Review of studies evaluating the effectiveness of risk minimisation measures evaluated by PRAC (EffectiveRMM)

First published: 24/03/2022

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/45979

EU PAS number

EUPAS45978

Study ID

45979

DARWIN EU® study

No

Study countries

☐ Netherlands

Study description

This is a systematic review of industry sponsored PASS evaluating RMM effectiveness assessed by the PRAC between 2016 and 2019. The study was conducted to provide better understanding of the types of data collected, the study designs and analytical methods used, and to provides a better understanding of those PASS where a conclusion on RMM effectiveness could be drawn in order to help improve regulatory decision-making.

Study status

Finalised

Research institutions and networks

Institutions

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

Netherlands

First published: 01/03/2010

Last updated: 23/05/2024

Institution **Educational Institution** **ENCePP partner**

Contact details

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Primary lead investigator

Helga Gardarsdottir

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/02/2020

Actual: 03/02/2020

Study start date

Planned: 01/07/2020

Actual: 01/07/2020

Data analysis start date

Planned: 01/03/2021

Actual: 01/03/2021

Date of final study report

Planned: 01/12/2021

Actual: 01/12/2021

Sources of funding

- EMA
- Other

More details on funding

Utrecht University

Study protocol

EUPAS_Reg_RMM_study.pdf(228.71 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Other

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

Descriptive study of industry sponsored PASS

Data collection methods:

Secondary use of data

Main study objective:

The aim of this review of industry-sponsored post-authorisation safety studies (PASS) evaluating the effectiveness of risk minimisation measures (RMM) assessed by PRAC between 2016 and 2019

Study Design

Non-interventional study design

Cross-sectional

Population studied

Short description of the study population

Data will be considered eligible when originating from industry-sponsored PASS evaluating the effectiveness of RMM submitted and assessed by PRAC between 2016 and 2019.

All EU-RMP category 1, 2, or 3 PASS evaluating the effectiveness of RMM that were submitted to and assessed by the PRAC between 1 January 2016 and 31 December 2019 will be included in the study cohort.

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)

Estimated number of subjects

0

Study design details

Data analysis plan

A review of industry sponsored PASS evaluating effectiveness of RMMS was performed and extracted variables were analysed with descriptive statistics. Variables were summarised by the number and percentage per category.

Documents

Study publications

Grupstra R, Goedecke T, Scheffers J, Strassmann V, Gardarsdottir H. Review of S...

Data management

Data sources

Data source(s), other

EMA’s Document Records Electronic Archive Management (DREAM) system, European Review System for eCTDs (EURS)

Data sources (types)

Other

Data sources (types), other

Documents related to the assessment of industry-sponsored PASS evaluating the effectiveness of RMM stored both in DREAM and EURS

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