

# DARWIN EU® DUS of Antibiotics in the 'Watch' category of the WHO AWaRe classification of antibiotics for evaluation and monitoring of use

**First published:** 03/02/2023

**Last updated:** 25/09/2024

Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/103382>

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### **EU PAS number**

EUPAS103381

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### **Study ID**

103382

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### **DARWIN EU® study**

Yes

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## Study countries

- France
  - Germany
  - Netherlands
  - Spain
  - United Kingdom
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## Study description

This drug utilisation study aims to characterise the incidence of prescription of the 141 antibiotics in the 'Watch' list, including indication and treatment duration, for the period 2012-2021, stratified by year and country. For this study, databases from 5 European countries will be used namely IPCI (NI), CPRD Gold (UK), SIDIAP (Spain), IQVIA DA (Germany), IMASIS (Spain) and CHUBX (France). Specific objectives of this study are the following: (i) To investigate the incidence and prevalence of use of antibiotics (from the WHO Watch list) stratified by calendar year, age, sex and country/database during the study period 2012-2021. (ii) To explore duration of antibiotic use as well as indication for antibiotic prescribing/dispensing.

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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

## Real-World-Evidence, IQVIA NL

Netherlands

**First published:** 25/11/2022

**Last updated:** 20/06/2024

**Institution**

Other

ENCePP partner

## Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

**First published:** 05/10/2012

**Last updated:** 23/02/2024

**Institution**

Educational Institution

Laboratory/Research/Testing facility

Not-for-profit

ENCePP partner

PSMAR Spain, CHUBX France, University of Oxford  
UK

## Networks

### Data Analysis and Real World Interrogation Network (DARWIN EU®)

- Belgium
- Croatia
- Denmark
- Estonia
- Finland
- France
- Germany
- Hungary
- Netherlands
- Norway
- Portugal
- Spain
- United Kingdom

**First published:** 01/02/2024

**Last updated:** 11/06/2024

Network

## Contact details

### **Study institution contact**

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Study contact

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### **Primary lead investigator**

Katia Verhamme

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 03/11/2022

Actual: 03/11/2022

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### **Study start date**

Planned: 01/12/2022

Actual: 01/12/2021

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### **Data analysis start date**

Planned: 02/01/2023

Actual: 02/01/2023

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### **Date of final study report**

Planned: 06/02/2023

Actual: 15/02/2023

## Sources of funding

- EMA

## Study protocol

[D2.2.3\\_Darwin\\_EU\\_Study\\_Protocol\\_C1-003\\_v2.2.pdf](#)(970.76 KB)

## 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

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To investigate the incidence and prevalence of use of antibiotics (from the WHO Watch list) stratified by calendar year, age, sex and country/database during the study period 2012-2021. To explore duration of antibiotic use as well as indication for antibiotic prescribing/dispensing.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Retrospective study

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(J01A) TETRACYCLINES

TETRACYCLINES

(J01C) BETA-LACTAM ANTIBACTERIALS, PENICILLINS

BETA-LACTAM ANTIBACTERIALS, PENICILLINS

(J01DD) Third-generation cephalosporins

Third-generation cephalosporins

(J01F) MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

(J01G) AMINOGLYCOSIDE ANTIBACTERIALS

AMINOGLYCOSIDE ANTIBACTERIALS

(J01MB) Other quinolones

Other quinolones

(J01XX) Other antibacterials

Other antibacterials

## Population studied

### **Short description of the study population**

The study focused on population-level drug utilisation of antibiotics and patient-level drug utilisation analysis.

The population-level analysis includes individuals with 365 days of database history between 1 January 2012 and 31 December 2021, examining the prevalence and incidence of antibiotic use.

The patient-level analysis includes new users of antibiotics who have not used the antibiotic for 30 days between 1 January 2012 and 31 December 2021, with at least 365 days of visibility prior to their first antibiotic prescription/dispensing.

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### **Age groups**

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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### **Estimated number of subjects**

30000000

## Study design details

### **Data analysis plan**

Population-level antibiotic use: Annual period prevalence of antibiotic use and annual incidence rates per 100,000 person years. Patient-level antibiotic use: Large-scale patient-level characterisation will be conducted. Index date will be the date of the first prescription of the specific antibiotic for each person. Frequency of indication at index date will be assessed. Cumulative treatment duration will be estimated and the minimum, p25, median, p75, and maximum will be provided. For all analyses a minimum cell count of 5 will be used when reporting results, with any smaller counts obscured.

## Documents

### **Study results**

[StudyReport\\_C1-003\\_version3.1.pdf](#)(4.2 MB)

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### **Study report**

[Appendix\\_StudyReport\\_C1-003\\_v3.1.pdf](#)(1.14 MB)

## Data management

## Data sources

**Data source(s)**

Clinical Practice Research Datalink

The Information System for Research in Primary Care (SIDIAP)

Integrated Primary Care Information (IPCI)

IQVIA Disease Analyzer Germany

Institut Municipal d'Assistència Sanitària Information System

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**Data source(s), other**

CHUBX France

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**Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

## 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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## 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

## Data characterisation

**Data characterisation conducted**

No