# ARIA: Real-world utilization and outcomes with dacomitinib first-line treatment for EGFR mutation-positive advanced non-small cell lung cancer among Asian patients – A multi center chart review (A7471067)

**First published:** 02/12/2021

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Study Ongoing

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/44544

**EU PAS number**

EUPAS44543

**Study ID**

44544

**DARWIN EU® study**

No

**Study countries**

- ☐ China
- ☐ India
- ☐ Malaysia

**Study description**

This is a longitudinal, multi-center cohort study with mixed prospective and retrospective data collection. Data will be collected from eligible adults with EGFR mutation-positive advanced NSCLC treated with dacomitinib as first-line therapy from the date of advanced NSCLC diagnosis to the date of death, lost to follow-up, withdrawal of consent or end of study, whichever occurs first.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Pfizer

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

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

Institution

### IQVIA

- ☐ United Kingdom

**First published:** 12/11/2021

**Last updated:** 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

## Contact details

### Study institution contact

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Study contact

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### Primary lead investigator

Chew Hooi Wong

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 20/03/2020

Actual: 20/03/2020

### Study start date

Planned: 05/05/2021

Actual: 11/06/2021

### Date of final study report

Planned: 31/10/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## 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:**

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

**Main study objective:**

1. To describe demographics, as well as clinical and disease characteristics of patients on first-line dacomitinib therapy for treatment of EGFR mutation-positive advanced NSCLC. 2. To describe starting dose of dacomitinib as first-line therapy, dose modification (if any), related timing and reason for dose modification, interruption or discontinuation. 3. To describe DOT and TTF of dacomitinib

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

VIZIMPRO

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**Medical condition to be studied**

EGFR gene mutation

## 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)

**Estimated number of subjects**

300

## Study design details

**Outcomes**

1. Demographics, as well as clinical and disease characteristics of patients on first-line dacomitinib therapy for treatment of EGFR mutation-positive advanced NSCLC. 2. Starting dose of dacomitinib as first-line therapy, dose modification (if any), related timing and reason for dose modification, interruption or discontinuation. 3. DOT and TTF of dacomitinib, 1. Real-world PFS of patients. 2. All adverse events (AEs) for patients treated with dacomitinib. 3. TTF, PFS, overall survival (OS) and AEs, as well as starting dose and dose modification of dacomitinib in a subgroup of patients with common EGFR mutations (exon 19 deletion or exon 21 L858R substitution) enrolled in China.

**Data analysis plan**

There will be no hypothesis testing in this study. All statistical analyses will be descriptive and no P-values will be reported in this study.

# Data management

## Data sources

**Data sources (types)**

Electronic healthcare records (EHR)

## 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