

# Incidence, prevalence, and characterisation of medicines with suggested drug shortages in Europe

**First published:** 02/10/2023

**Last updated:** 22/02/2024

Study

Planned

## Administrative details

### EU PAS number

EUPAS106954

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### Study ID

107398

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### DARWIN EU® study


No

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### Study countries

 Belgium

 Bulgaria

 Denmark

 Estonia

-  Finland
  -  France
  -  Germany
  -  Italy
  -  Montenegro
  -  Netherlands
  -  Portugal
  -  Serbia
  -  Spain
  -  Türkiye
  -  United Kingdom
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## **Study description**

This study aims to characterise the incidence and prevalence of medicines with (suggested) shortages and their alternatives for the period 2010-2023, stratified by healthcare setting and time period in each database. Furthermore, we aim to describe incident and prevalent patients receiving a prescription / dispensation of a medicine with (suggested) shortages for the period 2010-2023, stratified by year in each database, including information on potential indication, treatment duration, and dosage.

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## **Study status**

Planned

## Research institutions and networks

### Institutions

# Pharmaco- and Device epidemiology, University of Oxford

 United Kingdom

**First published:** 12/09/2023

**Last updated:** 11/07/2024


**Institution**

**Educational Institution**

**ENCePP partner**

## Networks

### European Health Data Evidence Network (EHDEN)

 Netherlands

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

**Last updated:** 04/08/2025

**Network**

## Contact details

### Study institution contact

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**Study contact**

[theresa.burkard@ndorms.ox.ac.uk](mailto:theresa.burkard@ndorms.ox.ac.uk)

### Primary lead investigator

Daniel Prieto-Alhambra

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 01/11/2018

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### **Study start date**

Planned: 01/01/2010

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### **Date of final study report**

Planned: 30/09/2024

## Sources of funding

- Other

## More details on funding

EHDEN

## Study protocol

[EHDENMegaStudy\\_drugshortage v1.0\\_FINAL.pdf](#) (950.09 KB)

[EHDENMegaStudy\\_drugshortage v2.0\\_FINAL.pdf](#) (950.92 KB)

## 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 type:**

Non-interventional study

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#### **Main study objective:**

To investigate the incidence and prevalence of use of medicines with (suggested) shortages and their alternatives stratified by annual period (calendar year) and healthcare setting for each database during the study period 2010-2023, and to characterize the patients and the use of medicines regarding potential indication, treatment duration, and dosage.

### Study Design

#### **Non-interventional study design**

Other

### Study drug and medical condition

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

(B01AD11) tenecteplase

tenecteplase

(L04AC14) sarilumab

sarilumab

## **Population studied**

### **Age groups**

- 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)
- 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**

200000

## **Study design details**

### **Outcomes**

To investigate the incidence and prevalence of use of medicines with (suggested) shortages and their alternatives stratified by annual period

(calendar year) and healthcare setting for each database during the study period 2010-2023. To characterise the patients and the use of medicines regarding potential indication, treatment duration, and dosage.

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### **Data analysis plan**

Population-level drug utilisation study: annual period prevalence of the medicine use and annual incidence proportion. Patient-level drug utilisation study: Large-scale patient-level characterisation will be conducted in incident and in prevalent users, defined as follows: I) in incident users, the index date will be the date of a prescription qualifying as a "new prescription" (i.e. after at least 30 days of non-use) of the specific medicine of interest for each person, II) the index date in prevalent users will be the earliest date of a prescription in the calendar year. Frequency of potential indication at index date will be assessed. Treatment duration will be estimated and the minimum, p25, median, p75, and maximum will be provided. Furthermore, daily dosage will be estimated and the minimum, p25, median, p75, and maximum will be provided.

## 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)**

Clinical Practice Research Datalink

Integrated Primary Care Information (IPCI)

Institut Municipal d'Assistència Sanitària Information System / Hospital del Mar / PSMAR / (Hospital del Mar Information System)

The Information System for Research in Primary Care (SIDIAP)

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**Data source(s), other**

LPD France

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**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

**Data characterisation**

**Data characterisation conducted**

No