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)

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000370

Study ID

1000000370

DARWIN EU® study

No

Study countries

United States

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Institution

Analysis Group, Inc.

Contact details

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Primary lead investigator

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Primary lead investigator

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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

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:

Non-interventional study

Study drug and medical condition

Name of medicine

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

Data management

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