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

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 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: 30 centers are involved in the study

Contact details

Study institution contact

Huang Kui kui.a.huang@pfizer.com

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

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

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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)

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

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

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