Measuring the impact of medicines regulatory interventions – systematic review and methodological considerations

First published: 20/10/2017

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS21337

Study ID

24545

DARWIN EU® study

No

Study countries

United Kingdom

Study description

The evaluation of the public health impact of regulatory interventions is important but there is currently no common methodological approach to guide this evaluation. This systematic review of the literature (Medline and Embase) provides a descriptive overview of the analytical methods used for measuring the impact of pharmacovigilance regulatory actions to safeguard public health.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Thomas Goedecke

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 01/03/2017

Study start date
Actual: 28/04/2017

Data analysis start date
Actual: 01/07/2017

Date of final study report
Planned: 01/08/2017

Actual: 20/12/2017

Sources of funding

- EMA

Study protocol

Protocol EUPAS21337 Measuring Impact Regulatory Interventions Systematic Review_Final Apr2017.pdf (121.9 KB)

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:

Other

Study topic, other:

Impact of pharmacovigilance regulatory actions

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Systematic literature review

Data collection methods:

Secondary use of data

Main study objective:

1. Perform a systematic review of published studies evaluating the impact of pharmacovigilance regulatory interventions worldwide, 2. Describe the study design used to evaluate the impact of pharmacovigilance regulatory interventions,3. Describe the analytical approach used to determine whether impact occurred, including the type of outcome measures,

Study Design

Non-interventional study design

Systematic review and meta-analysis

Population studied

Short description of the study population

N/A

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)

Estimated number of subjects

0

Study design details

Data analysis plan

Descriptive statistics of extracted variables (totals and percentage)

Documents

Study results

Goedecke_et_al-2018-British_Journal_of_Clinical_Pharmacology.pdf (860.18 KB)

Study publications

Goedecke T, Morales DR, Pacurariu A, Kurz X. Measuring the impact of medicines ...

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

Systematic literature search 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

Unknown