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

**First published:** 19/06/2024

**Last updated:** 14/03/2025

Study Finalised

## Administrative details

**EU PAS number**

EUPAS1000000219

**Study ID**

1000000219

**DARWIN EU® study**

Yes

**Study countries**

- [ ] Belgium
- [ ] Germany
- [ ] Netherlands
- [ ] Spain

United Kingdom

**Study description**

The overall aim of this study is to characterise the use of ADHD medications in the period of 2010 to 2023. The specific objectives are:
1. To estimate the monthly and yearly period prevalence of use of each ADHD medicine, overall and stratified by age and gender in each database.
2. To estimate the monthly, quarterly, and yearly incidence of use of each ADHD medicine, overall and stratified by age and gender in each database.
3. Among new users of each ADHD medicine, to identify the indication at the time of the initial prescribing/dispensing, overall and stratified by age, sex, and quarter.
4. Among new 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, sex, indication at index, and quarter.
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 and quarter of the year.
6. To identify the treatment pathway of each individual who initiated an ADHD medicine, including treatment add-on, switch and concurrent medication/co-prescribing, stratify by calendar time of initiation.

**Study status**

Finalised

# Research institutions and networks

## Institutions

## Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

☐ United Kingdom

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

**Last updated:** 01/02/2024

**Institution** | **Educational Institution** | **Hospital/Clinic/Other health care facility**

# 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

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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: 26/03/2024

Actual: 26/03/2024

**Study start date**

Planned: 26/06/2024

**Data analysis start date**
Planned: 12/08/2024

**Date of final study report**
Planned: 30/09/2024

Actual: 24/02/2025

## Sources of funding

- EMA

## Study protocol

DARWIN EU_D2.2.3_Protocol_P3-C1-004_DUS_ADHD_V4.pdf (2.01 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:**

Disease /health condition

**Study type:**

Non-interventional study

**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

**Study design:**

Cohort studies will be conducted using routinely collected health data from 6 databases. The study will comprise two consecutive parts (see protocol).

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name, other**

Lisdexamfetamine (N06BA12)

Methylphenidate (N06BA04)

Atomoxetine (ATC code: N06BA09)

Dexamfetamine (N06BA02)

Guanfacine (C02AC02)

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

ATOMOXETINE

GUANFACINE HYDROCHLORIDE

METHYLPHENIDATE

**Anatomical Therapeutic Chemical (ATC) code**

(C02AC02) guanfacine

guanfacine

(N06BA02) dexamfetamine

dexamfetamine

(N06BA04) methylphenidate

methylphenidate

(N06BA09) atomoxetine

atomoxetine

(N06BA12) lisdexamfetamine

lisdexamfetamine

**Medical condition to be studied**

Attention deficit hyperactivity disorder

**Additional medical condition(s)**

ADHD

# Population studied

**Short description of the study population**

Population-level utilisation of ADHD medications: general population.
All people aged 3 years and older (Rocco et al. 2021), 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 objective 3 and 4, new user cohort of each ADHD medication will be created at drug substance level, using 365 days washout window.
In objective 5 and 6, new users will be identified using the first record of any of the ADHD medications of interest within the study period, having no previous records for ANY study medication any time prior to entry. The index date will be defined as the date of the first eligible medication record.
Five new user cohorts of the medications licensed for ADHD treatment will be constructed separately: the stimulants dexamphetamine, lisdexamfetamine, and methylphenidate, and the non-stimulants atomoxetine and guanfacine.

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**Age groups**

- **Paediatric Population (< 18 years)**
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

## Study design details

**Setting**

This study will be conducted using routinely collected data from 6 databases in 5 European countries. All databases were previously mapped to the OMOP CDM.

## Documents

**Study report**

DARWIN EU_Report_P3-C1-004_ADHD_V5.pdf (3.02 MB)

# 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 Practice Research Datalink (CPRD) GOLD

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

IQVIA Longitudinal Patient Data - Belgium

IQVIA Disease Analyzer Germany

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

Systems)

## Use of a Common Data Model (CDM)

**CDM mapping**

Yes

**CDM Mappings**

**CDM name**

OMOP

**CDM website**

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

## Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

Unknown