Data characterization of population-based data sources: ConcePTION pipeline

First published: 16/06/2023

Last updated: 22/02/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS50142

Study ID

107620

DARWIN EU® study

No

Study countries

Finland

France

Italy

Norway

Spain

United Kingdom

Study description

The use of real-world data (RWD) and real-world evidence (RWE) in regulatory decision making is increasing (https://rwe-navigator.eu/use-real-world-evidence/sources-of-real-world-data/). In order to make best use of RWD many data sources in a scalable rapid and reproducible manner, many groups and consortia have turned to the use of common data models (CDMs). This approach aims to transform data from different databases into a common format (i.e data model). This data can then be analyzed using scripts written based on that common data format. In this study, we will develop the pipeline of three-levels quality checks for the ConcePTION CDM which include the evaluation of the Extract-Transform-Load (ETL) process, quantify the completeness of the databases, and assessment of counts and distributions of variables and dates. The characterization study will be based on at least 12 data sources, covering at least 6 European countries: France, Finland, Norway, Italy, UK, and Spain (approx. 36.2 million individuals). After each check an html report visualizing the results will be produced. In the final study report, incidence rates from literature will be presented together with incidence rates estimated for the current study. Discrepancies will be identified and interpreted based upon descriptions of the data source(s), algorithms for identification of events, and design choices including inclusion and exclusion criteria in published studies vs. those employed for this protocol. The output of this study will be a series of scripts openly available on an online repository. All the quality checks reports will undergo through an approval process assessed by the conception quality check advisor and the data access provider representative.

Study status

Ongoing

Research institutions and networks

Institutions

University Medical Center Utrecht (UMCU)

Netherlands

First published: 24/11/2021

Last updated: 22/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Julius Center

Networks

ConcepTION

First published: 01/02/2024

Last updated: 01/02/2024

Network

Contact details

Study institution contact

Vjola Hoxhaj v.hoxhaj@umcutrecht.nl

Study contact

v.hoxhaj@umcutrecht.nl

Primary lead investigator

Vjola Hoxhaj

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 01/04/2019

Study start date
Actual: 08/05/2021

Data analysis start date
Planned: 01/02/2023

Date of final study report
Planned: 31/01/2024

Sources of funding

- EU institutional research programme

More details on funding

IMI ConcePTION

Study protocol

ConcePTION Data Characterization Indicators_populationbased_V1.1_08NOV2019 (2).pdf (2.22 MB)

ConcePTION Data Characterization Indicators_populationbased_Revised_13Nov2023.pdf (2.83 MB)

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 type:

Non-interventional study

Main study objective:

To assess integrity of the ETL and internal consistency of the CDM instance for each DAP. To produce high-level characterization results describing the final outcomes of these checks in terms of missingness in key variables, distributions

of key variables, and internal inconsistency. To assess the data quality and determine 'fit for purpose' for studies on drugs safety and utilization.

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)

Estimated number of subjects

36.320.000

Study design details

Data analysis plan

First, we will construct frequency tables based on categorical data and we will plot the distribution of continuous variables and dates. We will use these outputs to identify outlinear, picks, drops, and trends on the data sources. After

we will analyzed the missing data pattern, repeated events and incidence rate. Last, we will check the compliance with conception CDM.

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)

SAIL Databank

The Information System for Research in Primary Care (SIDIAP)

ARS Toscana

EUROmediCAT central database

Data source(s), other

FISABIO Spain, Bourdeux France, NorPD, SIDIAP, Drugs and Pregnancy Finland, Emilia Romagna GPs drug prescription

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Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Drug dispensing/prescription data

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