

DARWIN EU® - Evaluating and investigating modelling approaches for the prediction of use of drugs for public health emergencies and/or at risk of shortages in the DARWIN EU® Network

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Study

Ongoing

Administrative details

EU PAS number

EUPAS1000001130

Study ID

1000001130

DARWIN EU® study

Yes

Study countries

 Denmark

 Germany

-  Lithuania
 -  Netherlands
 -  United Kingdom
-

Study status

Ongoing

Research institutions and networks

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

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Primary lead investigator

Marta Pineda Moncusí

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/06/2026

Actual: 25/06/2026

Study start date

Planned: 22/09/2026

Actual: 22/09/2026

Date of final study report

Planned: 15/12/2026

Study protocol

[DARWIN EU_Protocol_P5-C3-006_C2-004_Network characterisation_V4.0.pdf](#)

(2.58 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:

Disease epidemiology

Method development or testing

Data collection methods:

Secondary use of data

Main study objective:

1. To temporally and geographically evaluate the predictive performance of a selected subset of previously developed forecasting models for predicting the use of drugs for public health emergencies at risk of shortages.
2. To refine and improve the forecasting methods (ARIMA/ARIMAX) for prospective predictions in the selected subset of models through a set of alternative modelling assumptions, parameter specifications, handling of censored values, seasonality structures, and external covariates.
3. To apply the analysis and learnings from Objective 1 and Objective 2 on a new set of drugs of interest selected based on their use in public health emergencies and their risk of shortages.

Explorative objective

4. To explore the feasibility and usability of advanced forecasting methods, including alternative statistical forecasting methods and machine learning/deep learning (ML/DL) methods.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Population studied

Short description of the study population

All objectives

Inclusion criteria

- Under observation at any time during the study period (1 January 2022 to 31 December 2025).
- At least 365 days of prior history for all individuals aged 1 year or older at the index date. No prior history is required for individuals under the age of 1.

Exclusion criteria

- Missing information on age or sex.

Additional eligibility criteria for Objective 1 and 3

Exclusion criteria

- Diagnosis of the index condition at any time before the index date (-inf, -1).

Additionally, for Objective 1, a population of sex- and age-matched individuals without the condition of interest and with the same index date will be defined.

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.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No