# DARWIN EU® Overall survival in patients with locally advanced or metastatic non-small cell lung cancer treated with selected immunotherapies as first line of treatment

**First published:** 22/04/2024

**Last updated:** 10/03/2026

Study Finalised

## Administrative details

**EU PAS number**

EUPAS1000000112

**Study ID**

1000000112

**DARWIN EU® study**

Yes

**Study countries**

France

Netherlands

Spain

**Study description**

Comparative Effectiveness Study

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

**First published:** 03/11/2022

**Last updated:** 02/05/2024

Institution | Educational Institution | ENCePP partner

### IQVIA NL, Real-World-Evidence

Netherlands

**First published:** 25/11/2022

**Last updated:** 21/03/2025

Institution | Other | ENCePP partner

## Parc de Salut Mar Barcelona (PSMAR)

Spain

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

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

Institution | Hospital/Clinic/Other health care facility

# Networks

## Data Analysis and Real World Interrogation Network (DARWIN EU®)

- Belgium
- Croatia
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Italy
- Netherlands
- Norway
- Portugal
- Spain
- Sweden

United Kingdom

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

**Last updated:** 30/04/2025

Network

# Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Talita Duarte-Salles

Primary lead investigator

# Study timelines

**Date when funding contract was signed**

Planned: 26/06/2023

Actual: 26/06/2023

**Study start date**

Planned: 29/02/2024

Actual: 26/03/2024

**Date of final study report**

Planned: 07/03/2025

Actual: 30/04/2025

## Sources of funding

- EMA

## Study protocol

DARWIN EU_D2.2.3_Protocol_P2-C3-003_NSCLC_v3.2_Clean.pdf (884.56 KB)

DARWIN EU_Protocol_P2-C3-003_NSCLC_V5_Amendment.pdf (1014.16 KB)

## Regulatory

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

Yes

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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:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Study design:**

New user matched cohort study.

**Main study objective:**

The overall aim of this study is to assess the overall survival of patients with locally advanced or metastatic NSCLC who initiate first-line treatment with selected immunotherapies (pembrolizumab, atezolizumab, cemiplimab, nivolumab, durvalumab, and ipilimumab) and how it compares to the survival of locally advanced or metastatic NSCLC patients treated with chemotherapies as first line.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

IMFINZI

KEYTRUDA

LIBTAYO

OPDIVO

TECENTRIQ

YERVOY

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**Medicinal product name, other**

o Chemotherapies (cisplatin, carboplatin, pemetrexed, paclitaxel, docetaxel, gemcitabine, and vinorelbine)
given as monotherapy or in combination (as per the label) and as first line of treatment.

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

ATEZOLIZUMAB

CARBOPLATIN

CEMIPLIMAB

CISPLATIN

DOCETAXEL

DURVALUMAB

IPILIMUMAB

NIVOLUMAB

PACLITAXEL

PEMBROLIZUMAB

PEMETREXED

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**Anatomical Therapeutic Chemical (ATC) code**

(L01BA04) pemetrexed

pemetrexed

(L01BC05) gemcitabine

gemcitabine

(L01CA04) vinorelbine

vinorelbine

(L01CD01) paclitaxel

paclitaxel

(L01CD02) docetaxel

docetaxel

(L01FF01) nivolumab

nivolumab

(L01FF02) pembrolizumab

pembrolizumab

(L01XA01) cisplatin

cisplatin

(L01XA02) carboplatin

carboplatin

(L01FX04) ipilimumab

ipilimumab

(L01FF03) durvalumab

durvalumab

(L01FF05) atezolizumab

atezolizumab

(L01FF06) cemiplimab

cemiplimab

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**Medical condition to be studied**

Non-small cell lung cancer metastatic

Non-small cell lung cancer

Non-small cell lung cancer stage IIIA

Non-small cell lung cancer stage III

Non-small cell lung cancer stage IIIB

# Population studied

**Short description of the study population**

Patients with locally advanced or metastatic NSCLC.

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**Age groups**

- Adults (18 to < 65 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)

# Study design details

**Data analysis plan**

All analyses will be conducted separately for each database, and will be carried out in a federated manner, allowing analyses to be run locally without sharing patient-level data.

First, we will run cohort diagnostics to evaluate data availability and data quality in terms of identification of locally advanced or metastatic NSCLC as well as recording of cancer treatments of interest.

Before sharing the study package, test runs of the analytics will be performed on a subset of the data sources and quality control checks will be performed.

After all the tests are passed (see section 10 Quality Control), the final package will be released in a version-controlled study repository for execution against all the participating data sources.

Data partners will locally execute the analytics against the OMOP-CDM in R Studio and review and approve the default aggregated results. They will then

be made available to the Principal Investigators and study team in secure online repository (Data Transfer Zone). All results will be locked and timestamped for reproducibility and transparency.
All analyses will be reported by database, overall and stratified by age and sex when possible (minimum cell count reached). Results from objective 1 will further be stratified by calendar year.

## Documents

**Study report**

DARWIN EU_Final Report_P2-C3-003_NSCLC_V5.pdf (2.84 MB)

# 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)**

Clinical Data Warehouse of the Bordeaux University Hospital
Institut Municipal d'Assistència Sanitària Information System / Hospital del Mar / PSMAR / (Hospital del Mar Information System)
Netherlands Cancer Registry

## Use of a Common Data Model (CDM)

**CDM mapping**

Yes

**CDM Mappings**

**CDM name**

OMOP

**CDM website**

https://www.ohdsi.org/Data-standardization/

## Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

Unknown