# Systematic Review and meta-analysis of PASS Studies Assessing the Effectiveness of Risk Minimisation Measures

**First published:** 20/03/2018

**Last updated:** 02/07/2024

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS23245

**Study ID**

23435

**DARWIN EU® study**

No

**Study countries**

- ☐ Germany
- ☐ Spain
- ☐ United Kingdom

**Study description**

Risk minimisation measures are designed to mitigate potentially manageable risks of medicines. The effectiveness of these measures is uncertain. This cumulative systematic review and meta-analysis of PASS studies conducted to evaluate the effectiveness of risk minimisation studies provides data upon which to assess the future role of these studies.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### OXON Epidemiology

☐ Spain

☐ United Kingdom

**First published:** 06/12/2010

**Last updated:** 15/03/2024

**Institution** | **Laboratory/Research/Testing facility** | **Non-Pharmaceutical company** | **ENCePP partner**

### Bayer AG

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

Bayer Epidemiology Berlin

## Contact details

**Study institution contact**

Esther Artime esther.artime@oxonepi.com

Study contact

esther.artime@oxonepi.com

**Primary lead investigator**

Nawab Qizilbash MBChB MRCP(UK) BSc MSc DPhil(Oxon.)

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 28/03/2016

**Study start date**

Actual: 28/03/2016

**Date of final study report**

Planned: 25/05/2018

## Sources of funding

- Other

## More details on funding

OXON Epidemiology

## 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 type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

Scoping review (including literature review)

**Main study objective:**

To describe study characteristics, results, and regulatory consequences, in EU PASS RM Survey Study reports registered in the EU PAS Register.To quantify and pool (where appropriate) data on participation rates, receipt, knowledge, behaviour, use and reading in EU RM Survey Study reports registered in the EU PAS Register.

## Study Design

**Non-interventional study design**

Systematic review and meta-analysis

## 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)

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**Estimated number of subjects**

0

## Study design details

**Outcomes**

Study characteristics, participation rates, receipt, knowledge, behaviour, use and reading, and regulatory consequences

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**Data analysis plan**

Analyses are mainly descriptive, with numbers. proportions and Forest plots and other graphs. Where feasible, aggregate study-level data will be pooled overall and by aRMM type using random and fixed effects models.

## Documents

**Study publications**

Vora P, Artime E, Soriano-Gabarro M, Qizilbash N, Asiimwe A. A Review of Studie...

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# 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**

EU PAS Register, EMA, Pharmaceutical companies, MedLINE

# 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