Evaluation of the Effectiveness of Risk Minimisation Measures: A Joint PASS Survey and Drug Utilisation Study among Health Care Professionals to Assess their Knowledge and Attitudes on Prescribing Conditions of valproate in France, Germany, Spain, Sweden and United Kingdom

First published: 23/10/2015 Last updated: 02/07/2024



## Administrative details

#### **EU PAS number**

EUPAS11379

### Study ID

23396

#### DARWIN EU® study

No

#### **Study countries**

France
Germany
Spain
Sweden
United Kingdom

### **Study description**

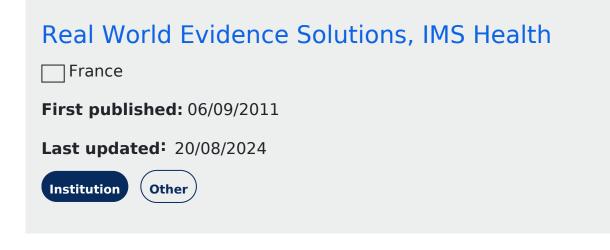
Evaluation of the Effectiveness of Risk Minimisation Measures: A Joint PASS Survey and Drug Utilisation Study among Health Care Professionals to Assess their Knowledge and Attitudes on Prescribing Conditions of valproate in France, Germany, Spain, Sweden and United Kingdom

### Study status

Finalised

## Research institutions and networks

## Institutions



# Contact details

### Study institution contact

Toussi Massoud mtoussi@fr.imshealth.com

Study contact

mtoussi@fr.imshealth.com

## Primary lead investigator

Toussi Massoud

Primary lead investigator

# Study timelines

### Date when funding contract was signed

Planned: 30/11/2015 Actual: 01/06/2016

Study start date Planned: 31/03/2015 Actual: 31/08/2016

## Date of final study report Planned: 30/11/2016 Actual: 09/05/2017

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

A consortium of MAHs

# 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 topic:

Disease /health condition Human medicinal product

## Study type:

Non-interventional study

## Scope of the study:

Drug utilisation Other

### If 'other', further details on the scope of the study

Survey

### Data collection methods:

Primary data collection

### Main study objective:

The objective of the survey is to measure the effectiveness of the DHPC and educational material (EM), implemented as part of risk minimisation measures, by ascertaining the proportion of targeted physicians who understood and implemented the latest prescribing conditions and safety information about valproate provided in the DHPC and EM.

# Study Design

### Non-interventional study design

Cross-sectional

# Study drug and medical condition

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

SODIUM VALPROATE VALPROATE SEMISODIUM VALPROIC ACID VALPROMIDE

## Medical condition to be studied

Epilepsy Bipolar disorder Migraine Pregnancy

# Population studied

### Short description of the study population

Prescribers of valproate in settings of 5 European countries (France, Germany, Spain, Sweden, UK).

### Age groups

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**

Pregnant women

### Estimated number of subjects

1067

# Study design details

### Data analysis plan

The statistical analysis will be conducted using the SAS® softwareV9.4on Windows<sup>™</sup> (SAS Institute, North Carolina, USA).The statistical results of the five countries will be presented in the same report, overall, per country and per physician's specialty group.All the analysis will be descriptive in nature and no statistical comparison will be done in this study.Continuous variables will be described by their number (of valid cases, of missing values), mean, standard deviation, and median, Q1, Q3, minimum and maximum.Categorical variables will be described as the total number and relative percentage per category. These will be the percentage per category.Free text answers to open-ended questions will be categorised by theme, listed according to the frequency.Confidence intervals of 95% will be evaluated, when relevant.The proportions of correct and appropriate answers to selected questions asked in the questionnaire will be expressed among physicians.

## Documents

#### **Study results**

valproate-PASS survey report abstract v1 2018-01-16.pdf(99.08 KB)

## 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

Physician and prescription survey

# 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**

Unknown