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

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Study   Ongoing

Administrative details

EU PAS number

EUPAS1000000664

Study ID

1000000664

DARWIN EU® study

Yes

Study countries

☐ Denmark

☐ France

☐ Greece

- [ ] Hungary
- [ ] Italy
- [ ] Portugal
- [ ] 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 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.

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

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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

Sources of funding

- EMA

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

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

Name of medicine, 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

Research Repository @Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

Semmelweis University Clinical Data

Data source(s), other

Papageorgiou General Hospital

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