Can We Rely on Results From IQVIA Medical Research Data UK Converted to the Observational Medical Outcome Partnership Common Data Model?

First published: 16/01/2020

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/33722

EU PAS number

EUPAS33148

Study ID

33722

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Exploring and combining results from more than one real world data (RWD) source might be necessary in order to explore variability and demonstrate generalisability of the results, or for regulatory requirements. However, the heterogeneous nature of RWD poses challenges when working with more than one source, some of which can be solved by analysing databases converted into a common data model (CDM).The main objective of the study was to evaluate the implementation of the Observational Medical Outcome Partnership (OMOP) CDM on IQVIA Medical Research Data (IMRD) UK data. A drug utilisation study describing the prescribing of codeine for pain in children was used as a case study to be replicated in IMRD-UK and its corresponding OMOP CDM transformation. Differences between IMRD-UK source and OMOP CDM were identified and investigated.

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

Gianmario Candore

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/07/2018

Actual: 02/07/2018

Study start date

Planned: 02/07/2018

Actual: 02/07/2018

Data analysis start date

Planned: 02/07/2018

Actual: 02/07/2018

Date of final study report

Planned: 16/09/2019

Actual: 16/09/2019

Sources of funding

- EMA

Study protocol

Protocol - final.pdf(690.92 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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Other

If ‘other’, further details on the scope of the study

Compare results from the original database versus the transformed database into OMOP CDM

Data collection methods:

Secondary use of data

Main study objective:

The main objective was to compare the prescribing of codeine for treatment of pain in children in the OMOP CDM converted database against results in the original IMRD-UK source database. The specific objective was to explore any potential loss of information and inaccuracy resulting from the conversion, and, if so, whether these changes would have impacted on the interpretation of study results

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive analyses

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R05DA04) codeine

codeine

Population studied

Short description of the study population

Children below the age of 18 years.

Age groups

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Special population of interest

Pregnant women

Estimated number of subjects

40000

Study design details

Data analysis plan

Results will be analysed descriptively. Differences between OMOP CDM and IMRD-UK source data will be identified and, if found to have appreciable impact on the study results, further investigated.Joinpoint regression analysis with log-linear model will be used to evaluate statistically significant changes in prescribing trend

Documents

Study publications

Candore, G., Hedenmalm, K., Slattery, J., Cave, A., Kurz, X. and Arlett, P. (20...

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Data source(s), other

THIN

Data sources (types)

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