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

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## Administrative details

**Study description** 

<b>EU PAS number</b> EUPAS45978		
Study ID		
45979		
DARWIN EU® study		
No		
Study countries  Netherlands		

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



## Contact details

## Study institution contact

Helga Gardarsdottir h.gardarsdottir@uu.nl

Study contact

h.gardarsdottir@uu.nl

# **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

## **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 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

# Data quality specifications

#### **Check conformance**

Unknown

## **Check completeness**

Unknown

## **Check stability**

Unknown

## **Check logical consistency**

Unknown

## Data characterisation

#### **Data characterisation conducted**

No