# French Epidemiological Strategy and Medical Economics Lung Cancer (ESME-LC) Database

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Data source



Cancer registry

# Administrative details

#### Administrative details

#### **PURI**

https://redirect.ema.europa.eu/resource/1000000385

**Data source ID** 

1000000385

Data source acronym

**ESME-LC** 

**Data holder** 

Unicancer

#### Data source type

Cancer registry

#### Main financial support

Funding from industry or contract research

Funding from public-private partnership

#### **Care setting**

Hospital inpatient care

#### **Data source qualification**

If the data source has successfully undergone a formal qualification process (e.g., from the EMA, ISO or other certifications), this should be described.

Yes

#### **Description of the qualification**

ISO certification for project management activities

#### **Data source website**

https://recherche.unicancer.fr/en/programs/esme/

### Contact details

#### Lise Bosquet



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# Data source regions and languages

#### **Data source countries**

France

#### **Data source languages**

English

French

#### Data source establishment

#### Data source established

02/10/2017

#### Data source time span

First collection: 01/01/2015

The date when data started to be collected or extracted.

#### **Publications**

### Data source publications

A real-world study of patients with advanced non-squamous non-small cell lung cancer with EGFR exon 20 insertion: clinical characteristics and outcomes Chouaid C, Filleron T, Debieuvre D, Pérol M, Girard N, Dansin E, Léna H, Gervais R, Cousin S, Otto J, Schott R, Planchard D, Madroszyk A, Kaderbhai C, Dubray-Longeras P, Hiret S, Pichon E, Clément-Duchêne C, Chenuc G, Simon G, Bosquet L, Quantin X Targeted Oncol. 2021 Nov;16(6):801-11

Treatment strategies for unresectable locally advanced non-small cell lung cancer in the real-life ESME cohort Girard N, Pérol M, Simon G, Audigier-Valette C, Gervais R, Debieuvre D, Schott R, Quantin X, Coudert B, Lena H, carton M, Robain M, Filleron T, Cpouaid C Lung Cancer. 2021 Dec;62:119-27

Biomarker testing in older patients treated for an Advanced or Metastatic Non-squamous Non-Small-Cell Lung Cancer: the French ESME real-life multicenter cohort experience Lamy T, Cabarrou B, Planchard D, Quantin X, Schneider S, Bringuier M, Besse B, Girard N, Chouaid C, Filleron T, Simon G, Baldini C Cancers. 2021 Dec;14(1):92

Impact of immune checkpoint inhibitors on the management of locally advanced or metastatic non-small cell lung cancer in real-life practice in patients initiating treatment between 2015 and 2018 in France and Germany Griesinger F, Pérol M, Girard N, Durand-Zaleski I, Zacharias S, Bosquet L, Janicke M, Quantin X, Groth A, Fleitz A, Cajella A, Patel S, Lacoin L, Daumont MJ, Penrold JR, Carroll R, Waldenberger D, Reynaud D, Thomas M, Chouaid C. Lung cancer. 2022 Oct;172:65-74

Effectiveness of nivolumab in patients with advanced non-small cell lung cancer in real-life practice in France and Germany: analysis of the ESME-AMLC and CRISP cohorts Chouaid C, Thomas M, Debieuvre D, Durand-Zaleski I, Zacharias S, Bosquet L, Groth A, Fleitz A, Calleja A, Patel S, Lacoin L, Dauont MJ, Penrod JR, Carroll R, Waldenberg D, Cotté FE, Audigier-Valette C, Griesinger F Cancers. 2022 Dec;14(24):6148

Enrolment of older adults with advanced or metastatic non-small cell lung cancer in first-line clinical trials in the multicentre ESME cohort Bringuier M, Carton M, Debieuvre D, Pasquier D, Pérol M, Filleron T, Léna H, Quantin X, Simon S, Baldini C J Geriatric Oncol. 2023 Mar;14(2)

An Adjusted Treatment Comparison Comparing Amivantamab Versus Real-World Clinical Practice in Europe and the United States for Patients with Advanced Non-Small Cell Lung Cancer with Activating Epidermal Growth Factor Receptor Exon 20 Insertion Mutations Chouaid C, Bosquet L, Girard N, Kron A, Scheffer M, Griesinger F, Sebastian M, Trigo J, Viteri S, Rodrigues B, Rahhali N, Cabrieto J, Diels J, Perualila NJ, Schioppa CA, Sermo, J, Toueg R, Erdmann N, Mielke J, Nematian-Samani M, Martin-Fernandez C, Pfaira I, Li T, Mahadevia P,

Treatment patterns and clinical outcomes of extensive stage small cell lung cancer (SCLC) in the real-world evidence ESME cohort before the era of immunotherapy Audigier-Valette C, Filleron T, Debieuvre D, Léna H, Pérol M, Chouaid C, Simon G, Quantin X, Girard N Resp Med Res. 2023 Mar;84:101012

Survival outcomes of patients with metastatic Non-Small Cell Lung Cancer receiving chemotherapy or immunotherapy as first-line in a real-life setting Belaroussi Y, Bouteiller F, Bellera C, Pasquier D, Pérol M, Debieuvre D, Filleron T, Girard N, Schott R, Mathoulin-Pellissier S, Martin AL, Cousin S Scientific Reports 2023 Jun;13(1):9584

Reduced risk of secondary primary extra pulmonary cancer in advanced /metastatic lung cancer patients treated with immune checkpoint inhibitors Heudel P, De Monfort A, Debieuvre D, Chouaid C, Carton M, Audigier-Valette C, Fillerin T, Chabaud S, Stancu A, Quantin X, Hiret S, Bosquet L, Blay JY Lung Cancer 2023 Jun;182:107280

Clinical characteristics and survival outcomes of patients with advanbced NSCLC according to KRAS mutational status in the French Real-life ESME cohort Thomas QD, Quantin X, Lemercier P, Chouaid C, Schneider S, Filleron T, Remon-Masip J, Pérol M, Debieuvre D, Audigier-Valette C, Justeau G, Loeb A, Hiret S, Clment-Duchene C, Dansin E, Stancu A, Pichon E, Bosquet L, Girard N, Du Rusquec P. ESMO Open 2024

Real-world overview of therapeutic strategies and prognosis of older patients with advanced or metastatic non-small cell lung cancer from the ESME database Cabart M, Mourey L, Pasquier D, Schneider S, Lena H, Girard N, Chouaid C, Schott R, Hiret S, Debieuvre D, Quantin X, Madroszyk A, Dubray-Longeras P, Pichon E, Baranzelli A, Justeau G, Pérol M, Bosquet L, Cabarrou B. J Geriatric Oncol 2024

Timizing treatment strategies for EGFR-mutated NSCLC treated with osimertinib: real-world outcomes and insights Thomas QD, Girard N, Bosquet L, Cavaillon S, Filleron T, Eltaief S, Chouaid C, Lena H, Debieuvre D, Pérol M, Quantin X Cancers 2024

# Data elements collected

# The data source contains the following information

#### Disease information

Does the data source collect information with a focus on a specific disease? This might be a patient registry or other similar initiatives.

Yes

#### **Disease details**

Small cell lung cancer

Non-small cell lung cancer

#### Rare diseases

Are rare diseases captured? In the European Union a rare disease is one that affects no more than 5 people in 10,000.

No

#### **Pregnancy and/or neonates**

Does the data source collect information on pregnant women and/or neonatal subpopulation (under 28 days of age)?

Hospital admission and/or discharge
No
ICU admission
Is information on intensive care unit admission available?
No
Cause of death
Captured
Prescriptions of medicines
Captured
Prescriptions vocabulary
other
Prescriptions vocabulary, other
international nonproprietary name (INN) for anti-cancer drugs only
Dispensing of medicines
Captured
Dispensing vocabulary
other
Dispensing vocabulary, other
international nonproprietary name (INN) for anti-cancer drugs only
Advanced therapy medicinal products (ATMP)

Is information on advanced therapy medicinal products included? A medicinal product for human use that is either a gene therapy medicinal product, a somatic cell therapy product or a tissue engineered products as defined in Regulation (EC) No 1394/2007 [Reg (EC) No 1394/2007 Art 1(1)].

Yes

#### **Contraception**

Is information on the use of any type of contraception (oral, injectable, devices etc.) available?

No

#### Indication for use

Does the data source capture information on the therapeutic indication for the use of medicinal products?

Not Captured

#### **Medical devices**

Is information on medicinal devices (e.g., pens, syringes, inhalers) available?

No

#### Administration of vaccines

No

#### **Procedures**

Does the data source capture information on procedures (e.g., diagnostic tests, therapeutic, surgical interventions)?

Captured

#### **Procedures vocabulary**

Not coded (Free text)

#### **Healthcare** provider

Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available? The healthcare provider refers to individual health professionals or a health facility organisation licensed to provide health care diagnosis and treatment services including medication, surgery and medical devices.

No

#### **Clinical measurements**

Is information on clinical measurements (e.g., BMI, blood pressure, height) available?

Yes

#### **Genetic data**

Are data related to genotyping, genome sequencing available?

Not Captured

#### Biomarker data

Does the data source capture biomarker information? The term "biomarker" refers to a broad subcategory of medical signs ( objective indications of medical state observed from outside the patient), which can be measured accurately and reproducibly. For example, haematological assays, infectious disease markers or metabolomic biomarkers.

Captured

#### Biomarker data vocabulary

Other

#### Biomarker vocabulary, other

oncogenic drivers (EGFR / KRAS / ALK/ etc.) coded with COSMIC catalog

#### **Patient-reported outcomes**

Is information on patient-reported outcomes (e.g., quality of life) available?

No

#### Patient-generated data

Is patient-generated information (e.g., from wearable devices) available?

#### Units of healthcare utilisation

Are units of healthcare utilisation (e.g., number of visits to GP per year, number of hospital days) available or can they be derived? Units of healthcare utilisation refer to the quantification of the use of services for the purpose of preventing or curing health problems.

No

#### **Unique identifier for persons**

Are patients uniquely identified in the data source?

Yes

#### **Diagnostic codes**

Not Captured

#### **Medicinal product information**

Captured

#### **Medicinal product information collected**

Active ingredient(s)

Route of administration

#### **Medicinal product vocabulary**

Other

#### If 'other,' what vocabulary is used?

international nonproprietary name (INN)

#### **Quality of life measurements**

Not Captured

#### Lifestyle factors

Captured

#### **Lifestyle factors**

Other

Tobacco use

#### Lifestyle factors included other

Cannabis, Asbestos

#### **Sociodemographic information**

Captured

#### Sociodemographic information collected

Age

Gender

Sex

# Quantitative descriptors

# Population Qualitative Data

#### Population age groups

Adult and elderly population (≥18 years)

Elderly (≥ 65 years)

# Estimated percentage of the population covered by the data source in the catchment area

61 000 patients included in the 2024 ESME-LC database.

This database compiles data from existing data available from patient's

electronic medical records (EMR) at 38 participating hospitals (19 French comprehensive cancer centers and 19 public hospitals).

Description of the population covered by the data source in the catchment area whose data are not collected (e.g., people who are registered only for private care)

Comprehensive inclusion of all patients treated for lung cancer in the 38 participating hospitals.

# **Population**

#### **Population size**

61000

# Population by age group

Age group	Population size
Adults (18 to < 46 years)	1984
Elderly (≥ 65 years)	33079

# Data flows and management

### Access and validation

**Governance details** 

Documents or webpages that describe the overall governance of the data source and processes and procedures for data capture and management, data quality check and validation results (governing data access or utilisation for research purposes).

### ESME program\_governance\_2025.pdf

English (79.65 KB - PDF)

View document

#### **Biospecimen access**

Are biospecimens available in the data source (e.g., tissue samples)?

No

#### Access to subject details

Can individual patients/practitioners/practices included in the data source be contacted?

No

#### **Description of data collection**

The database includes data related to patient demographics, tumor characteristics (diagnosis, histology, relapses, metastatic disease, etc.), treatments (dates, INN, route of administration, treatment protocols, reason for termination, etc.), and clinical events. Data is collected at each participating site by technicians who are specifically trained for the project using an electronic data collection (eDC) tool.

Data imported into the final database are controlled, recoded, and harmonized before import according to the data management plan. All coding procedures are predefined by the data manager. There is no transmission of individual data; all data is centralized within each hospital using a shared anonymous format. All data is exclusively obtained retrospectively; no attempts are made

to recover non available data from the patient's medical record by contacting healthcare providers or patients.

ESME LC Data Platform aims to be a clinical and therapeutic database centralizing existing and available data from different sources used in the participating hospitals.

Data does not contain any personal data on patients. In compliance with the authorization delivered by the French Data Protection agency to Unicancer, only aggregated statistical reports and publication are released ouside Unicancer.

# Event triggering registration

#### Event triggering registration of a person in the data source

Disease diagnosis

Start of treatment

# **Event triggering de-registration of a person in the data source**Other

**Event triggering de-registration of a person in the data source, other** patient opposition to data use

#### **Event triggering creation of a record in the data source**

patient demographics, tumor characteristics (diagnosis, histology, relapses, metastatic disease, etc.), treatments (dates, INN, route of administration, treatment protocols, reason for termination, etc.), and clinical events.

# Data source linkage

#### Linkage

Is the data source described created by the linkage of other data sources (prelinked data source) and/or can the data source be linked to other data source on an ad-hoc basis?

Yes

#### Linkage description, pre-linked

SNDS : Système National des données de santé (France) / will be available from second semester 2025.

#### Linkage description, possible linkage

probabilistic linkage

# Data management specifications that apply for the data source

#### Data source refresh

Yearly

#### Informed consent for use of data for research

Not Required

#### Possibility of data validation

Can validity of the data in the data source be verified (e.g., access to original medical charts)?

No

#### **Data source preservation**

Are records preserved in the data source indefinitely?

#### Data source preservation length (years)

20 years years

#### **Approval for publication**

Is an approval needed for publishing the results of a study using the data source?

Yes

#### **Data source last refresh**

23/09/2024

# Common Data Model (CDM) mapping

#### **CDM** mapping

Has the data source been converted (ETL-ed) to a common data model?