# Non-Interventional Study - Use of lorlatinib in treatment-naïve adult patients with metastatic or locally advanced anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer (NSCLC) from India. (B7461047)

**First published:** 18/03/2024

**Last updated:** 23/09/2024

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS1000000025

**Study ID**

1000000025

**DARWIN EU® study**

No

**Study countries**

India

**Study description**

This is an ambispective, multi-center, observational study investigating the safety and effectiveness of lorlatinib in advanced ALK-positive NSCLC patients in India according to the local labelling information.

This study will be conducted by design of retro-prospective approach. Therefore, there is no visit or activity mandated for the patients by this study. The investigator will collect patient’s data and record the information on each patient’s Case Report Form (CRF).

All patients diagnosed with advanced ALK-positive NSCLC with or without brain metastases, treatment naïve for metastatic disease, and prescribed lorlatinib according to routine clinical practice at up-to 10 centers in India and willing to participate will be followed for 18 months after taking informed consent from them.

All assessments described in this protocol are performed as part of normal clinical practice or standard practice guidelines for the patient population and healthcare provider specialty in India where this noninterventional study is being conducted.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

## Pfizer

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

**Last updated:** 01/02/2024

Institution

## Indegene Limited

# Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Nishtha Sehra

Primary lead investigator

# Study timelines

**Date when funding contract was signed**

Planned: 18/04/2023

Actual: 18/04/2023

**Study start date**
Planned: 15/03/2024

Actual: 09/05/2024

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**Date of final study report**
Planned: 15/12/2026

## Sources of funding

- Pharmaceutical company and other private sector

## Regulatory

**Was the study required by a regulatory body?**

No

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

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

**Data collection methods:**

Combined primary data collection and secondary use of data

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

LORLATINIB

**Medical condition to be studied**

Non-small cell lung cancer

# Data management

## 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