

# Drug Utilisation Study of Intuniv® (guanfacine extended release) in European Countries, Study protocol I: Database study (Intuniv data base study Europe)

**First published:** 25/04/2017

**Last updated:** 11/11/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS18735

---

### Study ID

48508

---

### DARWIN EU® study

No

---

### Study countries

☐ Denmark

☐ Germany

☐ Norway

- ☐ Spain
  - ☐ Sweden
  - ☐ 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 an approach was chosen which includes multiple data sources to gather drug utilization data for Intuniv in European target countries. In case longitudinal patient level data do not exist in a target country, a prescriber survey will be conducted, which is described in a separate protocol.

---

### Study status

Finalised

## Research institutions and networks

### Institutions

#### Real World Solutions, IQVIA

- ☐ Netherlands
- ☐ United Kingdom (Northern Ireland)

**First published:** 28/04/2011

**Last updated:** 22/03/2024

**Institution**

**Other**

**ENCePP partner**

### Contact details

**Study institution contact**

Matthew Page matt.page@takeda.com

Study contact

[matt.page@takeda.com](mailto:matt.page@takeda.com)

**Primary lead investigator**

Dorothea von Bredow

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 30/08/2016

Actual: 30/08/2016

---

**Study start date**

Planned: 01/02/2019

Actual: 15/11/2018

---

**Date of interim report, if expected**

Planned: 30/06/2019

Actual: 11/06/2019

---

**Date of final study report**

Planned: 30/06/2023

Actual: 01/05/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Takeda Pharmaceutical Company Limited

## Study protocol

[INTUNIV EU DUS\\_DATABASE Protocol v7.0\\_17Jul2018clean-redact.pdf](#) (16.67 MB)

[INTUNIV\\_EU\\_DUS\\_Protocol Amend v7.2\\_CLEAN\\_FINAL\\_26-JUL-2022\\_redacted.pdf](#)  
(564.71 KB)

## 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:**

Disease /health condition

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: Drug utilization study for the next 5 years with Intuniv® with annual data in European countries. Study objectives: 1.characterize patients, focussing on indications other than ADHD, children <6 years, adults 2. describe prescribing patterns of Intuniv® among physicians 3. assess compliance with indication, visits and measurements needed during the first year of treatment</6></6>

## Study Design

**Non-interventional study design**

Other

---

**Non-interventional study design, other**

Multi-country retrospective analysis

## Study drug and medical condition

**Name of medicine**

INTUNIV

---

**Study drug International non-proprietary name (INN) or common name**

GUANFACINE HYDROCHLORIDE

---

**Anatomical Therapeutic Chemical (ATC) code**

(A) ALIMENTARY TRACT AND METABOLISM

ALIMENTARY TRACT AND METABOLISM

(C02AC02) guanfacine

guanfacine

---

**Medical condition to be studied**

Attention deficit hyperactivity disorder

## Population studied

**Short description of the study population**

The study population included patients with attention deficit hyperactivity disorder (ADHD) who have been prescribed Intuniv® identified from the electronic medical record databases and national registries.

---

**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**

5000

## Study design details

### **Data analysis plan**

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

## Documents

### **Study results**

[Intuniv EU database study redacted abstract final report.pdf](#)(2.94 MB)

---

## Data management

## Data sources

**Data source(s)**

Danish registries (access/analysis)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

THIN® (The Health Improvement Network®)

Longitudinal Patient Data Spain - OMOP

The Norwegian Prescribed Drug Registry

---

**Data sources (types)**

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

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