# DARWIN EU® Drug utilization study of prescription opioids

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## Administrative details

EU PAS number
EUPAS105641
Study ID
106383
DARWIN EU® study
res es e
Study countries
Belgium
Estonia
France
Germany
Netherlands
Spain

#### Study description

Prescription opioids, while effective for managing severe pain, have led to a public health crisis due to misuse, addiction, and overdose, particularly in the US.

Recently, concerns have been growing in Europe due to increasing opioid use and related mortality.

Factors such as chronic pain, mental health disorders, and advanced age can exacerbate misuse and the development of dependence.

Given the potential for global spread of this issue, enhanced surveillance and indepth research into opioid utilization patterns are imperative.

A drug utilization study using a Common Data Model (CDM) is a promising approach to supplement European opioid monitoring systems, providing more granular data to inform evidence-based decisions on this complex topic.

The European Medicines Agency commissioned this DARWIN EU© CC study to:

- (i) To investigate the annual incidence and annual period prevalence of use of opioids (overall, active drug substance, strength (weak/strong opioids) and route (oral, transdermal or parenteral)), stratified by calendar year, age, sex and country/database during the study period 2012-2022.
- (ii) To determine duration of prescription opioid use, as well as characteristics of new users and indication for opioid prescribing/dispensing, all stratified by calendar year and country/database.

#### **Study status**

Finalised

## Contact details

#### **Study institution contact**

Annika Jodicke study@darwin-eu.org

Study contact

study@darwin-eu.org

#### **Primary lead investigator**

## Annika Jodicke

**Primary lead investigator** 

## Study timelines

#### Date when funding contract was signed

Actual: 30/03/2023

#### Study start date

Actual: 01/01/2012

#### Date of final study report

Actual: 06/11/2023

## Study protocol

Study Protocol P2 C1-002 Version 2.1 final.pdf (1.78 MB)

## 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

EUPAS1000000479 EUPAS1000000615

## Methodological aspects

Study type

Study type list

#### Study type:

Non-interventional study

#### Scope of the study:

Drug utilisation

#### Main study objective:

- (i) To investigate the annual incidence and annual period prevalence of use of opioids stratified by calendar year, age, sex and country/database during the study period 2012-2022.
- (ii) To determine duration of prescription opioid use, as well as characteristics of new users and indication for opioid prescribing/dispensing, all stratified by calendar year and country/database.

## Study drug and medical condition

#### Study drug International non-proprietary name (INN) or common name

**BUPRENORPHINE** 

NALOXONE HYDROCHLORIDE DIHYDRATE

**OXYCODONE** 

**PENTAZOCINE** 

TILIDINE

#### **Anatomical Therapeutic Chemical (ATC) code**

(N01AH) Opioid anesthetics

Opioid anesthetics

(N02AX) Other opioids

Other opioids

(R05DA) Opium alkaloids and derivatives

Opium alkaloids and derivatives

## Population studied

#### Age groups

- Infants and toddlers (28 days 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)</li>
- Adults (18 to < 46 years)</li>
- Adults (46 to < 65 years)</li>
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

#### **Estimated number of subjects**

19000000

## Study design details

#### Data analysis plan

Population-level opioid use: Annual period prevalence of opioid use and annual incidence rates per 100,000 person years will be estimated.

Patient-level opioid use: Large-scale patient-level characterization will be conducted at index date, including patient demographics, and history of comorbidities and comedication.

Frequency of indication at index date, and in the immediate time before will be calculated.

Cumulative treatment duration will be estimated for the first treatment era and the minimum, p25, median, p75, and maximum will be provided.

For all analyses a minimum cell count of 5 will be used when reporting results, with any smaller counts will be noted as <5.

#### **Documents**

#### **Study report**

DARWIN EU StudyReport P2 C1 002 Opioids V3 final EUPAS.pdf (9.16 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)

The Information System for Research in Primary Care (SIDIAP)

Integrated Primary Care Information (IPCI)

IQVIA Longitudinal Patient Data - Belgium

IQVIA Disease Analyzer Germany

Auria Clinical Informatics (FinOMOP)

Estonian Biobank

Clinical Data Warehouse of the Bordeaux University Hospital

#### Data sources (types)

Electronic healthcare records (EHR)

Other

## Use of a Common Data Model (CDM)

#### **CDM** mapping

Yes

#### **CDM Mappings**

#### **CDM** name

**OMOP** 

#### **CDM** website

https://www.ohdsi.org/Data-standardization/

## Data quality specifications

## **Check stability**

**Check conformance** 

Unknown

## **Check logical consistency**

Unknown

## Data characterisation

#### **Data characterisation conducted**

No