

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

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

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

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000089

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### Study ID

1000000089

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### DARWIN EU® study

Yes

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### Study countries

 France

 Portugal

 Spain

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### 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
-  Netherlands
-  Norway
-  Portugal
-  Spain
-  Sweden
-  United Kingdom

**First published:** 01/02/2024

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**Network**

## Contact details

### Study institution contact

Ilse Schuemie [study@darwin-eu.org](mailto:study@darwin-eu.org)

**Study contact**

[study@darwin-eu.org](mailto: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

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **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

### 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)

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

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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

## Data characterisation

**Data characterisation conducted**

No