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

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Institution

Contact details

Study institution contact

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Study contact

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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

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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 applyig 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