DARWIN EU® – Monitoring prescription of medicines for public health emergencies at risk of shortages

First published: 11/02/2025

Last updated: 06/05/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000473

Study ID

1000000473

DARWIN EU® study

Yes

Study countries

- [ ] Belgium
- [ ] Finland
- [ ] France
- [ ] Germany

☐ Netherlands

☐ Spain

Study description

The extended mandate of EMA reinforcing the role of the Agency in crisis preparedness and management of medicinal products and medical devices became applicable on 1st March 2022 (Regulation on EMA’s extended mandate becomes applicable | European Medicines Agency (europa.eu).

EMA is now responsible for monitoring medicine shortages that might lead to a crisis situation, as well as reporting shortages of critical medicines during public health emergencies (PHE). Such shortages would make it difficult or impossible to meet the treatment needs of individual patients or populations. The Agency has also the mandate to coordinate responses of EU / EEA countries to shortages of critical medical devices and in-vitro diagnostics in crisis situations.

Scientific and commercial data on monthly prescriptions of medicines that may be critical in PHE can help understanding trends and seasonal variations. In conjunction with time series and forecasting models, as well as data on medicines supply, such data will contribute to the on-going efforts of the Agency to better monitor and coordinate its response to shortages of critical medicines.

This study aims at generating monthly number of prescriptions of selected medicines over the last 10 years and to fit Autoregressive Integrated Moving Average (ARIMA) prediction models to such data.

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

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Marta Pineda Moncusi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/01/2025

Actual: 14/01/2025

Study start date

Planned: 29/01/2025

Actual: 29/01/2025

Date of final study report
Planned: 30/05/2025

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P3-C2-004_RR Shortages_V4.pdf(646.99 KB)

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:

Retrospective cohort studies will be conducted using routinely-collected health data from 7 databases.

Main study objective:

(i) To estimate monthly incidence rates of use prescriptions or dispensations of the 11 selected medicines during a 10-year period from the most recent data available, stratified by age and sex, in each of the databases.
(ii) To conduct time series modelling by fitting an ARIMA model to data generated in objective 1 for short-term (12-month) forecasting.

Study drug and medical condition

Name of medicine

AMOXICILLIN

AZITHROMYCIN

CEFOTAXIME

CEFTRIAXONE

CEFUROXIME

CLARITHROMYCIN

MEROPENEM

PENICILLIN VK

PIPERACILLIN/TAZOBACTAM TEVA

Anatomical Therapeutic Chemical (ATC) code

(J01CA04) amoxicillin

amoxicillin

(J01FA10) azithromycin

azithromycin

(J01DD01) cefotaxime

cefotaxime

(J01DD04) ceftriaxone

ceftriaxone

(J01DC02) cefuroxime

cefuroxime

(J01FA09) clarithromycin

clarithromycin

(J01DH02) meropenem

meropenem

(J01CE02) phenoxymethylpenicillin

phenoxymethylpenicillin

(J01CR05) piperacillin and beta-lactamase inhibitor

piperacillin and beta-lactamase inhibitor

Population studied

Short description of the study population

The study cohort will comprise all individuals present in the database during the study period (the last 10 years of available data counting backwards from the respective latest date of data lock of the respective databases).

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)

IQVIA Disease Analyzer Germany

IQVIA Longitudinal Patient Data - Belgium

Integrated Primary Care Information (IPCI)

Institut Municipal d'Assistència Sanitària Information System

Clinical Data Warehouse of the Bordeaux University Hospital

InGef Research Database

Data source(s), other

H12O

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown