DARWIN EU® - Enhanced Preparedness of the DARWIN EU Network for regulatory questions in oncology – DARWIN OncoNet

First published: 10/11/2025

Last updated: 17/07/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000824

Study ID

1000000824

DARWIN EU® study

Yes

Study countries

- Croatia
- Denmark
- Estonia
- Finland

France
Germany
Greece
Hungary
Italy
Netherlands
Norway
Spain
Sweden
United Kingdom

Study description

There is a regulatory need to perform real-world data (RWD) studies in oncology. However, several
DARWIN EU® studies were not feasible due to the absence of key variables, limited granularity of data, and
analytical pipelines required to address specific regulatory questions. Some of these data elements are
available in certain data sources (source data) within the DARWIN EU® Data Network but have not yet been
mapped to the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM).
This study focuses on improving data quality (with specific focus on extensiveness and reliability) related to
oncology in the DARWIN EU® Data Network, as well as enhancing the analytical pipelines that will facilitate
future oncology studies in DARWIN EU®. This initiative is important for advancing the use of RWD in cancer
research by ensuring accurate, detailed data representation, and the availability of appropriate analytical

tools.

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**

Networks

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

Belgium

Croatia

Denmark

Estonia

Finland

France

Germany
Greece
Hungary
Italy
Lithuania
Netherlands
Norway
Poland
Portugal
Spain
Sweden
United Kingdom
United States

First published: 01/02/2024

Last updated: 05/11/2026

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: 29/09/2025

Actual: 29/09/2025

Study start date
Planned: 12/12/2025

Actual: 12/12/2025

Date of final study report
Planned: 01/12/2026

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P4-C4-002_OncoNet_V4.0.pdf (1.65 MB)

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Method development or testing

Data collection methods:

Secondary use of data

Study design:

Cohort studies will be conducted using routinely collected health data from 18 data sources from 14 countries across Europe.

Main study objective:

o characterise and map oncology-related data into the Observational Medical Outcomes Partnership Common Data Model (OMOP CDM) for individuals with selected cancer types by:

1.1. Characterising individuals with selected cancer types in terms of age at the

time of diagnosis, sex, performance status, cancer stage, cancer grade, clinical and laboratory measurements, and cancer treatments and procedures before and after data mappings.
1.2. Providing guidance and support in mapping data on tumour grade, stages (American Joint Committee on Cancer/Union for International Cancer Control (AJCC/UICC) Tumour, Node, Metastasis (TNM) classification), selected cancer treatments (treatment episodes, regimens, and information regarding cycles/sequencing), and biomarkers to the OMOP CDM.
1.3. Developing and implementing phenotypes for the definition of cancer subtypes, grades, and stages (AJCC/UICC TNM), and cancer-specific measurements (tumour-specific biomarkers) at and after cancer diagnosis in individuals with selected cancer types.
To develop and evaluate algorithms to identify oncological treatment episodes, regimens, and lines of therapy, and to describe regimen level treatment patterns received by patients with selected cancers.
To identify available data elements to describe treatment response, cancer progression and recurrence, and relevant time-to-event endpoints.
To create a database with aggregate counts related to oncology to support future feasibility assessments in the DARWIN EU® Data Network.

Study Design

Non-interventional study design
Cohort

Population studied

Short description of the study population

The study population will include all individuals who meet the eligibility criteria at study entry.

Age groups

- **In utero**
- **Paediatric Population (< 18 years)**
  - Neonate
    - Preterm newborn infants (0 – 27 days)
    - Term newborn infants (0 – 27 days)
  - Infants and toddlers (28 days – 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
- **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)

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)

Estonian Biobank

Clinical Data Warehouse of the Bordeaux University Hospital

UK Biobank

InGef Research Database

Semmelweis University Clinical Data

Papageorgiou General Hospital Database

Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)

Danish Health Data Registries

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

TaUH patient cohort (FinOMOP)

Research Repository @Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

The Cancer Registry of Norway

Institut Municipal d'Assistència Sanitària Information System / Hospital del Mar / PSMAR / (Hospital del Mar Information System)

Health Impact - Swedish Population Evidence Enabling Data-linkage

Netherlands Cancer Registry

Data source(s), other

Finnish Care Register for Health Care, Auria Clinical Informatics, Hospital Universitario 12 de Octubre

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

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

CDM version

https://ohdsi.github.io/CommonDataModel/cdm54.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No