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

First published: 21/07/2025

Last updated: 21/07/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000678

Study ID

1000000678

DARWIN EU® study

Yes

Study countries

- [ ] Denmark
- [ ] Germany
- [ ] Spain
- [ ] Sweden

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).

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.

Study status

Ongoing

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

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Study contact

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Primary lead investigator

Xintong Li

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 06/05/2025

Actual: 06/05/2025

Study start date
Planned: 08/07/2025

Actual: 08/07/2025

Date of final study report
Planned: 28/11/2025

Sources of funding

- EMA

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 type:

Non-interventional study

Data collection methods:

Secondary use of data

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

Name of medicine

LISDEXAMFETAMINE

Name of medicine, other

Methylphenidate, Atomoxetine, Dexamphetamine, Guanfacine

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.

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

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

Unknown