

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

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

**Last updated:** 15/01/2025

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/10000000089>

### EU PAS number

EUPAS10000000089

### Study ID

10000000089

### 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
- ☐ Hungary
- ☐ Netherlands
- ☐ Norway
- ☐ Portugal
- ☐ Spain
- ☐ United Kingdom

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Network

## Contact details

### Study institution contact

Ilse Schuemie

Study contact

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### 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

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

**Study type:**

Non-interventional study

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## 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

Unidade Local de Saúde de Matosinhos

### 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

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## Data characterisation

**Data characterisation conducted**

No