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

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### Administrative details

**Study description** 

EU PAS number	
EUPAS107458	
Study ID	
107467	
DARWIN EU® study	
No	
Study countries	
☐ Netherlands	

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**



### Contact details

Study institution contact

### ML De Bruin m.l.debruin@uu.nl

Study contact

m.l.debruin@uu.nl

### 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)** 

## 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