

# DARWIN EU® - Use of antiretroviral therapies in paediatric patients

**First published:** 09/04/2025

**Last updated:** 10/04/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000545

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### Study ID

1000000545

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### DARWIN EU® study

Yes

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### Study countries

- ☐ Germany
  - ☐ Norway
  - ☐ Spain
  - ☐ United Kingdom
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### Study description

Human immunodeficiency viruses (HIV) are retroviruses that can cause acquired immunodeficiency syndrome (AIDS), a condition that leads to progressive failure of the immune system making an individual vulnerable to opportunistic infections and cancers.(1-3)

The optimisation of HIV treatment has been facilitated by a long-term joint collaborative effort between international organizations, academic institutions, innovator and generic manufacturers and other stakeholders, particularly over the last decade.

The WHO PADO initiative for instance marks progress and discusses also pediatric needs. Several FDCs have been authorised for use in pediatric patient in the latest years.

This study is intended to help the assessment of a current request for a pediatric investigation plan (PIP) waiver and future similar requests, submitted under the assumption that studies in pediatrics are not possible as HIV infection is very low in this population and that the treatments needs of such patients are already met by existing medications in first line.

To support this paediatric waiver request, real-world data (RWD) from prescription data from Germany and Spain indicating very low number of children living with HIV in EU countries was submitted. And although there may be very few young patients living with HIV infection in the EU, it is relevant for the PDCO to know more about prevalent cases of HIV in in this population and better understand prescription patterns in various age groups and understand the prevalence of the use of fix-dose combination (FDC) products.

This study will establish the prevalence of HIV infection amongst pediatric patients as well as the prevalence and incidence of antiretroviral therapy within this pediatric population particularly for FDC products, to estimate the current utilisation of some active substances.

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## **Study status**

Ongoing

## **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

☐ Netherlands

☐ Norway

- ☐ Portugal
- ☐ Spain
- ☐ Sweden
- ☐ United Kingdom

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

**Last updated:** 30/04/2025

Network

## Contact details

### Study institution contact

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Study contact

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

### Primary lead investigator

Guido van Leeuwen

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 05/11/2024

Actual: 27/11/2024

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### Study start date

Planned: 04/02/2025

Actual: 01/04/2025

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**Date of interim report, if expected**

Planned: 30/05/2025

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**Date of final study report**

Planned: 01/09/2025

## Sources of funding

- EMA

## Study protocol

[DARWIN EU\\_Protocol\\_P3-C1-020\\_Paediatric HIV\\_V3.pdf](#) (758.76 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 topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Study design:**

This study will use routinely collected health data from 4 databases in the DARWIN EU® network of data partners from 4 countries.

All databases were previously mapped to the OMOP CDM.

Data source

- Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (BIFAP), Spain (object

**Main study objective:**

1. To describe the prevalence and incidence of HIV in the paediatric general population in a sample of European countries (Spain, Germany and Norway), overall and stratified by sex, age group (0-<1, 1-<2, 2-<5, 5-<12, 12-<18) and calendar year
2. To describe the prevalence and incidence of use of HIV-specific medication in the paediatric HIV population in a sample of European countries (Germany and Norway) particularly fixed-dose combinations, overall and stratified by sex, age group (0-<1, 1-<2, 2-<5, 5-<12, 12-<18) and calendar year.

3. To describe the prevalence and incidence of use of HIV-specific medication in the paediatric general population in a sample of European countries (Germany, Norway, and the United Kingdom) particularly fixed-dose combinations, overall and stratified by sex, age group (0-<1, 1-<2, 2-<5, 5-<12, 12-<18) and calendar year.

## Study Design

### **Non-interventional study design**

Cohort

## Population studied

### **Short description of the study population**

The study population will include all individuals observed in one of the participating data sources during the study period (1st January 2010 to 31st December 2024) and having at least 1 year of database history.

For children within the age group of 0-<2 years, the need to have 365 days of prior database history will be dropped.

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### **Age groups**

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

## 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)

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

Norwegian Linked Health registry at University of Oslo

UK National Neonatal Research Database

InGef Research Database

## 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

## 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**

Unknown