# Strattera patient exposures and adherence in the United Kingdom, Germany, the Netherlands, and Sweden: 2016 Bi-annual assessment report. (B4Z-MC-B025)

**First published:** 29/09/2015

**Last updated:** 23/04/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS10786

**Study ID**

14862

**DARWIN EU® study**

No

**Study countries**

- ☐ Germany
- ☐ Netherlands
- ☐ Sweden

United Kingdom

**Study description**

The objective of this study is to describe atomoxetine utilisation patterns for patients treated in the United Kingdom, Germany, the Netherlands, and Sweden from the time period of 2008 through 2014. This will be done by:-Estimating number of patients exposed, stratified by age-Estimating duration of exposure, medication possession ratio, and dose over the most recent 24 months-Estimating number of patients restarting, gap between, and duration of additional exposures over most recent 24 months, for those who stopped taking Strattera-Describing common comorbidity and concomitant medications

**Study status**

Finalised

# Research institutions and networks

## Institutions

### IMS Health

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

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

Institution

# Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Meyers Kristin

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 26/08/2013

Actual: 26/08/2013

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**Study start date**

Planned: 01/10/2015

Actual: 01/10/2015

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**Data analysis start date**

Planned: 01/02/2016

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**Date of final study report**

Planned: 31/03/2016

Actual: 21/03/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

## Study protocol

B025 PASS.pdf (326 KB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

**Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The objective is to describe atomoxetine (Strattera) utilization patterns for patients treated in Germany, United Kingdom, Sweden, and the Netherlands.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(N06BA09) atomoxetine

atomoxetine

## Population studied

**Short description of the study population**

Patients treated in the United Kingdom, Germany, the Netherlands, and Sweden from the time period of 2008 through 2014.

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**Age groups**

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

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**Special population of interest**

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

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**Estimated number of subjects**

38152

## Study design details

**Outcomes**

Patient exposures, patient discontinuation and adherence, and descriptive statistics

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**Data analysis plan**

For each country, patient counts will be provided for the most recent 7 full calendar years. Counts and proportions will be tabulated by country, year, age group, and gender.Patient exposures, including treatment duration, duration of

exposure, daily average dose, and frequent comorbid diagnoses will be presented (where available).Measures of drug utilisation will be described for new users within the most recent 24 month follow-up period. This includes: 1) percentage of patient discontinuation, reinitiation, and adherence, 2) mean and median length of therapy, as well as daily dose, and 3) the distribution of the percentage of patients having undergone one or more treatment episodes over the 24 month observation period.Descriptive statistics including frequencies and proportions of patient count and demographics such as age and gender will be provided, as well as for population characteristics such as common comorbidities and concomitant medications.

## Documents

**Study results**

B025 PASS_Final study report_Abstract.pdf (99.7 KB)

# 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.

**Conflicts of interest of investigators**

B025 PASS_Final study report.pdf (602.53 KB)

## Data sources

**Data source(s)**

Clinical Practice Research Datalink

Sweden National Prescribed Drugs Register / Läkemedelsregistret

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**Data source(s), other**

Disease Analyzer United Kingdom, Longitudinal Prescription Data (IMS) Germany

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**Data sources (types)**

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Drug registry

Electronic healthcare records (EHR)

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

### Check logical consistency

Unknown

## Data characterisation

### Data characterisation conducted

No