

# START: Real-world study on sequential therapy with afatinib as first-line treatment in patients with epidermal growth factor receptor (EGFR) mutation-positive advanced non-small cell lung cancer (NSCLC)

**First published:** 21/11/2019

**Last updated:** 11/11/2021

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS32423

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### Study ID

44236

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### DARWIN EU® study

No

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### Study countries

## Study description

The START study observes afatinib as first-line treatment and sequential therapy in patients with epidermal growth factor receptor (EGFR) mutation-positive advanced non-small cell lung cancer

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## Study status

Ongoing

## Research institutions and networks

### Institutions

[Zhejiang University](#)

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

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

Institution

[The First Affiliated Hospital, College of Medicine](#)

[Peking Union Medical College Hospital](#)

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

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

Institution

## West China Hospital

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

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Institution

Guangdong Provincial People's Hospital China, Hunan Cancer Hospital China, Hainan Cancer Hospital China, Peking Union Medical College China, West China Hospital, Sichuan University China, The first affiliated hospital of Zhengzhou University China, Shandong Cancer Hospital China, Yunnan Cancer Hospital China, Peking University Third Hospital China, Shenyang Tenth People's Hospital China

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Yilong Wu

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 29/03/2019

Actual: 28/03/2019

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**Study start date**

Planned: 29/05/2020

Actual: 20/05/2020

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**Data analysis start date**

Planned: 15/02/2026

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**Date of interim report, if expected**

Planned: 31/03/2024

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**Date of final study report**

Planned: 30/04/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim China Investment Co., Ltd.

## 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

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#### **Scope of the study:**

Effectiveness study (incl. comparative)

Other

#### **If 'other', further details on the scope of the study**

Treatment pattern

**Main study objective:**

To determine in Chinese patients in real-world setting with EGFR mutation-positive non-small cell lung cancer (NSCLC) the time on treatment (TOT) of afatinib as first-line treatment followed by 3rd generation EGFR-TKI in the event that T790M resistance mutation was developed

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Non-interventional, prospective study based on newly-collected data

## Study drug and medical condition

**Medicinal product name**

GIOTRIF

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**Medical condition to be studied**

Non-small cell lung cancer stage IIIB

Non-small cell lung cancer metastatic

Non-small cell lung cancer stage IV

## Population studied

## 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

750

## Study design details

### Outcomes

TOT with afatinib as first-line treatment followed by 3rd generation EGFR-TKI in the event of the T790M resistance mutation is developed in patients with EGFR mutation-positive NSCLC. This will be assessed as the time from the start of afatinib as first-line treatment until the last dose of 3rd generation EGFR-TKI.

1.TOT with afatinib as first-line treatment followed by investigator's choice treatment in event of the T790M negative status in real-world setting  
2.OS from the start of afatinib until the date of death  
3.PFS as judged by an investigator with afatinib in first-line treatment  
4.ORR OR is defined as best overall response of CR and PR according to RECIST 1.1 with afatinib in first-line tre...

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### Data analysis plan

TOT will be analysed using Kaplan-Meier method, and the median TOT along with two-sided 90% confidence interval (CI) will be calculated. PFS and OS will be analysed similarly. ORR, DCR, and acquired resistance mutation type, and AEs will be summarised descriptively by frequency and proportions.

## 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

Prospective patient-based data collection

## 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**

No