# DARWIN EU® Drug utilization study of prescription opioids

**First published:** 04/07/2023

**Last updated:** 13/06/2025

Study Finalised

## Administrative details

**EU PAS number**

EUPAS105641

**Study ID**

106383

**DARWIN EU® study**

Yes

**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 in-depth 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.

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**Study status**

Finalised

# Contact details

**Study institution contact**

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**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

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**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

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**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)
- 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**

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

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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

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No