

# DARWIN EU® – Trends in utilisation of Attention-Deficit Hyperactivity Disorder (ADHD) Medications

**First published:** 21/07/2025

**Last updated:** 21/01/2026

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000678

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### Study ID

1000000678


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### DARWIN EU® study

Yes

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### Study countries

 Denmark

 Germany

 Spain

 Sweden

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## **Study description**

A first OTS study (EUPAS1000000219) has been performed in 2024 at the request of the SPOC Working Party (responsible for monitoring and reporting events that could affect the supply of medicines in the EU) that has been monitoring shortages of different medicines to treat Attention-Deficit Hyperactivity Disorder (ADHD), mainly due to an increased demand in multiple markets, production constraints related to raw material availability, new regulatory approvals for some medicines, and changes in the competitive landscape.

The main products under monitoring are lisdexamfetamine and methylphenidate, but three more have the indication in Europe (atomoxetine, dexamphetamine, and guanfacine). Currently, the situation has improved slightly in the EU and there are no critical shortages. However, it is anticipated that constraints in the supply will continue throughout 2025.

The initial study was conducted to better anticipate potential shortages and its impact on appropriate patient management, as it is important to assess the evolution of prescriptions over time and get an overview of how these ADHD medicines are used across Europe.

The Spanish Regulatory Authority (AEMPS), after having seen the results of the initial study, has asked the EMA if we could repeat the study with additional data partners, especially Spanish ones, as only one Spanish data partner was finally included in the first study, as reported

([https://catalogues.ema.europa.eu/system/files/2025-03/DARWIN%20EU\\_Report\\_P3-C1-004\\_ADHD\\_V5.pdf](https://catalogues.ema.europa.eu/system/files/2025-03/DARWIN%20EU_Report_P3-C1-004_ADHD_V5.pdf)).

This study is now being repeated to include additional data sources with more recent data.

In addition, since all ADHD medications are approved only for individuals aged six and older, their use in children under six years of age is considered off-label. Therefore, in the current study, we will add a stratum of young child aged below five years old to assess potential off-label use of these medications.

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

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

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

**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

Xintong Li

**Primary lead investigator**

## Study timelines

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

Planned: 06/05/2025

Actual: 06/05/2025

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### **Study start date**

Planned: 08/07/2025

Actual: 08/07/2025

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

Planned: 28/11/2025

Actual: 25/11/2025

## Sources of funding

- EMA

## Study protocol

[DARWIN EU\\_Protocol\\_P4-C2-006\\_RR\\_DUS\\_ADHD\\_V3.0.pdf](#) (1.79 MB)

## 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 type:**

Non-interventional study

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**Data collection methods:**

Secondary use of data

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**Study design:**

Cohort studies will be conducted using routinely collected health data from six databases.

**Main study objective:**

To estimate the monthly and yearly period prevalence of use of each ADHD medicine, overall and stratified by age and sex in each database.

2. To estimate the monthly, and yearly incidence of use of each ADHD medicine, overall and stratified by age and sex in each database.

3. Among incident users of each ADHD medicine, to identify the indication at the time of the initial prescribing/dispensing, overall and stratified by age and sex.

4. Among incident users of each ADHD medicine, to estimate the initial dose, cumulative dose, and time on treatment of the initial medication, overall and stratified by age and sex.

5. Among new users of any ADHD medicine, to estimate the total treatment duration, number of prescriptions overall and by medicine, stratified by initial medicine.

6. To identify the treatment pathway of each individual who initiated an ADHD medicine, including treatment add-on, switch, and concurrent medication/co-prescribing, stratified by calendar year of initiation, age group, and sex.

## Study Design

## **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Medicinal product name**

LISDEXAMFETAMINE

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### **Medicinal product name, other**

Methylphenidate, Atomoxetine, Dexamphetamine, Guanfacine

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### **Study drug International non-proprietary name (INN) or common name**

METHYLPHENIDATE HYDROCHLORIDE

GUANFACINE HYDROCHLORIDE

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### **Anatomical Therapeutic Chemical (ATC) code**

(N06BA04) methylphenidate

methylphenidate

(C02AC02) guanfacine

guanfacine

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### **Medical condition to be studied**

Attention deficit hyperactivity disorder

## Population studied

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

Population-level utilisation of ADHD medications: general population

All people aged 3 years and older [1], registered in the respective databases

since the 1st of January of 2010 to the latest available data, with at least 365 days of prior data availability, will participate in the population-level analysis of period prevalence and incidence of ADHD medications of interest.

Patient-level utilisation of ADHD medications: new user cohort

In objectives 3 and 4, incident user cohorts of any ADHD medication, as well as each ADHD medication, will be created, using a 365-day washout window.

## Documents

### **Abstract of study report**

[DARWIN EU\\_Report\\_P4-C2-006\\_RR\\_ADHD\\_V3.0.pdf](#) (4.83 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)**

Danish Health Data Registries

InGef Research Database

Norwegian Linked Health registry at University of Oslo

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

The Information System for Research in Primary Care (SIDIAP)

Health Impact - Swedish Population Evidence Enabling Data-linkage

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### **Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

## 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**

Unknown