DARWIN EU® - Assessment of immunoglobulin use in clinical practice

First published: 10/11/2025

Last updated: 01/07/2026

Study Finalised

Administrative details

EU PAS number

EUPAS1000000823

Study ID

1000000823

DARWIN EU® study

Yes

Study countries

Denmark

France

Germany

United Kingdom

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.

Study status

Finalised

Research institutions and networks

Institutions

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

Netherlands

First published: 03/11/2022

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
- Lithuania
- Netherlands
- Norway
- Poland
- Portugal
- Spain
- Sweden
- United Kingdom
- United States

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ellen Gerritsen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 11/08/2025

Actual: 11/08/2025

Study start date

Planned: 28/11/2025

Date of final study report

Planned: 27/03/2026

Actual: 29/06/2026

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P4-C1-020_Immunoglobulin use_V4.0.pdf (1.21 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 topic, other:

Immunoglobulins

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

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

mmunoglobulins: 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

Population studied

Short description of the study population

The study population included all individuals present in the data source (objective 1), those with a drug prescription or dispensing record of immunoglobulin (objective 2), or individuals with a first drug prescription or dispensing record of immunoglobulin (objectives 3 and 4) during the study period, between 01/01/2017 and 31/12/2024.

Study design details

Outcomes

The outcomes of interest were as follows:

• Prevalence of individuals with a recorded immunoglobulin prescription among the general population, including type of immunoglobulin, route of administration (objective 1).

• Proportion of individuals with a prespecified immunoglobulin brands prescription among prevalent immunoglobulin users (objective 2).

• Initial and cumulative dose, number of prescriptions, and treatment duration of prespecified immunoglobulin brands among treatment initiators (objective 3).

• Characterisation of individuals initiating treatment with prespecified immunoglobulin brands (objective 4).

Documents

Study report

DARWIN EU_Report_P4-C1-020_Immunoglobulin use_V5.0.pdf (2.01 MB)

Shiny App

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

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

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

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No