Review of PRAC assessed PASS evaluating risk minimisation measures (RMM) (EffectiveRMM2)

First published: 07/06/2022

Last updated: 27/11/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS47563

Study ID

47564

DARWIN EU® study

No

Study countries

Netherlands

Study description

This systematic review of PASS overseen or discussed by PRAC is aimed to provide a better understanding of factors associated with PASS that did not lead to a conclusion on the effectiveness of RMM, and to gain insights into factors associated with (in)effectiveness of RMM as presented in conclusive PASS.

Study status

Ongoing

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: 27/05/2026

Institution | Educational Institution | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Helga Gardarsdottir

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/03/2022

Actual: 01/03/2022

Study start date

Planned: 01/04/2022

Actual: 01/04/2022

Date of final study report

Planned: 01/09/2022

Sources of funding

- Other

More details on funding

European Medicines Agency, Utrecht University

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 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

Main study objective:

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Study Design

Non-interventional study design

Other

Non-interventional study design, other

Document review

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)

Estimated number of subjects

0

Study design details

Data analysis plan

For each PASS evaluating RMM effectiveness we assess if the PASS was conclusive (i.e. PRAC was able to draw conclusions on RMM effectiveness based on the PASS results) or inconclusive (i.e. the PASS did not allow to draw firm

conclusions on RMM effectiveness). We will use descriptive statistics to identify factors (e.g. specific study characteristics) associated with (in)effective RMM. A qualitative thematic analysis will be performed to identify methodological and other limitations that may have rendered the PASS inconclusive.

Documents

Study publications

Grupstra R, Goedecke T, Gardarsdottir H. Limitations Reported in Evaluating Eff...

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

Data is retrieved from documents

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