Impact of medicines regulatory interventions in Europe: a systematic review focusing on unintended consequences, data used and methodology

First published: 22/06/2022

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47826

EU PAS number

EUPAS47825

Study ID

47826

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Bulgaria
- [ ] Croatia
- [ ] Cyprus
- [ ] Czechia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Iceland
- [ ] Ireland
- [ ] Italy
- [ ] Latvia
- [ ] Liechtenstein
- [ ] Lithuania
- [ ] Luxembourg
- [ ] Malta
- [ ] Netherlands
- [ ] Norway
- [ ] Poland
- [ ] Portugal
- [ ] Romania
- [ ] Slovakia
- [ ] Slovenia
- [ ] Spain

Sweden

United Kingdom

Study description

The goal is to perform a comprehensive assessment of studies that evaluate the impact of pharmacovigilance regulatory interventions in the European Economic Area (EEA), focusing on identifying unintended consequences and highlighting the methodology and data used.

Study status

Ongoing

Research institutions and networks

Institutions

Division of Pharmacoepidemiology & Clinical Pharmacology (PECP), Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University

Netherlands

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Institution | Educational Institution | ENCePP partner

Contact details

Study institution contact

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Primary lead investigator

Helga Gardarsdottir

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/09/2021

Actual: 01/09/2021

Study start date

Planned: 01/01/2022

Actual: 13/12/2021

Date of final study report

Planned: 31/01/2023

Sources of funding

- Other

More details on funding

Utrecht University

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 type:

Non-interventional study

Main study objective:

The goal is to perform a comprehensive assessment of studies that evaluate the impact of pharmacovigilance regulatory interventions in the European Economic Area (EEA), focusing on identifying unintended consequences and highlighting the methodology and data used.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

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

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

0

Study design details

Data analysis plan

We will perform descriptive analysis (totals and percentages) for data extracted from identified articles.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

We will conduct bibliographic database searches in MEDLINE and EMBASE.

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