# Report on PRAC Pilot on Rapid Data Analytics

**First published:** 26/07/2021

**Last updated:** 27/07/2021

Study Finalised

## Administrative details

**EU PAS number**

EUPAS42268

**Study ID**

42291

**DARWIN EU® study**

No

**Study countries**

- [ ] France
- [ ] Germany
- [ ] United Kingdom

**Study description**

A pilot on rapid data analytics (referred to in this report as RDA) coordinated by the European Medicines Agency (EMA) was performed with the Pharmacovigilance Risk Assessment Committee (PRAC) from November 2019 to January 2021. Its aim was to test the feasibility and usefulness of a process for rapid identification, analysis and reporting of results of epidemiological questions that may arise in the context of regulatory assessments for which Real World Data (RWD) and Real-World Evidence (RWE) can support regulatory decisions by filling knowledge gaps identified during a procedure. The pilot was part of the 2020/2021 PRAC and Big Data Steering Group workplan and it should be seen as a first step towards the promotion of a wider use of RWD/RWE in the development, authorisation and post marketing surveillance of medicines.

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**Study status**

Finalised

# Research institutions and networks

## Institutions

### European Medicines Agency (EMA)

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

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

**Institution**

# Contact details

**Study institution contact**

Kelly Plueschke kelly.plueschke@ema.europa.eu

Study contact

kelly.plueschke@ema.europa.eu

**Primary lead investigator**

Kelly Plueschke

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 01/11/2019

Actual: 01/11/2019

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**Study start date**

Planned: 01/11/2019

Actual: 01/11/2019

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**Date of final study report**

Planned: 31/01/2021

Actual: 31/01/2021

## Sources of funding

- EMA

## Regulatory

**Was the study required by a regulatory body?**

No

**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, A pilot on rapid data analytics (referred to in this report as RDA) coordinated by the European Medicines Agency (EMA)

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

**Data collection methods:**

Secondary use of data

**Main study objective:**

A pilot on rapid data analytics coordinated by the EMA was performed with the PRAC from November 2019 to January 2021. Its aim was to test the feasibility and usefulness of a process for rapid identification, analysis and reporting of results of epidemiological questions that may arise in in the context of regulatory assessments.

# Study Design

**Non-interventional study design**

Cohort

Case-control

# Population studied

**Short description of the study population**

NA

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**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**

100000

## Study design details

**Data analysis plan**

Please refer to the executive summary

## Documents

**Study results**

PRAC Pilot Rapid Data Analytics - Executive summary.pdf(110.89 KB)

# Data management

## Data sources

**Data source(s)**

THIN® (The Health Improvement Network®)

**Data sources (types)**

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

## 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