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

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Last updated: 10/11/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000663

Study ID

1000000663

DARWIN EU® study

Yes

Study countries

- ☐ Croatia
- ☐ Denmark
- ☐ Finland

- [ ] Germany
- [ ] 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 ‘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.

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

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.

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