

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

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Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/29261>

### EU PAS number

EUPAS19066

### Study ID

29261

### DARWIN EU® study

No

### Study countries

☐ France

☐ Germany

☐ United Kingdom

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### Study description

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

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### Study status

Finalised

## Research institutions and networks

### Institutions

[European Medicines Agency \(EMA\)](#)

**First published:** 01/02/2024

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Institution

[European Medicines Agency](#)

## Contact details

### Study institution contact

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### Study 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

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### Study start date

Planned: 03/10/2016

Actual: 10/10/2016

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### 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

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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:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**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).

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### **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)

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### **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.

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## 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)

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## Study publications

[Hedenmalm, K., Slattery, J., Skibicka-Stepien, I. et al. Prescribing patterns o...](#)

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# Data management

# Data sources

## Data source(s)

THIN® (The Health Improvement Network®)

**Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## 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

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## Data characterisation

**Data characterisation conducted**

No