

# DARWIN EU® - Acute myeloid leukaemia: incidence, patient characteristics, treatments, and survival in the period 2015–2024

**First published:** 08/10/2025

**Last updated:** 10/11/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000773

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### Study ID

1000000773

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### DARWIN EU® study

Yes

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### Study countries


 Croatia

 Denmark

 Finland

 Germany

 Netherlands

 Norway

 Spain

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## **Study description**

Acute myeloid leukaemia (AML) is an aggressive haematological malignancy characterised by the uncontrolled proliferation of myeloid precursors. It primarily affects older adults but is also diagnosed in children.

Despite advances in diagnostics and treatment, survival remains poor, especially among elderly patients.

Diagnosis relies on blast counts and genetic markers, with evolving classifications emphasising molecular features. Standard treatment includes induction chemotherapy and, in eligible patients, allogeneic stem cell transplant. Although novel targeted therapies show promise, further evidence is needed to support their safety.

This study aims to generate real-world evidence on AML incidence, patient characteristics, treatment patterns, and survival, utilising routinely collected healthcare data, to inform both clinical and regulatory decision-making.

This will be the basis for further work on dedicated algorithms from source data to improve data quality and availability in AML.

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## **Study status**

Ongoing

## **Research institutions and networks**

### **Institutions**

# Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

 Netherlands

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**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

[study@darwin-eu.org](mailto:study@darwin-eu.org)

### Primary lead investigator

Anton Barchuk

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 16/06/2025

Actual: 16/06/2025

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### Study start date

Planned: 26/09/2025

Actual: 26/09/2025

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### **Date of final study report**

Planned: 30/01/2026

## Sources of funding

- EMA

## Study protocol

[DARWIN EU\\_Protocol\\_P4 C1-007\\_AML\\_in\\_DARWIN\\_EU\\_V3.0.pdf](#) (1 MB)

[DARWIN EU\\_Protocol\\_P4-C2-011\\_AML\\_in\\_DARWIN\\_EU\\_V2.0.pdf](#) (1 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 topic, other:**

Acute myeloid leukaemia

**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:**

Cohort studies will be conducted using routinely collected health data

**Main study objective:**

1. To estimate the annual incidence of AML in children (<18 years old) and adults ( $\geq 18$ ).
2. To characterise AML patients in terms of demographics, performance status, conditions, disease characteristics, measurements, and procedures.
3. To describe treatment patterns in AML patients.
4. To estimate overall survival 1, 3, and 5 years for patients with newly diagnosed AML.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

### **Medical condition to be studied**

Acute myeloid leukaemia

## Population studied

### **Short description of the study population**

For the estimation of incidence, all individuals present in the data source will be included in the denominator according to the requirements described in section 8.4 of the protocol. Only individuals with newly diagnosed AML will be included in the study for objectives 2-4.

#### Objective 1 inclusion criteria

- Observation in the period 01/01/2015 to 31/12/2024
- Minimum 365 days of available history before contributing to person-time at risk (except for children <1 year)

#### Objective 2-4 inclusion criteria

- First diagnosis of AML in the period of 01/01/2015 to 31/12/2024
  - Minimum 365 days of available history before diagnosis date (except for children <1 year)
  - No prior history of AML before the study period
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### **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)**

Danish Health Data Registries

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

The Cancer Registry of Norway

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

InGef Research Database

Netherlands Cancer Registry

The Information System for Research in Primary Care (SIDIAP)

HARMONY Alliance Foundation Platform

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### **Data source(s), other**

Finnish Care Register for Health Care, Hospital Universitario 12 de Octubre

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### **Data sources (types)**

[Disease registry](#)

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

### **CDM mapping**

Yes

### **CDM Mappings**

### **CDM name**

OMOP

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### **CDM website**

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

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### **CDM version**

<https://ohdsi.github.io/CommonDataModel/index.html>

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No