

# A cross-sectional survey of patients and caregivers receiving Blincyto in routine clinical practice in Europe to evaluate the effectiveness of additional risk minimisation measures

**First published:** 22/02/2017

**Last updated:** 22/02/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS17829

### Study ID

32768

### DARWIN EU® study

No

### Study countries

- France
- Germany

- Italy
- Spain
- United Kingdom

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### **Study description**

Educational materials targeting patients /caregivers and HCPs (physicians, nurses and pharmacists) have been implemented to help minimize the risks of neurological events and the potential for medication errors (MEs). A survey of patients and caregivers will help assess whether the processes put in place for the Blincyto educational efforts are effective in achieving a sufficient level of receipt and knowledge.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

#### Amgen

- United States

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**Institution**

Multiple centres: 25 centres are involved in the study

## 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: 05/09/2016

Actual: 05/09/2016

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### **Study start date**

Planned: 29/09/2017

Actual: 10/08/2017

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**Data analysis start date**

Planned: 29/03/2019

Actual: 28/03/2019

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**Date of final study report**

Planned: 29/11/2019

Actual: 13/12/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[20150228 Protocol Ver 1 0 2016-10-18 redaction\\_Marked.pdf](#) (2.84 MB)

[01.02.06 Public Redacted Protocol Ver 1.0 2016-11-06 English.pdf](#) (1.98 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)?**

EU RMP category 3 (required)

## Methodological aspects

## Study type

**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:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

The primary objectives of the study are to describe receipt of the educational materials and knowledge about the patient/caregiver educational materials, among patients with Ph- R/R B-precursor ALL receiving Blincyto and their caregivers.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

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

BLINATUMOMAB

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## **Medical condition to be studied**

Acute lymphocytic leukaemia

## **Population studied**

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

1. Patient/caregiver completing questionnaire is 18 years of age or older.
2. Patient and/or caregiver of a patient with Ph- R/R B-precursor ALL who has received Blincyto as an outpatient.
3. Patient/caregiver completing questionnaire can read and understand the native language of the country in which the study is being conducted.

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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**

100

## **Study design details**

### **Outcomes**

Proportion of subject who received the brochure, a mean score of knowledge questions answered correctly, Behaviour, understanding and usage

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### **Data analysis plan**

Categorical data will be summarized by counts and percentages. Continuous data will be summarized using number, mean, standard deviation (SD), median, quartiles, minimum and maximum and in the case of non-normally distributed data, median, range and interquartile range. 95% confidence intervals will be presented to three decimal places. The statistical analysis will include a summary of the study conduct, a descriptive analysis and the analysis of the objectives.

## Documents

### Study results

[20150228 Observational Research Study Report Published Report\\_Redacted.pdf](#)  
(153.97 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

## 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

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## Data characterisation

**Data characterisation conducted**

No