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

**First published:** 10/11/2025

**Last updated:** 21/01/2026

Study Ongoing

## 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**

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

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Network

## Contact details

**Study institution contact**

Natasha Yefimenko study@darwin-eu.org

Study contact

study@darwin-eu.org

**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: 30/01/2026

## 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

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

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Data collection methods:**

Secondary use of data

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**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.

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**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)

# 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