# DARWIN EU® Rates of occurrence of treatment-related intercurrent events in patients with major depressive disorder

**First published:** 03/10/2023

**Last updated:** 25/09/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS106685

**Study ID**

107562

**DARWIN EU® study**

Yes

**Study countries**

- [ ] Germany
- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom

**Study description**

What is the incidence of treatment-related intercurrent events common in clinical trials in patients with major depressive disorder?
Study objectives, to examine the proportion of patients with newly diagnosed major depressive disorder who start treatment with antidepressants, NSRIs, SSRIs, or other anti-depressants, as well as those who switch or discontinue treatment at specific intervals 4, 6, 8, 12, and 24 weeks after treatment initiation, stratified by age, sex, and country - database during the study period 2013 - 2022, to estimate the duration of antidepressant, use in patients with newly diagnosed major depressive disorder who initiate treatment with antidepressants, NSRIs, SSRIs, or other antidepressants, stratified by age, sex, and country - database during the study period 2013 - 2022, to assess the proportions of patients with newly diagnosed major depressive disorder who initiate, switch, or discontinue treatment with psycholeptics, antipsychotics, anxiolytics, hypnotics, and sedatives at specific intervals 4, 6, 8, 12, and 24 weeks after starting antidepressant therapy, stratified by age, sex, and country - database during the study period 2013 - 2022.

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**Study status**

Finalised

# Research institutions and networks

## Institutions

### Clinical Practice Research Datalink (CPRD)

United Kingdom

**First published:** 15/03/2010

**Last updated:** 17/01/2025

Institution | Laboratory/Research/Testing facility | ENCePP partner

## Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

☐ Spain

**First published:** 05/10/2012

**Last updated:** 23/05/2025

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | 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**

Johnmary Arinze

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**
Planned: 27/07/2023

Actual: 27/07/2023

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**Study start date**
Planned: 01/01/2013

Actual: 01/01/2013

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**Date of final study report**
Planned: 30/12/2023

Actual: 03/06/2024

## Sources of funding

- EMA

## Study protocol

Study Protocol P2 C1-008 Version 3.1 final.pdf(693.82 KB)

## 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 type:**

Non-interventional study

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**Main study objective:**

To examine the proportion of patients with newly diagnosed major depressive disorder who start treatment with antidepressants and psycholeptics and of those the proportion who switch or discontinue treatment by specific timepoints after treatment initiation, stratified by age group, sex, and country.

## Study Design

**Non-interventional study design**

Cohort

## Population studied

**Age groups**

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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**Estimated number of subjects**

19300000

## Study design details

**Outcomes**

Treatment initiation, treatment discontinuation and treatment switch.

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**Data analysis plan**

Percentage of patients initiating treatment with specific antidepressants or psycholeptics. Percentage of patients switching treatment to specific antidepressants or psycholeptics. Percentage of patients discontinuing treatment with specific antidepressants or psycholeptics. Estimation of the mean, median, 25th percentile, 75th percentile, minimum, and maximum durations of antidepressant use.

## Documents

**Study report**

DARWIN_EU_D2.2.4_Report_P2-C1-008_MDD_V5.1.pdf(1.41 MB)

# 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)**

Institut Municipal d'Assistència Sanitària Information System

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

Clinical Practice Research Datalink (CPRD) GOLD

IQVIA Disease Analyzer Germany

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**Data sources (types)**

Electronic healthcare records (EHR)

Other

## 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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## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No