Assess Incidence and Prevalence of Brain Metastasis and Its impact on Clinical Outcomes among Anaplastic Lymphoma Kinase (ALK) Positive Metastatic Non-small Cell Lung Cancer Patients Receiving ALK Inhibitors as First-Line Treatment in the United States (ALK+ mNSCLC)

First published: 12/12/2024

Last updated: 13/10/2025

Study Finalised

Administrative details

EU PAS number

EUPAS1000000370

Study ID

1000000370

DARWIN EU® study

No

Study countries

United States

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Analysis Group, Inc.

Contact details

Study institution contact

Andreea Marculescu andreea.marculescu@pfizer.com

Study contact

andreea.marculescu@pfizer.com

Primary lead investigator

Devin Abrahami 0000-0001-5269-2377

Primary lead investigator

ORCID number:

0000-0001-5269-2377

Study timelines

Date when funding contract was signed

Planned: 15/08/2024

Actual: 15/08/2024

Study start date

Planned: 02/12/2024

Actual: 10/12/2024

Date of final study report

Planned: 31/03/2025

Actual: 27/06/2025

Study protocol

A8081077 final Protocol_Redacted.pdf (6.68 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Feasibility analysis

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

XALKORI

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

CRIZOTINIB

Anatomical Therapeutic Chemical (ATC) code

(L01ED01) crizotinib

crizotinib

Medical condition to be studied

Non-small cell lung cancer metastatic

Additional medical condition(s)

Anaplastic Lymphoma Kinase (ALK) Positive Metastatic Non-small Cell Lung Cancer

Documents

Study report

A8081077 Non-Interventional Study Report Abstract 11Apr2025_Redacted.pdf (131.3 KB)

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Not applicable