

# DARWIN EU® - Drug Utilisation Study on Antibiotics in the 'Watch' category of the WHO AWaRe classification of antibiotics for evaluation and monitoring of use

**First published:** 04/07/2025

**Last updated:** 10/11/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000665

### Study ID

1000000665

### DARWIN EU® study

Yes

### Study countries

☐ Croatia

☐ Denmark

☐ Finland

- ☐ France
  - ☐ Germany
  - ☐ Hungary
  - ☐ Netherlands
  - ☐ Spain
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### **Study description**

The WHO 2023 AWaRe classification (who.int) of antibiotics for evaluation and monitoring of use classifies 258 antibiotics into 3 categories (Access/Watch/Reserve) according to their impact on antimicrobial resistance. The Watch list includes antibiotic classes that have higher resistance potential and includes most of the highest priority agents among the Critically Important Antimicrobials for Human Medicine and/or antibiotics that are at relatively high risk of selection of bacterial resistance. These medicines should be prioritized as key targets of stewardship programs and monitoring.

The DARWIN EU®\_ P1-C1-003 study focused on the Watch category and this study is now repeated to include more recent data and more data sources. This study will improve our understanding of the use of antibiotics in the Watch category in routine health care delivery, including indication, treatment duration and trends over time. The results will contribute to the EU efforts to monitor use of antibiotics as part of the global fight against antimicrobial resistance.

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### **Study status**

Ongoing

## Research institutions and networks

### Institutions

## Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

☐ Netherlands

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**Last updated:** 02/05/2024

**Institution**

**Educational Institution**

**ENCEPP partner**

## Networks

### Data Analysis and Real World Interrogation Network (DARWIN EU®)

- ☐ Belgium
- ☐ Croatia
- ☐ Denmark
- ☐ Estonia
- ☐ Finland
- ☐ France
- ☐ Germany
- ☐ Greece
- ☐ Hungary
- ☐ Italy
- ☐ Netherlands
- ☐ Norway
- ☐ Portugal

- ☐ Spain
- ☐ Sweden
- ☐ United Kingdom

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

**Last updated:** 30/04/2025

Network

## Contact details

### Study institution contact

Natasha Yefimenko [study@darwin-eu.org](mailto:study@darwin-eu.org)

Study contact

[study@darwin-eu.org](mailto:study@darwin-eu.org)

### Primary lead investigator

Marzyeh Amini

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 17/12/2024

Actual: 17/12/2024

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### Study start date

Planned: 16/05/2025

Actual: 16/05/2025

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

Planned: 30/09/2025

## Sources of funding

- EMA

## Study protocol

[DARWIN EU\\_Protocol\\_P3-C2-003\\_DUS Antibiotics Watch List\\_V3.0.pdf](#) (2.07 MB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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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:**

Herbal 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:**

1. To investigate the incidence of use of antibiotics (from the WHO AWaRe Watch category) stratified by age, sex, calendar year/month, and antibiotics class during the study period 2012-2024.
2. To characterise antibiotic (WHO AWaRe Watch category 2023) use by duration of use over the study period 2012 to 2024 stratified by calendar year and by antibiotics class.
3. To characterise antibiotic use (WHO AWaRe Watch category 2023) by indication of use over the period 2012 to 2024 stratified by calendar year and by antibiotics class.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

## Medicinal product name, other

All antibiotics on the WHO AWaRe watch category 2023

## Population studied

### Short description of the study population

The study domain includes all persons present in the data sources in the study period: 01/01/2012 to 31/12/2024 (or the latest available date) with at least 365 days observation time. This will be used as the denominator population for calculating incidence rates.

## 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 Data Warehouse of the Bordeaux University Hospital

Danish Health Data Registries

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

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

PSMAR / (Hospital del Mar Information System)

IQVIA Disease Analyzer Germany

Integrated Primary Care Information (IPCI)

Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)

The Information System for Research in Primary Care (SIDIAP)

Semmelweis University Clinical Data

## 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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### CDM version

<https://ohdsi.github.io/CommonDataModel/index.html>

## 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**

Unknown