DARWIN EU® - RR2 Drug utilisation study of prescription opioids

First published: 11/06/2025

Last updated: 07/11/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000615

Study ID

1000000615

DARWIN EU® study

Yes

Study countries

- [ ] Croatia
- [ ] Finland
- [ ] Germany
- [ ] Hungary
- [ ] Italy
- [ ] Portugal

Sweden

Study description

A drug utilisation study of prescription opioids based on a Common Data Model (CDM) will provide useful information on the trends of prescription opioids and the characteristics of prescription opioid users in Europe.
By supplementing the conventional European monitoring systems for aggregated opioid consumption, this study will offer detailed data on these drugs incl. their strength and route of administration, thereby enabling well-informed, evidence-based decision-making in addressing this multifaceted topic.
Following the completion of P2-C1-002 (EUPAS105641) and P3-C2-002 (EUPAS1000000479) (see section 'Other study identifiers'), EMA requested a routine repeated study to include additional databases and more recent data.

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

Amy Lam

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 11/03/2025

Actual: 11/03/2025

Study start date

Planned: 02/06/2025

Actual: 02/06/2025

Date of final study report

Planned: 01/10/2025

Sources of funding

- EMA

Study protocol

DARWIN EU Protocol_P4-C2-001_DUS Opioids_V2.pdf (1003.16 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

EUPAS105641

EUPAS1000000479

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study topic, other:

Opioids

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

A cohort study will be conducted using routinely-collected health data from 7 databases.

Main study objective:

This study aims to assess the incidence and prevalence of prescription opioids for the period 2012-2024, stratified by history of cancer/no history of cancer and age, sex, calendar year and country, as well as characterisation of new users, indications and treatment duration overall and in people with history of cancer/no history of cancer stratified by calendar year and country

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N01AH) Opioid anesthetics

Opioid anesthetics

(N02A) OPIOIDS

OPIOIDS

(R05DA) Opium alkaloids and derivatives

Opium alkaloids and derivatives

Population studied

Short description of the study population

The study cohort will comprise all individuals present in the database during the study period (2012-2024) and with at least 365 days of data availability (not applicable to hospital databases) before the day they become eligible for study inclusion.

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)

Egas Moniz Database

Auria Clinical Informatics (FinOMOP)

Health Impact - Swedish Population Evidence Enabling Data-linkage

InGef Research Database

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

Research Repository @Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

Semmelweis University Clinical Data

Data sources (types)

Administrative healthcare records (e.g., claims)

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