# Extrapyramidal symptoms in patients treated with Abilify Maintena®: Cohort study with a 2-year follow-up using European automated healthcare databases

**First published:** 06/10/2017

**Last updated:** 06/03/2024

Study Ongoing

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/36996

**EU PAS number**

EUPAS21056

**Study ID**

36996

**DARWIN EU® study**

No

**Study countries**

- [ ] Germany
- [ ] Italy
- [ ] Sweden

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**Study description**

This post-authorisation safety study (PASS) will be conducted using longitudinal automatic healthcare databases. It uses a non-comparative historical cohort design to further assess the risk of EPS-related events linked to the use of Abilify Maintena®, in routine clinical practice.All new users of Abilify Maintena® (incident users) between country-specific market entry date and the end of the inclusion period will be included in the analysis. The first observed prescription of Abilify Maintena® for a patient after market entry is called the index prescription, and the index date relates to the date of this index prescription. The crude incidence of EPS-related events and incidence per patient-month will be estimated, using the number of exposed patients with at least one EPS-related event (during treatment exposure period). In addition, an analysis on time to EPS onset will be performed using Kaplan-Meier estimator of survival function and Cox proportional hazards regression model. In addition, a Cox proportional hazards regression model will be performed to measure the effect of known risk factors described in Section 9.3.3 Other Variables on the occurrence of EPS-related event in this population.

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**Study status**

Ongoing

# Research institutions and networks

## Institutions

## H. Lundbeck

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

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

Institution

## Leibniz Institute for Prevention Research and Epidemiology - BIPS

☐ Germany

**First published:** 29/03/2010

**Last updated:** 26/02/2024

Institution | Not-for-profit | ENCePP partner

## RTI Health Solutions (RTI-HS)

☐ France

☐ Spain

☐ Sweden

☐ United Kingdom

☐ United Kingdom (Northern Ireland)

☐ United States

**First published:** 21/04/2010

**Last updated:** 13/03/2025

Institution | Not-for-profit | ENCePP partner

## Global Database Studies, IQVIA

- [ ] Czechia
- [ ] Finland
- [ ] Germany
- [ ] Slovakia
- [ ] Spain

**First published:** 17/01/2011

**Last updated:** 31/07/2024

Institution | Other | ENCePP partner

# Contact details

**Study institution contact**

Non-interventional Research Manager H. Lundbeck A/S

Study contact

LundbeckClinicalTrials@lundbeck.com

**Primary lead investigator**

Non-interventional Research Manager H. Lundbeck A/S

Primary lead investigator

# Study timelines

**Date when funding contract was signed**

Planned: 07/07/2015

Actual: 07/07/2015

**Study start date**

Planned: 09/10/2017

Actual: 25/11/2017

**Data analysis start date**

Actual: 20/08/2018

**Date of final study report**

Planned: 31/03/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

H. Lundbeck A/S

## Study protocol

15893N_Abstract_EUPAS_register_FINAL.pdf(137.97 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 type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

**Main study objective:**

Aims of this study are to further assess the risk of EPS-related events linked to the use of Abilify Maintena®, in routine clinical practice.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine, other**

Abilify Maintena

**Medical condition to be studied**

Schizophrenia

# Population studied

**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)

**Special population of interest**

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

**Estimated number of subjects**

1500

# Study design details

**Data analysis plan**

In this non-comparative study, only descriptive statistics will be used. Summary statistics (mean, standard deviation, median, inter-quartile range, minimum and maximum values) will be presented for continuous variables. Counts and percentages will be presented for categorical and binary variables. In addition, an analysis on time to EPS onset will be performed using Kaplan-Meier estimator of survival function and Cox proportional hazards regression models.

# Data management

## Data sources

**Data source(s)**

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Caserta claims database

German Pharmacoepidemiological Research Database

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**Data sources (types)**

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

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**Data sources (types), other**

Population-based registers

## 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