

# Survey of Physicians, Pharmacists, and Nurses Involved in the Prescribing, Preparation and Administration of Blincyto in Europe to Evaluate the Effectiveness of Additional Risk Minimization Measures (20150163)

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

**Last updated:** 13/12/2019

Study

Finalised

## Administrative details

### EU PAS number

EUPAS16626

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### Study ID

32764

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### DARWIN EU® study

No

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### 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 physicians, nurses and pharmacists will be conducted to help assess whether the processes put in place for the Blincyto educational efforts are effective in achieving a sufficient level of receipt of the materials, and knowledge and behavior around key messages in the materials

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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**

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: 02/09/2016

Actual: 02/09/2016

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### Study start date

Planned: 28/04/2017

Actual: 28/04/2017

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### **Data analysis start date**

Planned: 21/01/2019

Actual: 09/01/2019

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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 Inc.

## Study protocol

[20150163 Protocol Ver 1 0 2016-10-18 English redaction\\_Marked.pdf](#) (1.74 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 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:**

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 the receipt of the Blincyto brochures, and knowledge and behaviours outlined in the Blincyto brochures among physicians, nurses and pharmacists

## 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**

Philadelphia chromosome negative

## Population studied

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

Physicians, nurses, or pharmacists who have managed, administered, or prepared Blincyto for at least 1 adult patient ( $\geq 18$  years of age at Blincyto initiation) with

Philadelphia chromosome-negative relapsed or refractory B-precursor.

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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**

200

## Study design details

### **Outcomes**

Proportion of subject who received the brochure, a mean score of knowledge questions answered correctly, a mean score of behavior questions with correct responses, Understanding and usage of the brochures

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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. All 95% confidence intervals will be presented to three decimalplaces. The statistical analysis will include a summary of the study conduct, a descriptive analysis and the analysis of the objectives.

## Documents

### Study results

[20150163 Observational Research Study Report Published Report](#)

[\(1\)\\_Redacted.pdf](#) (166.62 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

## Data characterisation

### **Data characterisation conducted**

No