# DARWIN EU® Monitoring prescription of essential medicines administered in ICU

**First published:** 27/03/2024

**Last updated:** 14/08/2026

Study Finalised

## Administrative details

**EU PAS number**

EUPAS1000000089

**Study ID**

1000000089

**DARWIN EU® study**

Yes

**Study countries**

France

Portugal

Spain

**Study description**

Research question:
What is the annual prescription rate of selected medicines of importance for public health emergencies, specifically used in Intensive Care Unit (ICU)?
Study objectives:
- To estimate annual rate of prescription of selected medicines in a cohort of patients being hospitalized, stratified by Intensive Care Unit (ICU) admission (yes/no).
- To characterize the two cohorts of hospitalized patients (ICU admission (yes/no)) who initiated treatment with drug of interest in terms of demographics, presence of COVID-19 infection (yes/no), and use of mechanical ventilation (yes/no).
- To determine dose at treatment initiation and duration of treatment with selected medications in the overall cohort of hospitalized patients being treated with the drug of interest as well as in groups stratified by admission to ICU and mechanical ventilation. Optionally, consumption of the specified drugs at hospital level may be provided.

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**Study status**

Finalised

# Research institutions and networks

## Networks

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

Belgium

Croatia

Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Italy
Lithuania
Netherlands
Norway
Poland
Portugal
Spain
Sweden
United Kingdom
United States

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Network

## Contact details

**Study institution contact**

Ilse Schuemie study@darwin-eu.org

Study contact

study@darwin-eu.org

**Primary lead investigator**

Dina Vojinovic

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 12/12/2023

Actual: 12/12/2023

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**Study start date**

Planned: 01/01/2015

Actual: 01/01/2015

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**Date of final study report**

Planned: 15/05/2024

Actual: 13/12/2024

## Sources of funding

- EMA

## Study protocol

DARWIN_EU_D2.2.3_Protocol_P2-C1-014_DUS of medicines in ICU at risk of shortages_v2.1.pdf (861.84 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:**

• Population-level cohort study (Objective 1, Population-level drug utilisation study of selected medicines of importance for public health emergencies, specifically used in hospital/ICU).

• New drug user cohort (Objective 2 and Objective 3)

**Main study objective:**

1. To estimate annual rate of prescription of selected medicines in a cohort of patients being hospitalised, stratified by ICU admission (yes/no).
2. To characterize the two cohorts of hospitalised patients (ICU admission (yes/no)) who initiated treatment with drug of interest in terms of demographics, presence of COVID-19 infection (yes/no), and use of mechanical ventilation (yes/no).
3. To determine the dose at treatment initiation and duration of treatment with selected medications in the cohort of hospitalised patients being treated with drug of interest, stratified by ICU admission (yes/no) and mechanical ventilation (yes/no). Optionally, consumption of the specified drugs at hospital level may be provided.

# Study Design

**Non-interventional study design**

Cohort

# Population studied

**Short description of the study population**

Population-level drug utilisation: Population-level drug utilisation study included all patients being
hospitalised in the respective databases in the period between 1st of January 2015 and 31st of December 2023
(or the latest date of data availability of respective database, whatever comes first).

Patient-level drug utilisation: Patient-level drug utilisation study included hospitalised patients who were
initiating treatment with selected prespecified medication categorised by ICU admission (yes/no) at the time
of treatment initiation, in the period between 1st of January 2015 and 31st of December 2023 (or the latest
date of data availability of respective database, whatever comes first).

## Study design details

**Setting**

Inpatient setting

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**Summary results**

CONCLUSION

This study provides critical insights into the usage patterns of key medicines during public health emergencies, highlighting differences in ICU and non-ICU settings. The detailed data, including demographic characteristics, prescription rates, and treatment durations, offer valuable information for healthcare planning and resource and medicine allocation.

## Documents

**Study report**

DARWIN EU_Report_P2-C1-014_DUS of medicines in ICU at risk of shortages_V3.pdf (1.85 MB)

# Data management

## Data sources

**Data source(s)**

Clinical Data Warehouse of the Bordeaux University Hospital

Institut Municipal d'Assistència Sanitària Information System / Hospital del Mar / PSMAR / (Hospital del Mar Information System)

Unidade Local de Saúde de Matosinhos

## 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