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

First published: 08/01/2024

Last updated: 30/01/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS107932

Study ID

199005

DARWIN EU® study

Yes

Study countries

- [ ] Belgium
- [ ] Germany
- [ ] Spain
- [ ] United Kingdom

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). 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 ongoing efforts of the Agency to better monitor and coordinate its response to shortages of critical medicines. This study aims at generating monthly prescription rates 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

IQVIA NL, Real-World-Evidence

Netherlands

First published: 25/11/2022

Last updated: 21/03/2025

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: 23/05/2025

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

University of Oxford, PSMAR

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: 06/09/2023

Actual: 06/09/2023

Study start date
Planned: 01/01/2013

Actual: 01/01/2013

Date of final study report
Planned: 31/01/2024

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P2_C1_012_V4.1.pdf(651.28 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 type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

To estimate monthly incidence rates of use prescription or dispensation of the 11 selected medicines during the last 10 years of available data, stratified by age and sex, in each of the databases.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

AMOXICILLIN

AZITHROMYCIN

BENZYLPENICILLIN

CEFTRIAXONE

CLAVULANIC ACID

MEROPENEM TRIHYDRATE

PHENOXYMETHYLPENICILLIN POTASSIUM

TAZOBACTAM SODIUM

Anatomical Therapeutic Chemical (ATC) code

(J01CA04) amoxicillin

amoxicillin

(J01CE01) benzylpenicillin

benzylpenicillin

(J01CE02) phenoxymethylpenicillin

phenoxymethylpenicillin

(J01CR02) amoxicillin and beta-lactamase inhibitor

amoxicillin and beta-lactamase inhibitor

(J01CR05) piperacillin and beta-lactamase inhibitor

piperacillin and beta-lactamase inhibitor

(J01DC02) cefuroxime

cefuroxime

(J01DD01) cefotaxime

cefotaxime

(J01DD04) ceftriaxone

ceftriaxone

(J01DH02) meropenem

meropenem

(J01FA09) clarithromycin

clarithromycin

(J01FA10) azithromycin

azithromycin

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

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)

Estimated number of subjects

59800000

Study design details

Data analysis plan

Analyses will be conducted separately for each database. Before study initiation, test runs of the analytics are performed on a subset of the data sources or on a simulated set of patients and quality control checks are performed. Once all the tests are passed the final package is released in the version controlled Study Repository for execution against all the participating data sources. The data partners locally execute the analytics against the OMOP

CDM in R Studio and review and approve the by default aggregated results before returning them to the Coordination Centre. Sometimes multiple execution iterations are performed, and additional fine tuning of the code base is needed. A service desk will be available during the study execution for support. The study results of all data sources are checked after which they are made available to the team in the Digital Research Environment and the Dissemination Phase can start. All results are locked and timestamped for reproducibility and transparency.

Documents

Study report

DARWIN EU_P2_C1_012 Study Report_Risc of shortatges_v3.1.pdf(3.25 MB)

Data management

Data sources

Data source(s)

The Information System for Research in Primary Care (SIDIAP)

Institut Municipal d'Assistència Sanitària Information System

Clinical Practice Research Datalink (CPRD) GOLD

IQVIA Disease Analyzer Germany

IQVIA Longitudinal Patient Data - Belgium

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Secondary care Hospital

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

No