

# 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

### EU PAS number

EUPAS7389

### Study ID

18665

### DARWIN EU® study

No

### Study countries

☐ Austria

☐ Belgium

☐ Denmark

- ☐ France
  - ☐ Germany
  - ☐ Ireland
  - ☐ Italy
  - ☐ Netherlands
  - ☐ Sweden
  - ☐ United Kingdom
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## 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 kui.a.huang@pfizer.com

Study contact

[kui.a.huang@pfizer.com](mailto: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

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### Study start date

Planned: 22/09/2014

Actual: 30/09/2014

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### 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

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**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

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**Study type:**

Non-interventional study

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**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

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**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.

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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)
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### 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)

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## 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

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### Data sources (types), other

Physician survey

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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**Check logical consistency**

Unknown

Data characterisation

**Data characterisation conducted**

Unknown