# 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)

**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**

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

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

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Other

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**Study topic, other:**

Impact of pharmacovigilance regulatory actions

**Study type:**

Non-interventional study

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**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

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**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

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**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