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: 14/08/2026

Study Finalised

Administrative details

EU PAS number

EUPAS1000000665

Study ID

1000000665

DARWIN EU® study

Yes

Study countries

Croatia

Denmark

Finland

France
Germany
Hungary
Netherlands
Spain

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.

Study status

Finalised

Research institutions and networks

Institutions

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

Netherlands

First published: 03/11/2022

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
- Lithuania
- Netherlands
- Norway

Poland
Portugal
Spain
Sweden
United Kingdom
United States

First published: 01/02/2024

Last updated: 05/11/2026

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Marzyeh Amini

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/12/2024

Actual: 17/12/2024

Study start date
Planned: 16/05/2025

Actual: 16/05/2025

Date of final study report
Planned: 30/09/2025

Actual: 10/12/2025

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

• Population-level cohort study (Objective 1, Population-level drug utilisation study on ‘Access, Watch,
Reserve’ categories antibiotics)
• New drug user cohort study (Objectives 2 and 3, Patient-level drug utilisation analysis with regard to
duration and indication of antibiotics use)

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.

Study design details

Setting

This study was conducted using routinely collected data from 12 primary/secondary care data sources in the DARWIN EU® network of data partners from 11 European countries. All data were a priori mapped to the OMOP CDM.

Summary results

CONCLUSION

This multi-country analysis highlights variation in antibiotic use across the WHO 2023 AWaRe categories. In the Access group, penicillins, β-lactam/β-lactamase inhibitors, 1st-generation cephalosporins, and nitrofuran derivatives were most

prescribed, with amoxicillin, amoxicillin–clavulanic acid, and nitrofurantoin leading. Declines in broad-spectrum antibiotics and moderate increases in narrow-spectrum options such as pivmecillinam have occurred. The Watch category showed consistently higher use of macrolides, fluoroquinolones, and cephalosporins compared with other Watch antibiotics, with azithromycin, ciprofloxacin, and cefuroxime being the most commonly prescribed agents. Despite decreasing trends after 2018, broad-spectrum use remained, with seasonal peaks for respiratory and urinary infections and higher incidence rates in females and older adults. The Reserve category displayed low but increasing use of linezolid, daptomycin, and tigecycline, reflecting their expanding role in resistant infections.

Collectively, these findings demonstrate both progress and ongoing challenges in optimizing antibiotic use.

Documents

Report

Supplementary materials

Shiny App

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

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

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

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown