# Survey to Assess the Effectiveness of SPRAVATO® Educational Materials for Additional Risk Minimization Measures in the European Union (PCSNSP002812)

**First published:** 25/11/2020

**Last updated:** 24/12/2024

Study Finalised

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/50105

**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**

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**Study contact**

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**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

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**Study start date**

Planned: 31/10/2023

Actual: 04/10/2023

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**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-PCSNSP002812-94975_EDMS-RIM-94975_2.0.pdf(223.71 KB)

REDACTED_Protocol-Amend 3-FD-PCSNSP002812-94975_983036.pdf(934.26 KB)

## Regulatory

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

Yes

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**Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

## Other study registration identification numbers and links

EMEA/H/C/004535/MEA003

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Other

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**Study topic, other:**

Survey

**Study type:**

Non-interventional study

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**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

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**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 ≥80% of correct responses on all survey questions will be considered indicative of satisfactory effectiveness.

## Documents

**Study report**

REDACTED_CSR-Body-PCSNSP002812-1399963_1487251.pdf(3.32 MB)

# Data management

## 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