

# DARWIN EU® - Capturing suicidality and depression related variables in databases

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

**Last updated:** 23/03/2026

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000825

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### Study ID

1000000825

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### DARWIN EU® study

Yes

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### Study countries

 Denmark

 Estonia

 Finland

 France

 Germany

 Greece

-  Netherlands
  -  Norway
  -  Portugal
  -  Spain
  -  Sweden
  -  United Kingdom
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## Study description

Depression is a prevalent health condition causing significant healthcare utilisation, morbidity, and mortality. Self-harm, suicidal ideation, attempt, and suicide also comprise a complex and significant public health issue. Safety concerns on the use of medicines in these populations or medicines as a cause of these conditions are increasingly common. A better understanding on how well data on these areas are captured will be important to inform the feasibility of conducting Real world data (RWD) studies on these populations or their use as outcomes in DARWIN EU® studies.

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## 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

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Study contact

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

### Primary lead investigator

Nicholas Hunt

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 31/08/2025

Actual: 31/08/2025

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### Study start date

Planned: 12/12/2025

Actual: 12/12/2025

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### Date of final study report

Planned: 01/09/2026

## Sources of funding

- EMA

## Study protocol

[DARWIN EU\\_Protocol\\_P4-C1-022\\_P4-C2-015\\_P4-C2-016\\_suicide characterisation\\_V4.0\\_Clean.pdf](#) (1.89 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

Feasibility analysis

**Data collection methods:**

Secondary use of data

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**Study design:**

The retrospective cohort study will comprise of:

- A descriptive epidemiology study including the general population will be conducted to address objective 1 and 2c.
- A descriptive study including individuals with the events of interest will be conducted to address objective 2a, 2b, and 3.

**Main study objective:**

To estimate the incidence and prevalence of individuals with a record of suicide, suicide-related

events, depression, healthcare utilisation, symptom measurement data, procedures, and

depression remission within the DARWIN EU® network.

2. To characterise reporting of suicide, suicide-related events, depression, symptom measurement,

healthcare utilisation, and resolution reporting within the DARWIN EU® network in terms of:

a) Mean and median of number of event reporting per individual within the study period.

b) The mean cumulative function of event recording

c) Describe the values of depression symptom measurement data.

3. To describe the characteristics of individuals with records of suicide, suicide-related events, and

depression in terms of demographic characteristics, concomitant medications, comorbidities, procedures, and lifestyle factors.

## Study Design

### **Non-interventional study design**

Cohort

## Population studied

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

For objective 1 and 2c, the general population will constitute the study population:

Inclusion criteria

- Minimum 365 days of available history before index date (except for hospital data sources)
- Aged  $\geq 10$  years of age. This age cutoff is based on the World Health Organisation (WHO) definition for adolescence (age 10 to 19), since we do not expect relevant results in lower age groups.[3]

For objective 2a, 2b. and 3:

Inclusion criteria

- Minimum 365 days of available history before index date (except for hospital data sources)
- Aged  $\geq 10$  years of age
- Condition or observation of completed suicide, suicide-related events (suicide attempt, suicide ideation, or self-harm), or depression

## Study design details

## Setting

This study will be conducted using routinely collected data from 23 data sources in the DARWIN EU® network of data partners from 14 European countries, of which 12 EU member states. All data were a priori mapped to the OMOP CDM.

## 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)

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

Danish Health Data Registries

Estonian Biobank

InGef Research Database

Integrated Primary Care Information (IPCI)

Clinical Practice Research Datalink (CPRD) GOLD

Papageorgiou General Hospital Database

Egas Moniz Database

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el  
Ámbito Público (Pharmacoepidemiological Research Database for Public Health  
Systems)

Institut Municipal d'Assistència Sanitària Information System / Hospital del Mar /  
PSMAR / (Hospital del Mar Information System)

The Information System for Research in Primary Care (SIDIAP)

Health Impact - Swedish Population Evidence Enabling Data-linkage

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

TaUH patient cohort (FinOMOP)

IATROS

Semmelweis University Clinical Data

Norwegian Linked Health registry at University of Oslo

Health Data Research Platform of the Balearic Islands (PRISIB)

The Valencia Health System Integrated Database

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

Hospital Universitario 12 de Octubre (H12O), Finnish Care Register for Health  
Care (FinOMOP-THL), Unidade Local de Saúde de Matosinhos Realtime Database  
(ULSM-RT)

## 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