Evaluation of the Effectiveness of a Xospata Routine Risk Minimisation Measure (RMM) and an Additional Risk Minimisation Measure (aRMM): A Cross-sectional Survey Study among Healthcare Professionals to Assess Awareness and Knowledge

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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/50133

EU PAS number
EUPAS37354

Study ID
50133

DARWIN EU® study
No

Study countries
Czechia
France
Germany
Italy
Netherlands
Sweden

Study description
This study will assess the awareness and knowledge of three selected safety concerns (Posterior Reversible Encephalopathy Syndrome PRES, QT prolongation, and Differentiation Syndrome DS) among HCPs. The primary objective is to describe HCPs' awareness and knowledge of the three selected safety responses (PRES, QT prolongation, and DS) associated with Xospata use. The secondary objective is to assess the percentage of HCPs that recall receiving and/or reviewing the Xospata routine RMM (SmPC) and the Xospata aRMM (HCP educational materials).

Study status
Finalised

Research institution and networks

Institutions

ICON Commersialisation & Outcomes (MAPI-ICON), ICON

Germany
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06/03/2024

Institution

ENCePP partner

Non-Pharmaceutical company

Contact details

Study institution contact
Registration Department Clinical Trial

Study contact

clinicaltrialregistration@astellas.com
Primary lead investigator
Kimball Samantha

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
20/03/2020

Study start date
Planned:
08/07/2021
Actual:
30/09/2021

Data analysis start date
Planned:
09/07/2022
Actual:
17/08/2022

Date of final study report
Planned:
11/11/2022
Actual:
21/11/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas

Study protocol

Xospata_NI-PASS Protocol_v2.0_09Dec2020 Redacted.pdf(1.95 MB)

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
EU RMP category 3 (required)

Other study registration identification numbers and links

Methodological aspects

Study type

Study type list

Study topic:
Other

Study topic, other:
Disease/Epidemiology study

Study type:
Non-interventional study

Scope of the study:
Effectiveness study (incl. comparative)
Safety study (incl. comparative)

Data collection methods:
Primary data collection

Main study objective:
The main objective of the study is to describe HCPs' awareness and knowledge of the three selected safety concerns (PRES, QT prolongation, and DS) associated with the use of Xospata and to assess percentage of HCPs that recall receiving and/or reviewing Xospata routine RMM (SmPC) and the Xospata aRMM (HCP educational materials).

Study Design

Non-interventional study design
Cross-sectional
Other

Non-interventional study design, other
Multi-national survey study

Population studied

Short description of the study population
A survey of health care professional, specifically those who specialize in blood diseases including hematologists and hematooncologists prescribing Xospata in the participating Europe countries (Czech Republic, France, Germany, Italy, Netherlands, and Sweden).
Inclusion Criteria:
1. HCPs who treat patients diagnosed with leukemias, including AML, who can prescribe Xospata in the participating European countries, and
2. HCPs who provide permission to share their responses in aggregate with the EMA and/or the NCAs

Exclusion Criteria:
1. HCPs who participated in the cognitive pre-testing of the survey, or
2. HCPs who have themselves or have immediate family members who have worked for Astellas, ICON (coordinating investigator), EMA, or the NCAs of the participating member states within the past 5 years.

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)

Estimated number of subjects
400

Study design details

Outcomes
The percentages of HCPs with correct responses to questions regarding knowledge of the three selected safety concerns (PRES, QT prolongation and DS) associated with the use of Xospata. The percentages of HCPs that recall receiving and/or reviewing the Xospata routine RMM (SmPC) and the Xospata aRMM (HCP educational materials).

Data analysis plan
A statistical analysis plan (SAP) will be developed to describe all planned analyses in detail, along with shells for variable lists, tables and figures to be produced. The study population included in the data analysis will include HCPs who completed at least one of the questions in the survey associated with the primary endpoints. Descriptive data analyses will be conducted. Levels of receipt, use, and knowledge will be calculated with 95% two-sided Confidence Intervals (CIs). These descriptive results will be reported for the overall population of respondents and by country, and for sub-groups such as HCP specialty, time since dissemination of HCP materials in each country, and history of prescribing Xospata, depending on the final distribution of data across these sub-groups. Additionally, a descriptive analysis of the characteristics of non-responders will be

completed.

Data management

Data sources

Data sources (types)
Other

Data sources (types), other
Invitations to participate will be targeted to 16,000 HCPs by either email or by post mail using available contact information with an anticipated response rate of approximately 2.5% (400 HCPs)

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