DARWIN EU® - Multiple myeloma: patient characterisation, treatments, and survival in the period 2012–2024

First published: 25/09/2025

Last updated: 06/10/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000757

Study ID

1000000757

DARWIN EU® study

Yes

Study countries

- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany

- [ ] Norway
- [ ] Spain
- [ ] Sweden

Study description

Multiple myeloma is a rare type of blood cancer with an estimated overall crude and age-standardized incidence rate of 6.7 and 2.8 per 100,000 persons in 2022 in Europe, respectively.

Survival rates have improved in recent years due to advancement in disease management and the introduction of new therapies, such as immunomodulatory agents, proteasome inhibitors, and monoclonal antibodies. However, unmet needs for new medicines remain for the patients who do not respond to current therapies.

The rarity of multiple myeloma poses challenges across Europe in obtaining a comprehensive understanding of patient characteristics at the time of diagnosis, the different therapies administered in subsequent treatment lines, and overall survival. This study aims to address these gaps, which are important from a regulatory point of view to provide context and help understand the added value of the newest medicines under development or recently approved.

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

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Study contact

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Primary lead investigator

Guido van Leeuwen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/04/2025

Actual: 08/04/2025

Study start date

Planned: 08/09/2025

Actual: 08/09/2025

Date of final study report
Planned: 31/12/2025

Sources of funding

- EMA

Study protocol

DARWIN_EU_Protocol_P4 C2-004_RR_Multiple_myeloma_V4.0.pdf (990.2 KB)

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 topic, other:

Multiple myeloma

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 using routinely collected health data. The study will comprise of:

• A patient-level characterisation will be conducted to address objective 1,2,3,4 to characterise patients with multiple myeloma diagnosed in the period 2012–2024.

Main study objective:

1. To describe demographic and clinical characteristics of patients with multiple myeloma at the time of diagnosis.
2. To describe multiple myeloma treatments (including combinations and regimen types, e.g. triplets, etc.).
3. To describe sequences of treatments and treatment combinations for multiple myeloma.
4. To estimate the overall survival of incident multiple myeloma patients during the study period (2012–2024).

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

The study population will include all individuals with a first diagnosis of multiple myeloma identified in the database between 01/01/2012 and 31/12/2024. Participants with a diagnosis of cancer (any, excluding non-melanoma skin cancer) any time prior to the diagnosis of multiple myeloma will be excluded.

Age groups

All

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)

Clinical Data Warehouse of the Bordeaux University Hospital

InGef Research Database

IMI 116026 HARMONY; IMI 945406 HARMONY PLUS - HARMONY Big Data Platform

The Cancer Registry of Norway

Data sources (types)

Cancer registry

Electronic healthcare records (EHR)

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

Unknown