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

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# Administrative details

#### **PURI**

https://redirect.ema.europa.eu/resource/1000000219

#### **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.

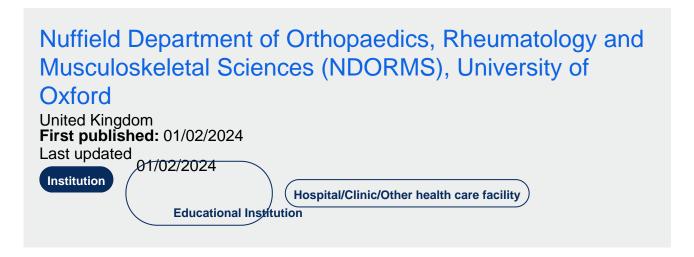
- 3. Among new users of each ADHD medicine, to identify the indication at the time of the initial prescribing/dispensing, overall and stratified by age, sex, and quarter.
- 4. Among new users of each ADHD medicine, to estimate the initial dose, cumulative dose, and time on treatment of the initial medication, overall and stratified by age, sex, indication at index, and guarter.
- 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

Planned

# Research institution and networks

## Institutions



# **Networks**

# Data Analysis and Real World Interrogation Network (DARWIN EU®)

Belgium

Croatia

Denmark

Estonia

Finland

France

Germany

Hungary

Netherlands

Norway

Portugal

Spain

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

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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:

# 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 list

**Study topic:** 

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

**Data collection methods:** 

Secondary data collection

#### 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

#### Name of medicine, 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

(N06BA02) dexamfetamine

(N06BA04) methylphenidate

(N06BA09) atomoxetine

(N06BA12) 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.

## 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.

# Data management

# Data sources

#### Data source(s)

Clinical Practice Research Datalink (CPRD) GOLD

**IPCI** 

The Information System for Research in Primary Care (SIDIAP)

Longitudinal Patient Data - Belgium

Disease Analyzer Germany

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

# Data quality specifications

#### **Check conformance**

Unknown

## **Check completeness**

Unknown

## **Check stability**

Unknown

## **Check logical consistency**

Unknown

# Data characterisation

#### Data characterisation conducted

Unknown