

# DARWIN EU® - Assessment of immunoglobulin use in clinical practice

**First published:** 10/11/2025

**Last updated:** 23/01/2026

Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000823

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### Study ID

1000000823


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### DARWIN EU® study

Yes

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### Study countries

 Denmark

 France

 Germany

 United Kingdom

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### Study description

Immunoglobulins can be routinely administered as replacement therapy in immunodeficient patients or are used as immunomodulating doses to treat various immune-related and inflammatory diseases. The global demand of immunoglobulins increases every year, resulting in intermittent shortages that could affect individuals with conditions that have limited alternative treatments. Prolonged low levels of certain immunoglobulins can increase the risk of certain infections and replenishment of these immunoglobulins can reduce this risk. This study aims to generate real-world evidence on the treatment and characteristics of individuals receiving immunoglobulins.

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### Study status

Planned

## Research institutions and networks

### Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

 Netherlands

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**Last updated:** 02/05/2024

















Institution

Educational Institution

ENCePP partner

## 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**

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

**Study contact**

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

### **Primary lead investigator**

Ellen Gerritsen

**Primary lead investigator**

## Study timelines

### **Date when funding contract was signed**

Planned: 11/08/2025

Actual: 11/08/2025

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### **Study start date**

Planned: 28/11/2025

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### **Date of final study report**

Planned: 27/03/2026

## Sources of funding

- EMA

## Study protocol

## 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 topic:**

Human medicinal product

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**Study topic, other:**

Immunoglobulins

**Study type:**

Non-interventional study

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**Data collection methods:**

Secondary use of data

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**Study design:**

A descriptive retrospective cohort study will be conducted.

**Main study objective:**

1. To describe clinical treatment of patients that receive immunoglobulin, including:

- a) Type of immunoglobulin use and route of administration (IV, SC, IM)
- b) Dose and frequency of dosing

2. To characterise patients using immunoglobulins:

a) while on treatment, including:

- common infections and antibiotics used

b) at baseline, including:

- any prior vaccinations (ATC J07)
- comorbidities (auto-immune disorders)
- pre-specified indications of use (authorized and off-label)

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name, other**

immunoglobulins: respiratory syncytial virus immune globulin intravenous, immunoglobulin G, freeze-dried pepsin-treated human normal immunoglobulin, pH4

treated acidic human normal immunoglobulin, pH4-treated acidic human normal

immunoglobulin (for s.c. injection), polyethylene glycol-treated human normal immunoglobulin, freeze-dried ph4-treated human normal immunoglobulin, freeze dried sulfonated human normal immunoglobulin, freeze-dried polyethylene glycol treated human normal immunoglobulin, immunoglobulin M human, immunoglobulin A, Rho(D) immune globulin, tetanus immune globulin, varicella-zoster immune globulin, hepatitis B immune globulin, rabies immune globulin human, Immunoglobulin Anti Rubella, human vaccinia immune globulin, staphylococcus epidermidis immunoserum rabbit, staphylococcus aureus immunoserum, cytomegalovirus immune globulin, diphtheria antitoxin, hepatitis A immunoglobulin (systemic), Immunoglobulin Anti Tickborne Encephalitis, pertussis immunoglobulin; systemic, measles immunoglobulin; systemic mumps immunoglobulin; systemic, anthrax immune globulin, Bacillus anthracis immunoserum rabbit, Nebacumab, raxibacumab, bezlotoxumab, obiltoxaximab, palivizumab, MOTAVIZUMAB, tixagevimab, ansuvimab, sotrovimab, REGDANVIMAB, casirivimab, nirsevimab, Sipavibart

## 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

IQVIA Disease Analyzer Germany

Clinical Practice Research Datalink (CPRD) GOLD

## 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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### CDM version

<https://ohdsi.github.io/CommonDataModel/index.html>

## 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