

# A Retrospective Cohort Study to Characterize Patient Characteristics and Treatment Outcomes Among Patients With Locally Advanced or Metastatic Non-small Cell Lung Cancer (NSCLC) in the French Epidemiological Strategy and Medical Economics Advanced or Metastatic Lung Cancer (ESME-AMLC) Database (20190402)

**First published:** 05/05/2021

**Last updated:** 29/07/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS40706

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### Study ID

50487

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**DARWIN EU® study**

No

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## Study countries

 France

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## Study description

A retrospective cohort study of locally advanced (stage IIIB/C) or metastatic (stage IIIB/C) non-small cell lung cancer (NSCLC) in the French Epidemiological Strategy and Medical Economics Advanced or Metastatic Lung Cancer (ESME-AMLC) Data Platform.

The study population consists of adult ( $\geq 18$  years of age) patients diagnosed with locally advanced or metastatic (stage IV) non squamous NSCLC between 1 Jan 2015 - 30 Jun 2022.

Patients are followed up from the date of diagnosis of advanced or metastatic NSCLC until death or date of last contact whichever occurs first.

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## Study status

Finalised

# Research institutions and networks

## Institutions

Unicancer

 France

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

**Last updated:** 22/11/2024

**Institution**

**Laboratory/Research/Testing facility**

**Not-for-profit**

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.  
medinfo@amgen.com

Study contact

[medinfo@amgen.com](mailto:medinfo@amgen.com)

### Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 07/08/2020

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### Study start date

Planned: 15/09/2020

Actual: 15/09/2020

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### Data analysis start date

Planned: 15/12/2020

Actual: 15/12/2020

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### Date of final study report

Planned: 30/06/2024

Actual: 27/05/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## 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 topic:**

Disease /health condition

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#### **Study type:**

Non-interventional study

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

Disease epidemiology

**Main study objective:**

The main objective of this study is to estimate overall survival (OS) and real-world progression-free survival (rwPFS) of patients with KRAS G12C-mutated locally advanced or metastatic NSCLC.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Non-small cell lung cancer

## 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**

45178

## Study design details

## Outcomes

- Overall survival (OS) of patients with KRAS G12C-mutated locally advanced or metastatic NSCLC
  - Real world progression-free survival (rwPFS) of patients with KRAS G12C-mutated locally advanced or metastatic NSCLC
  - OS and rwPFS of patients with locally advanced or metastatic NSCLC, overall and by biomarker status
  - Biomarker testing rates
  - Prevalence of KRAS G12C mutation
  - Demographics
  - Medical history
  - Clinical characteristics
  - Tumor characteristics
  - Treatment patterns
  - Concomitant medications
  - Genetic mutation profile
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## Data analysis plan

There are no formal hypotheses for the study. Descriptive analyses will be performed. For continuous variables, descriptive statistics will be presented. For categorical variables, the number and percentage of patients in each category will be reported with 95% two-sided CIs.

To describe time-to-event, Kaplan-Meier (KM) curves will be plotted, and KM estimates will be calculated.

## Documents

### Study results

[ESME\\_CBP\\_2023-17\\_Abstract\\_ISPE\\_VF\\_2024.02.09 \(1\).pdf](#) (639.6 KB)

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## 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 source(s), other

ESME-AMLC France

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### Data sources (types)

[Disease registry](#)

## 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