A cross-sectional study to evaluate the effectiveness of XALKORI Therapeutic Management Guide among physician prescribing XALKORI in Europe

First published: 02/09/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/18665

EU PAS number

EUPAS7389

Study ID

18665

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Ireland
- [ ] Italy
- [ ] Netherlands
- [ ] Sweden
- [ ] United Kingdom

Study status

Finalised

Research institutions and networks

Institutions

ICON Commercialisation & Outcomes

- [ ] Germany
- [ ] Ireland

First published: 19/03/2010

Last updated: 05/07/2024

Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Multiple centres: 60 centers are involved in the study

Contact details

Study institution contact

Huang Kui

Study contact

kui.a.huang@pfizer.com

Primary lead investigator

Huang Kui

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/07/2014

Actual: 18/08/2014

Study start date

Planned: 22/09/2014

Actual: 30/09/2014

Date of final study report

Planned: 31/03/2017

Actual: 30/03/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc

Study protocol

A8081049_PROTOCOL_Crizotinib Physician Survey_25March2014.pdf(958.16 KB)

A8081049_PROTOCOL AMENDMENT 2_Crizotinib Physician Survey_30 March 2015 Clean_register.pdf(346.74 KB)

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)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Evaluate the effectiveness of physician educational materials and assess whether physicians would provide patients with patient educational materials.

Data collection methods:

Primary data collection

Main study objective:

The overall objective of this study is to evaluate the effectiveness of the XALKORI TMG and PIB implemented to mitigate the risks of visual disorders, QTc prolongation, bradycardia, hepatotoxicity, neutropenia and leukopenia, and ILD/pneumonitis in 6 countries including Belgium, Denmark, France, Germany, Italy, and the Netherlands in the European Union (EU).

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

CRIZOTINIB

Population studied

Short description of the study population

Physicians who have prescribed XALKORI per SmPC at least once within 12 months prior to taking the survey.

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

150

Study design details

Data analysis plan

The survey population will include all physicians who are screened and eligible for this study. All statistical analyses in this study will be descriptive. All variables collected are categorical. Frequencies and percentages, with 95% CIs where appropriate, will be presented. Country specific analyses will be presented. Additional exploratory analyses and sensitivity analyses may be conducted.

Documents

Study results

Crizotinib A8081049 NI Study Report.pdf(6.54 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Physician survey

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

Unknown