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.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Kelly Plueschke

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/11/2019

Actual: 01/11/2019

Study start date

Planned: 01/11/2019

Actual: 01/11/2019

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

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

100.000

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

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)

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