Time intervals between key milestones of studies evaluating the effectiveness of Risk Minimisation Measures assessed by PRAC

First published: 31/10/2023

Last updated: 25/03/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS107458

Study ID

107467

DARWIN EU® study

No

Study countries

☐ Netherlands

Study description

This is a retrospective cohort study including completed PASS that evaluated RMM effectiveness.

This study involves a quantitative analysis of time intervals between key milestones of PRAC regulatory procedures for requesting and assessing protocols and study reports of RMM effectiveness PASS.

We will use a dataset of PASS evaluating RMM effectiveness assessed by PRAC between 2016 and 2022.

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

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Institution | Educational Institution | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

ML De Bruin

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/06/2023

Actual: 01/06/2023

Study start date

Planned: 01/08/2023

Actual: 01/08/2023

Data analysis start date

Planned: 01/11/2023

Date of final study report

Planned: 01/03/2024

Sources of funding

- Other

More details on funding

Medicines Evaluation Board

Study protocol

protocol 20240130.pdf(820.77 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 type:

Non-interventional study

Main study objective:

This retrospective cohort study of PASS overseen/discussed by PRAC is aimed to provide insights in the time intervals between key milestones of regulatory procedures for RMM effectiveness PASS assessed by PRAC 2016-2022 (follow-up on studies, EUPAS45978, EUPAS47563).

Study Design

Non-interventional study design

Other

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

This study mainly involved descriptive statistics to describe the cohort of PASS and duration of the intervals between key milestones.
Categorical variables will be assessed using frequencies and percentages.
Continuous variables will be assessed using medians and interquartile ranges or means and standard deviations (in case data follows a normal distribution).
Next to descriptive analyses, data will be analysed stratified on characteristics including study design, type of indicator, effectiveness of RMM and type of RMM evaluated.
This is done to evaluate whether these factors influence the duration of time intervals between key milestones.

Documents

Study publications

https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.3569

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

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