

# DARWIN EU® - Characteristics of individuals with acute graft vs. host disease with intestinal involvement

**First published:** 17/12/2025

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Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000878

### Study ID

1000000878

### DARWIN EU® study

Yes

### Study countries

☐ France

☐ Germany

☐ Spain

### 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

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

Study contact

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

### Primary lead investigator

Katia Verhamme

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 30/10/2025

Actual: 30/10/2025

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**Study start date**

Planned: 11/12/2025

Actual: 11/12/2025

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**Date of final study report**

Planned: 27/02/2026

## Sources of funding

- EMA

## 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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**Data collection methods:**

Secondary use of data

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**Study design:**

A cohort study will be conducted using routinely collected health data from 3 data sources from 3 countries across Europe.

**Main study objective:**

1. Describe the baseline characteristics (age, sex, transplant type, indication of transplant, treatment (corticosteroids, ruxolitinib, and other second line treatment for aGvHD), and mortality) of patients with aGvHD.
2. Describe the baseline characteristics (age, sex, transplant type, indication of transplant, treatment (corticosteroids, ruxolitinib, and other second line treatment for aGvHD), and mortality) of patients with aGvHD with intestinal involvement.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

## Medical condition to be studied

Acute graft versus host disease

## Population studied

### Short description of the study population

Inclusion criteria:

For objective 1, the study population will consist of all individuals with at least 365 days of database history, a diagnosis with aGvHD or aGvHD with intestinal involvement, and with a minimum age of 18 years at time of diagnosis.

Exclusion criteria:

- Individuals with a history of aGvHD prior to the start of the study period
  - Less than 365 days of database history prior to the index date
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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)

The Valencia Health System Integrated Database

InGef Research Database

IATROS

## 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