# Effectiveness of LORlatinib as a Real-World, first-line treatment in ALK-positive Advanced Non-Small Cell Lung Cancer Patients in Germany. (LOR-ALK).

**First published:** 26/06/2026

**Last updated:** 14/10/2026

Study Planned

## Administrative details

**EU PAS number**

EUPAS1000000583

**Study ID**

1000000583

**DARWIN EU® study**

No

**Study countries**

Germany

**Study description**

Research Question:
This is an observational, prospective study to address the data gaps in the real world setting on effectiveness, safety and Quality of Life data of first line Lorlatinib treatment.

- What is the effectiveness and spectrum of adverse events, mitigation strategies and patient reported quality of life aspects associated with lorlatinib as a first line treatment in an ALK+ NSCLC real-world population in Germany.
Primary objectives:
- To describe the real-world Progression Free Survival (rwPFS) rate: RwPFS rate 12-months and 18-months.
- To describe Time to the next treatment defined as the period from the start of the treatment to the start of the next line of treatment.

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**Study status**

Planned

# Research institutions and networks

## Institutions

### Pfizer

**First published:** 01/02/2024

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**Institution**

# Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Orly Livshits-Zacharias

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 29/11/2024

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**Study start date**

Planned: 10/08/2026

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**Date of interim report, if expected**

Planned: 30/03/2027

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**Date of final study report**

Planned: 30/09/2030

## Sources of funding

- Pharmaceutical company and other private sector

# Study protocol

B7461057_NIS PASS Study Protocol Amendment_V2.0_26May2026_Approved_Redacted.pdf (2.9 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:**

Drug utilisation

Effectiveness study (incl. comparative)

Evaluation of patient-reported outcomes

Other

Safety study (incl. comparative)

**If ‘other’, further details on the scope of the study**

Quality of Life data of first line Lorlatinib treatment.

**Data collection methods:**

Primary data collection

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**Study design:**

This is an observational, non-interventional, prospective, multicenter and international wide study with the category of a PASS (Post Authorization Safety Study), which primary endpoint will describe the effectiveness of lorlatinib as real-world progression free survival, assessed by the physician.

**Main study objective:**

• PFS measured from the date of first lorlatinib dose to the date of disease progression or death from any cause, assessed by physician.

• Time to Treatment Failure (TTF): time from date of treatment initiation to date of discontinuation of treatment for any reason, including progression of disease, treatment toxicity, and death from any cause whichever occurs first.

# Study Design

**Non-interventional study design**

Case-control

# Study drug and medical condition

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

LORLATINIB

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**Anatomical Therapeutic Chemical (ATC) code**

(L01ED05) lorlatinib

lorlatinib

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**Medical condition to be studied**

Non-small cell lung cancer

## Population studied

**Short description of the study population**

The study population includes adult patients aged 18 years or older diagnosed with non-small cell lung cancer in Germany who are carriers of the ALK gene rearrangement. Target population will be patients from 25 Italian sites and 25 German sites (clinics, or and primary care centers) with ALK-positive, metastatic non-small cell lung who have started first-line therapy with lorlatinib according to label prescription, with treatment duration of at least 1 day and up to 28 days.

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**Age groups**

- Adults (18 to < 65 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)

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**Special population of interest**

Other

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**Special population of interest, other**

with non-small cell lung cancer in Germany who are carriers of the ALK gene rearrangement

# Study design details

**Setting**

The study population includes adult patients aged 18 years or older diagnosed with non-small cell lung cancer in Germany who are carriers of the ALK gene rearrangement. Molecular diagnosis of ALK rearrangement is routinely performed in patients with non-small cell lung cancer according to the diagnostic guidelines of the German S3 lung cancer guideline. Given the estimated low incidence rate of 4-5% for this disease among the local population, the Principal Investigators decided to involve centers specializing in the molecular diagnosis of ALK.

Target population will be patients from 25 German sites (clinics, or and primary care centers) with ALK-positive, metastatic non-small cell lung who have started first-line therapy with lorlatinib according to label prescription, with treatment duration of at least 1 day and up to 28 days.

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**Outcomes**

Outcomes: (PFS, TTNT, ORR, DOR, DCR, IC-RR, time to brain radiation, duration of intracranial response, DOT, cumulative incidence of BM in patient population at 12 and 18 months, PFS2, IC-TTP, proportion of patients with extracranial progression, proportion of patients with oligoprogression, OS as well as PFS, ORR, and DOT for subsequent line after Lorlatinib), QoL and PRO (EORTC QLQ-C30, EORTC QLQ-LC13, WPAI:GH), and safety

(AEs, SAEs, non-serious AEs). AE, serious adverse events (SAE), and scenarios involving: exposure during breast feeding, medication error, overdose, misuse,

extravasation, lack of efficacy; exposure during pregnancy (EDP), occupational/environmental exposure and treatment-associated mortality as well as time to onset and duration of AEs.

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**Data analysis plan**

Patient data will be collected in the following periods:

• Pre-index period: since diagnosis to start lorlatinib treatment.

• Index Date: date of start of lorlatinib.

• Post-index period: visits performed under clinical practice since index date and until end of study period

Patient data collection will cease at the end of study completion.

# 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)**

Electronic healthcare records (EHR)

Non-interventional study

Patient surveys

## 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**

No