

# Proposals for Engaging Patients and Healthcare Professionals in Risk Minimisation from an Analysis of Stakeholder Input to the EU Valproate Assessment Using the Novel Analysing Stakeholder Safety Engagement Tool (ASSET)

**First published:** 23/06/2020

**Last updated:** 03/11/2020

Study

Finalised

## Administrative details

### EU PAS number

EUPAS35947

---

### Study ID

37897


---

### DARWIN EU® study

No

---

## Study countries

 Netherlands

---

## Study description

This study analysis the content of input provided by patient and healthcare professional representatives at the public hearing and dedicated stakeholder meeting for the valproate teratogenicity and risk management assessment by the Pharmacovigilance Risk Assessment Committee (PRAC) at EMA in 2017/2018. The content analysis applies theories on implementation of innovation in healthcare and leads to proposals to be considered by PRAC for piloting in order to enhance their engagement with patients and healthcare professionals with a view to increasing effectiveness of risk minimisation measures. The study is conducted under the PRAC Impact Strategy.

---

## Study status

Finalised

## Research institutions and networks

### Institutions

[European Medicines Agency \(EMA\)](#)

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

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

**Institution**

## Contact details

**Study institution contact**

Priya Bahri priya.bahri@ema.europa.eu

Study contact

[priya.bahri@ema.europa.eu](mailto:priya.bahri@ema.europa.eu)

**Primary lead investigator**

Priya Bahri

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 09/03/2017

Actual: 09/03/2017

---

**Study start date**

Planned: 26/09/2017

Actual: 26/09/2017

---

**Data analysis start date**

Planned: 06/11/2017

Actual: 06/11/2017

---

**Date of final study report**

Planned: 20/05/2020

Actual: 20/05/2020

## Sources of funding

- EMA

## Regulatory

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

No

---

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

Not applicable

## Methodological aspects

### Study type

#### Study type list

**Study topic:**

Human medicinal product

Disease /health condition

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Other

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

Stakeholder engagement analysis

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

(1) Analyse stakeholder input at public hearing and dedicated meeting for the 2017/18 EU procedure on valproate teratogenicity, (2) Draw proposals for enhancing PRAC engagement.

## Study Design

**Non-interventional study design**

Other

---

**Non-interventional study design, other**

Theory-based case study with qualitative content analysis

## Study drug and medical condition

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

VALPROIC ACID

---

**Medical condition to be studied**

Epilepsy

## Population studied

## **Short description of the study population**

Patient and healthcare professional representatives at the public hearing and dedicated stakeholder meeting for the valproate teratogenicity and risk management assessment by the Pharmacovigilance Risk Assessment Committee (PRAC) at EMA in 2017/2018.

---

## **Age groups**

- Adolescents (12 to < 18 years)
  - Adults (18 to < 46 years)
- 

## **Special population of interest**

Pregnant women

---

## **Estimated number of subjects**

60

# Study design details

## **Outcomes**

Stakeholder input content analysis findings and derived proposals for enhancing engagement between regulators, patients and healthcare professionals

---

## **Data analysis plan**

Development of content analysis tool based on established theories with coding scheme and rules, testing of tool prior to application, peer examination of research design, data analysis applying tool and adhering to coding rules

# Documents

## Study results

[Bahri P, Morales D, Inoubli A, Dogne JM, Straus S\\_Valproate hearing ASSET analysis and PRAC engagement proposals.pdf \(1.09 MB\)](#)

---

## Study publications

[Bahri P, Morales DR, Inoubli A, Dogné JM, Straus SM. Proposals for engaging pat...](#)

---

# 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

Stakeholder input at EMA meetings

## 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