DARWIN EU® – Frailty and polypharmacy among adults with selected cancers at the time of diagnosis

First published: 22/04/2024

Last updated: 11/11/2024





Administrative details

| EU PAS number | |
|--------------------------|--|
| EUPAS1000000120 | |
| Study ID | |
| 100000120 | |
| DARWIN EU® study | |
| Yes | |
| | |
| Study countries Belgium | |
| | |
| Belgium | |

| Spain | |
|----------------|--|
| United Kingdom | |

Study description

This study intends to investigate the ability to characterise frailty and polypharmacy in real-world data sources, to estimate the prevalence of frailty and polypharmacy in people aged 18 and above with selected cancers at the point of diagnosis and to describe their characteristics. While the focus is on older adults, the study will explore the full age range of adulthood to better contextualise the results.

Study status

Finalised

Research institutions and networks

Institutions

IQVIA NL, Real-World-Evidence

| First published: 25/11/2022 |
|---|
| Last updated: 21/03/2025 |
| Institution Other ENCePP partner |
| |
| Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol |
| ☐ Spain |
| First published: 05/10/2012 |
| Last updated: 23/05/2025 |
| Institution |
| |
| University of Oxford, University of Tartu |
| Networks |
| Data Analysis and Real World Interrogation Network (DARWIN EU®) Belgium Croatia |
| |

Netherlands

| ☐ 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

Ilse Schuemie study@darwin-eu.org

Study contact

study@darwin-eu.org

Primary lead investigator

Talita Duarte-Salles

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/04/2024

Study start date

Planned: 05/04/2024

Date of final study report

Planned: 31/05/2024

Actual: 09/07/2024

Sources of funding

EMA

Study protocol

DARWIN_EU_D2.2.3_Protocol_P2-C1-009_Frailty and Polypharmacy at cancer diagnosis_v2.3.pdf (1.58 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 type:

Non-interventional study

Study design:

A population-based cohort study of all incident cases of selected cancers will be conducted.

Main study objective:

The aim of this study is to estimate the prevalence of frailty and polypharmacy at the point of diagnosis of selected cancers in adults and to describe their characteristics.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Breast cancer

Ovarian cancer

Endometrial cancer

Prostate cancer

Colorectal cancer

Lymphoma

Additional medical condition(s)

Lung cancer, pancreatic cancer, leukemia and myeloma

Population studied

Short description of the study population

The study population will include all individuals aged 18 years and above with a primary diagnosis of selected cancers (lung, breast, ovary, endometrium, prostate, pancreas, colorectal cancer, lymphoma, leukemia and myeloma) recorded between 01/01/2017 and 31/12/2022, with at least one year of prior history available before cancer diagnosis. Individuals with a diagnosis of cancer (any, excluding non-melanoma skin cancer) any time prior to the diagnosis of one of the selected cancers will be excluded.

Additional eligibility of a minimum of 1 year of potential follow-up time prior to the end of last database observations will be imposed for the estimation of one-year hospitalisation and mortality rates if the data sources capture this information.

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)

Study design details

Setting

This study will be conducted using routinely collected health data from 6 databases in the DARWIN EU network of data partners from 6 European countries. All databases were previously mapped to the OMOP CDM.

Data sources

- 1. Clinical Practice Research Datalink (CPRD) GOLD, United Kingdom
- 2. IQVIA Disease Analyzer Germany (IQVIA DA Germany), Germany
- 3. IQVIA Longitudinal Patient Database Belgium (IQVIA LPD Belgium), Belgium
- 4. Integrated Primary Care Information Project (IPCI), The Netherlands
- 5. Estonian Biobank (EBB), Estonia
- 6. Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària (SIDIAP), Spain

Data analysis plan

Population-level descriptive epidemiology:

- Prevalence rates of the condition of interest

Patient-level characterisation:

- Large-scale characterisation
- Patient-level characteristics
- Prognosis / progression to a pre-specified outcome

Documents

Study report

DARWIN EU_D2.2.4_Report_P2-C1-009 Frailty and polypharmacy report_V4.pdf (5.9 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 Practice Research Datalink (CPRD) GOLD

Estonian Biobank

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

IQVIA Disease Analyzer Germany

IQVIA Longitudinal Patient Data - Belgium

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 | |