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

Study ID

48306

DARWIN EU® study

No

Study countries

☐ United States

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.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

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Last updated: 21/02/2024

Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

medinfo@amgen.com

Study contact

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

Study start date

Planned: 20/09/2021

Actual: 14/09/2021

Data analysis start date

Planned: 20/10/2021

Actual: 11/10/2021

Date of interim report, if expected

Actual: 15/10/2021

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

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

Study type:

Non-interventional study

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

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

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.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

200

Study design details

Outcomes

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

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)

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

Data sources (types), other

REMS program

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No