

# DARWIN EU® - Drug Utilisation Study on Antibiotics in the 'Reserve' 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

EUPAS1000000664

### Study ID

1000000664

### DARWIN EU® study

Yes

### Study countries

- Denmark
- France
- Greece

- Hungary
- Italy
- Portugal
- 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 Reserve category comprises critically important antibiotics that serve as last-resort options for treating confirmed or suspected infections caused by multidrug-resistant organisms. These antibiotics are recommended only when all alternative treatments have failed, due to their importance in combating life-threatening infections such as those caused by carbapenem-resistant Enterobacteriaceae and other extended-spectrum beta-lactamase producing bacteria.

As of the 2023 update, the Reserve category includes 27 antibiotics, reflecting the WHO's strategic effort to curb antimicrobial resistance (AMR) by promoting their strict and judicious use in both inpatient and outpatient settings. The inclusion of antibiotics in this group aims to preserve their efficacy by reducing overuse and misuse, particularly in low-resource settings where AMR surveillance may be limited.

The DARWIN EU® P1-C1-003 study focused on the Watch category but there is now interest in including also the other category (Reserve) 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 WHO AWaRe 'Reserve' category 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

Ongoing

## 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](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-C1-023\\_Reserve Antibiotics DUS\\_V3.0.pdf \(1.93 MB\)](#)

## 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:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

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**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 Reserve category) stratified by age, sex, calendar year/month, and antibiotics class during the study period 2012-2024.
2. To characterise antibiotic (WHO AWaRe 'Reserve' 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 Reserve list 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 listed under the WHO AWaRe 'Reserve' category 2023

## 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

Egas Moniz Database

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

Research Repository @Fondazione IRCCS Ca' Granda Ospedale Maggiore

Policlinico

Semmelweis University Clinical Data

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### Data source(s), other

Papageorgiou General Hospital

## 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

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# Data characterisation

## **Data characterisation conducted**

Unknown