

# Strattera patient exposures and adherence in the United Kingdom, Germany, the Netherlands, and Sweden: 2014 Bi-annual assessment report

**First published:** 03/04/2014

**Last updated:** 30/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS6305

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### Study ID

20485

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### DARWIN EU® study

No

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### Study countries

 Germany

 Netherlands

 Sweden

## Study description

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

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## Study status

Finalised

# Research institutions and networks

## Institutions

### Real World Evidence Solutions, IMS Health

 France

**First published:** 06/09/2011

**Last updated:** 20/08/2024

**Institution**

Other

## Contact details

### Study institution contact

Kellier Nicole [nkellier@lilly.com](mailto:nkellier@lilly.com)

**Study contact**

[nkellier@lilly.com](mailto:nkellier@lilly.com)

## Primary lead investigator

Kellier Nicole

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 16/08/2013

Actual: 16/08/2013

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### Study start date

Planned: 01/01/2014

Actual: 01/01/2014

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### Data analysis start date

Planned: 01/01/2014

Actual: 01/01/2014

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### Date of final study report

Planned: 28/03/2014

Actual: 09/04/2014

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

# Study protocol

[EU DUS PASS.pdf](#) (316.93 KB)

## Regulatory

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

Yes

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### **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

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Drug utilisation

#### **Data collection methods:**

**Main study objective:**

The objective of this study is to describe atomoxetine (Strattera) utilization patterns for patients treated in Germany, United Kingdom (UK), 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**

All patients with filled prescriptions of Strattera for the longest available duration in each selected database. In order to be eligible for inclusion patients will need at least two consecutive filled prescriptions.

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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**

0

## Study design details

### **Outcomes**

Patient exposures Patient discontinuation and adherence Descriptive statistics

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### **Data analysis plan**

For each country, patient counts will be provided for the most recent 5 full calendar years, and the moving annual total (MAT) will be provided for midyear of the most recent year of available data, when appropriate. Patient exposures including treatment duration, duration of exposure, daily average dose, and frequent comorbid diagnoses will be presented (where available). Patient

discontinuation and adherence will be described, including the percentage of patients reinitiating therapy and the percentage of patients remaining on therapy at monthly time intervals. This will include data on mean and median length of therapy as well as mean daily dose. Descriptive statistics including frequencies and proportions of patient count and demographics such as age and gender will be provided as well as frequencies and proportions for population characteristics such as common comorbidities and concomitant medication.

## Documents

### Study results

[StratteraB022 EUPASS\\_2014DUS\\_upload.pdf](#) (805.17 KB)

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## 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

**Data source(s), other**

Longitudinal prescription data Germany, Disease analyzer United Kingdom

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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

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**Check logical consistency**

Unknown

## Data characterisation

## **Data characterisation conducted**

Unknown