

# Healthcare Providers' Awareness of the Risks and Safety Associated With BLINCYTO® use: A 2021 REMS Assessment Survey (20210065)

**First published:** 26/08/2021

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS41626

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### Study ID

48306

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study description

An online cross-sectional survey will be conducted among pharmacists and nurses who have dispensed, prepared and/or administered BLINCYTO in the United States (US) in the past 12 months outside the clinical trial setting. Previous similar surveys were conducted at 18 months, 3 years and 5 years after the launch of BLINCYTO. This cross-sectional survey is being conducted 7-years after the launch of BLINCYTO in the US. A list of health care providers (HCPs) targeted by the Risk Evaluation and Mitigation Strategy (REMS) Program will be matched to the survey vendor's Panels and/or other target sources to determine a list of respondents. The main data collection method for this assessment will be online surveys. Before actual data collection, Naxion will conduct telephone-assisted online pilot surveys with appropriate HCPs on the proposed survey questions. The findings from the pre-test will be used to improve the survey instrument and generate a final document for the survey.

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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: 22/03/2021

Actual: 22/03/2021

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### Study start date

Planned: 20/09/2021

Actual: 14/09/2021

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### Data analysis start date

Planned: 20/10/2021

Actual: 11/10/2021

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### Date of interim report, if expected

Actual: 15/10/2021

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## Date of final study report

Planned: 03/12/2021

Actual: 19/07/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[20210065 Public Redacted Protocol Ver 1.0 English.pdf](#) (1.89 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)?

Non-EU RMP only

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

Other

**If 'other', further details on the scope of the study**

Awareness levels of risks and safety

**Data collection methods:**

Primary data collection

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**Main study objective:**

Evaluate the awareness and understanding of the preparation and administration errors associated with BLINCYTO use among pharmacists who have prepared BLINCYTO, and nurses who have administered BLINCYTO.

## Study Design

**Non-interventional study design**

Cross-sectional

Other

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**Non-interventional study design, other**

Online survey

## Study drug and medical condition

## **Medical condition to be studied**

Acute lymphocytic leukaemia

# Population studied

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

A survey of US pharmacists and nurses who have dispensed, prepared, and administered BLINCYTO therapy in the past 12 months. The study also included healthcare professionals who have been part of previous assessments at 18 months, 3 years, and 5 years after BLINCYTO launch.

Inclusion criteria:

- Inclusion criteria include HCPs, defined as nurses (RNs, BSNs), and hospital and/or home healthcare pharmacists who have dispensed, prepared and/or administered BLINCYTO therapy to patients outside of the clinical trial setting in the past 12 months.
- HCPs who have been part of previous assessments (at 18 months, 3 years, and 5 years after the launch of BLINCYTO) will also be eligible to participate.

Exclusion criteria:

- HCPs or their immediate family members (eg, spouse, children, and/or parent) who are or were employed by Amgen, Naxion, or the FDA will be excluded from participation.
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## **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
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## **Estimated number of subjects**

200

# Study design details

## **Outcomes**

Awareness of the risk of preparation and administration errors associated with use of BLINCYTO.

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## **Data analysis plan**

Separate analyses will be performed for nurses and pharmacists, as well as a pooled analysis of the two groups to assess the participants' understanding of the preparation and administration errors associated with the use of BLINCYTO. Categorical variables will be summarized using frequencies and proportions while quantitative data will be summarized using means and standard deviation for normally distributed data and medians and interquartile range for skewed data. For each survey question, the proportion and 95% confidence interval (CI) of each response option including the 'not sure' and 'I routinely look it up' response categories will be reported. For each knowledge question, the proportion of HCPs selecting the correct response and corresponding 95% CI will be calculated. Results will be presented for each HCP type separately, as well as pooled.

## **Documents**

### **Study results**

[REMS survey 20210065 Abstract\\_no\\_footer May19 2022\\_Redacted.pdf](#) (136.18 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

REMS program

## 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