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

First published: 26/09/2016

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





# 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
<b>Last updated:</b> 20/08/2024
<b>Institution</b> Other

## Contact details

Study institution contact

## Csaba Siffel csiffel0@shire.com

Study contact

csiffel0@shire.com

## **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

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

#### 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.

#### 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)

#### **Special population of interest**

Other

#### Special population of interest, other

Patients with attention deficit hyperactivity disorder

#### **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