# Drug utilization study for Elvanse® / Tyvense® / Elvanse® Adult in Europe

**First published:** 26/09/2016

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

Study Finalised

## Administrative details

**EU PAS number**

EUPAS15507

**Study ID**

44400

**DARWIN EU® study**

No

**Study countries**

- [ ] Denmark
- [ ] Finland
- [ ] Germany
- [ ] Ireland
- [ ] Norway
- [ ] Spain

- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

**Study description**

This is a multi-country drug utilization study using retrospective database analysis. A single database for all target countries is not available. Therefore, a study approach was chosen which includes multiple data sources to gather drug utilization data for Elvanse®/Tyvense® in European target countries. The study’s objective is to provide data on an annual basis for up to 5 years.

**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**

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Study contact

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**Primary lead investigator**

Dorothea von Bredow

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 24/07/2013

**Study start date**

Actual: 21/02/2014

**Data analysis start date**

Actual: 24/02/2014

**Date of interim report, if expected**

Actual: 09/04/2014

**Date of final study report**

Planned: 31/03/2018

Actual: 12/04/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Shire Pharmaceuticals

## Study protocol

SHP489-813 Elvanse DUS Protocol Version 3.0_26Feb2018 _clean_Redacted.pdf
(3.87 MB)

## Regulatory

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

No

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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

Disease /health condition

**Study type:**

Non-interventional study

**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

**Main study objective:**

Overall objective: The study’s objective is to provide data on an annual basis for the next 5 years in European countries to evaluate drug utilization. Study objectives:1. To characterize patients who are prescribed Elvanse®/Tyvense®2. To describe prescribing patterns of Elvanse®/Tyvense® among physicians3. To describe usage patterns of Elvanse®/Tyvense® among patients

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(N06BA12) lisdexamfetamine

lisdexamfetamine

**Medical condition to be studied**

Attention deficit hyperactivity disorder

## Population studied

**Short description of the study population**

Patients who have been prescribed Elvanse® / Tyvense ® at least once during the study period.

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**Age groups**

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**

Other

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**Special population of interest, other**

Patients with attention deficit hyperactivity disorder

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**Estimated number of subjects**

50000

## Study design details

**Data analysis plan**

The analysis will be done descriptively as specified in the statistical analysis plan.

## Documents

**Study results**

SHP489-813 Elvanse DUS Fifth R_FINAL_Watermarked.pdf(1.27 MB)

**Study publications**

Siffel C, Page M, Maxwell T, Thun B, Kolb N, Rosenlund M, von Bredow D, Keja J...

# 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

Danish registries (access/analysis)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

**Data sources (types)**

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

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

# Data characterisation

**Data characterisation conducted**

No