DARWIN EU® - Time to onset of thromboembolic events in adults with selected types of cancer

First published: 10/11/2025

Last updated: 13/05/2026

Study Finalised

Administrative details

EU PAS number

EUPAS1000000814

Study ID

1000000814

DARWIN EU® study

Yes

Study countries

- Belgium
- Denmark
- Estonia
- Finland

Germany
Netherlands
Spain
United Kingdom

Study description

Thromboembolic events are a common complication for individuals with cancer, with risk varying according to the cancer type, suggesting that mechanisms that play a role in the occurrence of these events may be specific to the cancer type itself or its treatment mechanisms. Haematological malignancies and lung, pancreas, stomach, bowel, and brain cancers are generally associated with a high risk of thrombosis, whilst prostate and breast cancers are associated with low risk of thrombosis.

When a safety signal of a thromboembolic event appears in cancer populations, it can be challenging to assess a potential association with the oncologic treatment without reliable information on the background risk. This study is intended to address this knowledge gap by generating evidence on the time to onset of different venous thromboembolic events among adults with selected cancer types.

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

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

Anton Barchuk

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/08/2025

Study start date

Planned: 28/10/2025

Actual: 28/10/2025

Date of final study report
Planned: 29/05/2026

Actual: 07/05/2026

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P4-C2-017_Thromboembolic events in selected cancers_V3.0.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 topic:

Disease /health condition

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.

Main study objective:

1. To estimate the thromboembolism-free survival within 5 years of the first cancer diagnosis in adults with each type of selected cancer, overall and stratified by age group, sex, and study subperiod.
2. To estimate the median time from the first cancer diagnosis to onset of thromboembolic events in individuals with thromboembolic events with each type of selected cancer, overall and stratified by age group, sex, and study subperiod.

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

Objective 1

Inclusion criteria

• First diagnosis of a selected cancer (index date) between 01/01/2016 and 31/12/2022 (inclusion period)

• Age ≥18 years at cancer diagnosis

• Minimum of 365 days of available history before the cancer diagnosis date

• Cancer diagnosis date ≥365 days prior to end of data availability of the data source

Exclusion criteria

• History of any cancer diagnosis ever before the selected cancer diagnosis date

Objective 2

Inclusion criteria

• The subset of the cohort for objective 1 who experienced the outcome (i.e., thromboembolic event) during follow-up.

The study design to address objective 1, including assessment windows, is visualised in Figure 1. For objective 2, we will include the subset of the cohort of adults with cancer that experienced a thromboembolic event during follow-up.

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)

Documents

Study report

DARWIN EU_Report_P4-C2-017_Thromboembolic events in selected cancers_V4.0.pdf (3.52 MB)

Shiny App

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)

IQVIA Longitudinal Patient Data - Belgium

IQVIA Disease Analyzer Germany

Danish Health Data Registries

Estonian Biobank

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

Clinical Practice Research Datalink (CPRD) GOLD

UK Biobank

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