

Survey to Assess the Effectiveness of SPRAVATO® Educational Materials for Additional Risk Minimization Measures in the European Union (PCSNP002812)

First published: 25/11/2020

Last updated: 24/12/2024

Study

Finalised

Administrative details

EU PAS number

EUPAS38144

Study ID

50105

DARWIN EU® study

No

Study countries


 Austria

 Belgium


 France

 Germany

 Italy

 Netherlands

 Spain

 Sweden

Study description

To determine the effectiveness of the medical education materials related to the understanding and management of SPRAVATO important identified risks of Drug abuse, Transient dissociative states and perception disorders, Disturbances in consciousness, and Blood pressure increased in Europe.

Study status

Finalised

Research institutions and networks

Institutions

[Johnson & Johnson](#)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Christian von Holt RA-RNDUS-ClnclTrlsEU@its.jnj.com

Study contact

RA-RNDUS-ClnclTrlsEU@its.jnj.com

Primary lead investigator

Christian von Holt

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/10/2020

Actual: 26/10/2020

Study start date

Planned: 31/10/2023

Actual: 04/10/2023

Date of final study report

Planned: 31/12/2024

Actual: 23/10/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen

Study protocol

[Protocol-FD-PCNSNP002812-94975_EDMS-RIM-94975_2.0.pdf](#) (223.71 KB)

[REDACTED_Protocol-Amend 3-FD-PCNSNP002812-94975_983036.pdf](#) (934.26 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)

Other study registration identification numbers and links

EMA/H/C/004535/MEA003

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

Survey

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

The objective of this survey is to determine the effectiveness of the educational materials at increasing awareness about the important identified risks related to SPRAVATO treatment of Drug abuse, Transient dissociative states and perception disorders, Disturbances in consciousness, and Blood pressure increased.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Survey

Population studied

Age groups

- Adults (18 to < 46 years)
 - Adults (46 to < 65 years)
-

Estimated number of subjects

270

Study design details

Data analysis plan

In order to consider the educational materials related to SPRAVATO as effective, a minimum total score of $\geq 80\%$ of correct responses on all survey questions will be considered indicative of satisfactory effectiveness.

Documents

Study report

[REDACTED_CSR-Body-PCSNP002812-1399963_1487251.pdf](#) (3.32 MB)

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 sources (types)

Other

Data sources (types), other

The data source for this survey will be the questionnaire used to survey HCPs involved in prescribing, administration and management of SPRAVATO treatment.

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