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: 02/01/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000112

EU PAS number

EUPAS1000000112

Study ID

1000000112

DARWIN EU® study

Yes

Study countries

- ☐ France
- ☐ Netherlands
- ☐ Spain

Study description

Comparative Effectiveness Study

Study status

Ongoing

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
☐ Hungary
☐ Netherlands
☐ Norway
☐ Portugal

☐ Spain

☐ United Kingdom

First published: 01/02/2024

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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 interim report, if expected
Planned: 28/06/2024

Date of final study report
Planned: 07/03/2025

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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

Name of medicine

IMFINZI

KEYTRUDA

LIBTAYO

OPDIVO

TECENTRIQ

YERVOY

Name of medicine, 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.

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

ATEZOLIZUMAB

CARBOPLATIN

CEMIPLIMAB

CISPLATIN

DOCETAXEL

DURVALUMAB

IPILIMUMAB

NIVOLUMAB

PACLITAXEL

PEMBROLIZUMAB

PEMETREXED

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

(L01XC11) ipilimumab

ipilimumab

(L01XC28) durvalumab

durvalumab

(L01XC32) atezolizumab

atezolizumab

(L01XC33) cemiplimab

cemiplimab

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.

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.

Data management

Data sources

Data source(s)

Clinical Data Warehouse of the Bordeaux University Hospital

Institut Municipal d'Assistència Sanitària 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