# DARWIN EU® - Drug utilisation study on antibiotics in the ‘Access’ category of the WHO AWaRe classification of antibiotics for evaluation and monitoring of use

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

**Last updated:** 10/03/2026

Study Finalised

## Administrative details

**EU PAS number**

EUPAS1000000663

**Study ID**

1000000663

**DARWIN EU® study**

Yes

**Study countries**

Croatia

Denmark

Finland

Germany

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 ‘Access’ category includes antibiotics that are recommended as first- or second-line treatments for a wide range of common infectious diseases.
These antibiotics are generally active against a broad spectrum of commonly encountered, susceptible pathogens and have a relatively lower risk of promoting antimicrobial resistance compared to agents in other categories.
The WHO emphasizes that ‘Access’ antibiotics should be widely available, affordable, and of assured quality across all healthcare settings to ensure equitable treatment, especially in low- and middle-income countries.
As of the 2023 update, the ‘Access’ group includes 84 antibiotics, such as amoxicillin and doxycycline, which are used to treat high-burden infections like pneumonia and urinary tract infections.(1, 2) Promoting the use of ‘Access’ antibiotics for appropriate indications is a key component of global antimicrobial stewardship strategies aimed at reducing the need for broader-spectrum agents and mitigating the spread of resistance.
The DARWIN EU®_ P1-C1-003 study focused on the Watch category but there is now interest in including also the other category (‘Access’) to characterise the use of most antibiotics, and increased focus on the indication for use.
This study will improve the understanding of the use of antibiotics 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**

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
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

Study contact

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

**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-C1-022_Access Antibiotics DUS_V3.0.pdf (1.92 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

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name, other**

All antibiotics listed under the WHO AWaRe ‘Access’ 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.

## 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)**

Danish Health Data Registries

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

IQVIA Disease Analyzer Germany

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

The Information System for Research in Primary Care (SIDIAP)

## 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