# An observational study to assess the effectiveness and safety of cemiplimab in patients with advanced non-small cell lung cancer (NSCLC) in routine clinical practice settings in Europe (CEMI-LUNG)

**First published:** 21/10/2026

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Study | Ongoing

## Administrative details

**EU PAS number**

EUPAS1000001128

**Study ID**

1000001128

**DARWIN EU® study**

No

**Study countries**

Austria

France

Germany

Italy

Spain

**Study description**

This study is focused on patients with non-small cell lung cancer (NSCLC) and have been prescribed a cemiplimab (Libtayo®) based treatment regimen under standard care. The goal of this study is to learn more about the use, benefits, and safety of cemiplimab based treatment regimens in participants with NSCLC.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Regeneron Pharmaceuticals

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

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Institution

# Contact details

**Study institution contact**

Study Director Regeneron
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Study contact
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**Primary lead investigator**

Study Director Regeneron
Primary lead investigator

## Study timelines

**Date when funding contract was signed**
Actual: 20/12/2021

**Study start date**
Actual: 26/10/2022

**Data analysis start date**
Planned: 04/12/2028

**Date of final study report**
Planned: 30/01/2029

## Sources of funding

- Other

## More details on funding

Pharmaceutical company and other private sector

## Regulatory

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

No

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

Not applicable

## Other study registration identification numbers and links

R2810-ONC-2325, NCT05363319, U1111-1275-9867

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Effectiveness study (incl. comparative)

Other

**If ‘other’, further details on the scope of the study**

Characterization of population receiving therapy

**Data collection methods:**

Primary data collection

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**Study design:**

This is a non-interventional, longitudinal study of patients with advanced NSCLC treated with a cemiplimab-based regimen (cemiplimab monotherapy or cemiplimab in combination with platinum-based chemotherapy) in accordance with the SmPC, in routine clinical practice.

**Main study objective:**

The primary objective of the study is to describe OS in patients with advanced NSCLC treated with a cemiplimab-based regimen in routine clinical practice.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Observational prospective product registry

## Study drug and medical condition

**Medicinal product name**

LIBTAYO

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

CEMIPLIMAB

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**Medical condition to be studied**

Non-small cell lung cancer

# Population studied

**Short description of the study population**

The source population for this study will be patients with either locally advanced NSCLC not suitable for definitive chemoradiation or metastatic NSCLC and who are initiating a cemiplimab-based regimen of treatment as part of routine clinical practice at the time of study enrollment. The study will aim to enroll approximately 500 adult patients from up to 50 sites across Europe.

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**Age groups**

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 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**

500

## Study design details

**Outcomes**

• Overall survival (OS)

• ORR, duration of response (DoR), time to response (TTR), PFS, and time to first subsequent anti-NSCLC treatment (TTST) in patients with advanced NSCLC treated with a cemiplimab-based regimen in routine clinical practice

• Incidence and severity of treatment-related adverse events (TRAEs), treatment-related serious adverse events (TRSAEs), immune-mediated adverse events (imAEs), and infusion related reactions (IRRs) in patients with advanced NSCLC treated with a cemiplimab-based regimen in routine clinical practice

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**Data analysis plan**

Data collected in this registry will be analyzed descriptively.

# 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 data source

**Data source(s), other**

Prospective patient-based data collection

**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