# Tramadol prescribing: a drug utilisation study using electronic data from France, Germany and the UK

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# Administrative details

| EU PAS number           |
|-------------------------|
| EUPAS19066              |
|                         |
| Study ID                |
| 29261                   |
| DARWIN EU® study        |
| No                      |
| Study countries  France |
| Germany                 |
| United Kingdom          |

#### **Study description**

These studies will examine patterns of tramadol prescribing using data from France, Germany and the UK between 2006 and 2016.

#### **Study status**

Finalised

## Research institutions and networks

## Institutions

## European Medicines Agency (EMA)

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Institution

# **European Medicines Agency**

## Contact details

#### **Study institution contact**

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#### **Primary lead investigator**

## **Daniel Morales**

**Primary lead investigator** 

# Study timelines

## Date when funding contract was signed

Planned: 03/10/2016 Actual: 10/10/2016

### Study start date

Planned: 03/10/2016 Actual: 10/10/2016

#### Date of final study report

Planned: 31/07/2017 Actual: 18/12/2017

# Sources of funding

EMA

# Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

# Methodological aspects

#### Study typo

#### **Study topic:**

Human medicinal product

#### **Study type:**

Non-interventional study

#### Scope of the study:

Drug utilisation

#### **Data collection methods:**

Secondary use of data

#### Main study objective:

The objectives of the study are to examine patterns of tramadol prescribing between 2006 and 2016 using data from France, Germany and the UK, with a focus on incident and prevalent tramadol prescribing, dose and duration of tramadol prescribing, clinical indications for tramadol prescribing.

## Study drug and medical condition

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

# Population studied

#### Short description of the study population

Adult patients who were prescribed with tramadol in general practice and continuously provided data over a 10-year period from 1 January 2006 to 30

June 2016 from French and German primary care electronic health record data from IMS® Disease Analyzer (October 2016 release).

#### Age groups

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)

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

100000

# Study design details

#### **Outcomes**

Trends in incident and prevalent tramadol prescribing overall and by age and gender. Clinical conditions recorded for people prescribed tramadol.

#### **Data analysis plan**

A descriptive analysis and yearly trends of tramadol prescribing will be measured in each database. The numerator will consist of a) patients prescribed tramadol and b) number of tramadol prescriptions. The denominator will consist of all other patients present in the database during the same year. Dose and duration of tramadol will be calculated using prescription information, with complete case analysis and imputation for missing prescription data applied.

## **Documents**

#### **Study results**

Prescribing patterns of tramadol in adults in IMS.pdf (165.49 KB)

#### **Study publications**

Hedenmalm, K., Slattery, J., Skibicka-Stepien, I. et al. Prescribing patterns o...

# 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)

THIN® (The Health Improvement Network®)

IQVIA Disease Analyzer Germany

Disease Analyzer - OMOP

## **Data sources (types)**

Electronic healthcare records (EHR)

# Use of a Common Data Model (CDM)

#### **CDM** mapping

# Data quality specifications

#### **Check conformance**

Unknown

## **Check completeness**

Unknown

## **Check stability**

Unknown

## **Check logical consistency**

Unknown

## Data characterisation

#### **Data characterisation conducted**

No