DARWIN EU® – Prevalence of selected cancers

First published: 19/08/2025

Last updated: 08/10/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000715

Study ID

1000000715

DARWIN EU® study

Yes

Study countries

- [ ] Croatia
- [ ] Denmark
- [ ] Germany
- [ ] Netherlands
- [ ] Norway

Study description

Substantial uncertainty surrounds the prevalence of rare blood cancers. Estimates generated from real-world data can be influenced by database type, setting, and quality.

This present study builds on a previous DARWIN EU® study (EUPAS50800), which estimated the prevalence of rare blood cancers using data from five sources in Europe, primarily reflecting primary care settings.

Across the databases included in the study, acute lymphocytic leukaemia and acute myeloid leukaemia were the least prevalent diseases, with the highest estimates for their 5-year partial point prevalence being 0.65 and 1.03 per 10,000, respectively.

The highest estimate of prevalence of diffuse large B-Cell lymphoma was 1.73 per 10,000, while the highest prevalence of follicular lymphoma was 2.83 per 10,000.

Lastly, the highest estimates for prevalence of chronic lymphocytic leukaemia and multiple myeloma were 4.13 and 4.27 per 10,000, respectively.

Importantly, the study assessed the impact of different design choices on the obtained results, including different windows for prevalence assessment (i.e., point vs. period prevalence) and outcome duration (i.e., complete vs. partial prevalence, using 2 and 5 years to define outcome duration).

Building on the methodological work of the previous study, the current study is now repeated to incorporate additional outcomes (i.e., pancreatic cancer and soft tissue sarcoma) and data sources, including registry data and claims data.

Importantly, this study will incorporate two national cancer registries in Europe, which will require the use of external sources, such as national estimates, to derive denominators for prevalence estimation.

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
- [ ] 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

Berta Raventos

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/04/2025

Actual: 09/04/2025

Study start date

Planned: 11/08/2025

Actual: 11/08/2025

Date of final study report
Planned: 30/01/2026

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P4-C2-005_Prevalence of selected cancers_V3.0.pdf

(952.47 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 topic:

Disease /health condition

Study topic, other:

Cancers

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

A cohort study will be conducted using routinely collected health data from 5 databases from 5 countries across Europe. This will consist of a descriptive epidemiological study providing point prevalence estimates of selected cancers in each participating database.

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

All individuals in the database during the study period will be eligible for inclusion in the study. No prior history requirement will be applied in the primary analysis.

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)

Study design details

Setting

The primary aim of this study is to estimate the point prevalence of rare blood cancers, pancreatic cancer, and soft tissue sarcoma across selected databases in Europe.

The secondary aim of this study is to compare the prevalence of selected

cancers included in the primary aim of the study, using denominator data available within the data source versus denominator data obtained from external sources.

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)

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

Danish Health Data Registries

InGef Research Database

Netherlands Cancer Registry

The Cancer Registry of Norway

Data sources (types)

Cancer registry

Disease registry

Electronic healthcare records (EHR)

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/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No