A cross-sectional study to evaluate the effectiveness of XALKORI Patient Information Brochure among non-small cell lung cancer (NSCLC) patients receiving XALKORI treatment in Europe

First published: 01/09/2014
Last updated: 02/07/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/18661

EU PAS number
EUPAS7393

Study ID
18661

DARWIN EU® study
No

Study countries
Austria
Belgium
Denmark
France
Germany
Ireland
Italy
Netherlands

Sweden
United Kingdom

Study status
Finalised

Research institution and networks

Institutions

ICON Commersialisation & Outcomes (MAPI-ICON), ICON

Germany
First published: 19/03/2010
Last updated
06/03/2024

Institution

Non-Pharmaceutical company

ENCePP partner

Multiple centres: 30 centers are involved in the study

Contact details

Study institution contact
Huang Kui

Study contact

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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

A8081050_PROTOCOL Crizotinib Patient Survey_25Mar2014.pdf(957.71 KB)

A8081050_PROTOCOL AMENDMENT 2_Crizotinib Patient Survey_30 March 2015 Clean_Register.pdf(354.13 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:
Disease /health condition
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 patient educational materials

Data collection methods:
Primary data collection

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

Study Design

Non-interventional study design
Cross-sectional

Study drug and medical condition

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

Medical condition to be studied
Non-small cell lung cancer stage III
Non-small cell lung cancer stage IV

Population studied

Short description of the study population
Non-small cell lung cancer patients who have received XALKORI treatment within 90 days prior to taking the survey from September 2014 to September 2016 at major university hospitals or cancer centers in the 10 participating countries including Belgium, Denmark, France, Germany, Italy, the Netherlands, Sweden, Austria, Ireland, and the United Kingdom

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)

Special population of interest
Other

Special population of interest, other
Non-small cell lung cancer patients

Estimated number of subjects
50

Study design details

Data analysis plan
All statistical summaries in this study will be descriptive. The study population will include all patients who are screened and eligible for this study. All variables collected in this study are categorical. Frequencies and percentages, with 95% confidence intervals (CIs) where appropriate, will be presented. Additional exploratory analyses and sensitivity analyses may be conducted.

Documents

Study results
Crizotinib A8081050 NI Study Report .pdf(4.33 MB)

Data management

Data sources

Data sources (types)
Other

Data sources (types), other
Patient 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