healthcare Providers' (HCPs) who have prescribed, dispensed, prepared and/or administered BLINCYTO in the US in the past 12 months outside the clinical trial setting.

Inclusion criteria included HCPs, defined as prescribers [MDs, DOs, Physician Assistants (PAs), Nurse Practitioners (NPs)], nurses (RNs, BSNs), and hospital and/or home healthcare pharmacists who have prescribed, dispensed, prepared and/or administered BLINCYTO therapy to patients outside of the clinical trial setting in the past 12 months.

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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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## **Estimated number of subjects**

300

# Study design details

## **Outcomes**

- HCP is aware of the risk of cytokine release syndrome associated with use of BLINCYTO
- HCP is aware of the risk of neurologic toxicity associated with use of BLINCYTO
- HCP is aware of the risk of preparation and administration errors associated with use of BLINCYTO, HCP is aware of the indication for BLINCYTO

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## **Data analysis plan**

In general, analyses will be performed for prescribers, nurses, and pharmacists separately, as well as for the pooled group of HCPs to assess the effectiveness of the entire REMS communication plan of BLINCYTO. Demographics and other characteristics of the HCPs will be summarized using proportions. For each survey question, the proportion and 95% CI of each response option including 'not sure' will be reported. For each knowledge question, the proportion of HCPs selecting the correct response and corresponding 95% confidence interval will be calculated.

## Documents

### Study results

[20190092 \(20170108\) csr-20190092-results abstract\\_public-redacted-approved.pdf](#) (133.12 KB)

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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**

Cross-sectional survey, primary 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