Establish an EU catalogue of sources of real-world data, characterised by a common set of metadata and data quality measurements

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Last updated: 12/06/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/49304

EU PAS number
EUPAS49303

Study ID
49304

DARWIN EU® study
No

Study countries
Belgium
Czechia
Denmark
Finland
France
Germany
Italy
Netherlands
Norway
Poland
Slovakia
Spain

Sweden
United Kingdom

Study description
Europe is generating unprecedented amounts of person-level information contained in Electronic Medical Record (EMR) systems. This includes structured data in the form of diagnoses, medication, and laboratory test results. These EMR datasets are often siloed by country, language, region, hospital and even department, captured in a disease specific context, however, these data contain invaluable insights for regulatory purposes. Metadata is traditionally defined as “data about data”. It’s a set of data that describes and gives information on other data providing context about their purpose, location, key-variables, generation, format, and ownership of a dataset. Metadata help both researchers and study sponsors to identify datasets for conducting specific studies. Currently, publicly available metadata is limited, not coherent between different sources, and not defined with a regulatory purpose in mind. Therefore, the Agency is currently developing an EU catalogue of real-world data sources which will replace the existing ENCePP catalogue in late 2023. To accommodate this process, the Agency awarded IQVIA to propose a methodology to grow and maintain the catalogue in a sustainable manner, as well as to catalogue an initial set of 24 data sources in 2022. The overall objective is to establish an EU catalogue of sources of real-world data, characterised by a common set of metadata and data quality measurements.

Study status
Finalised

Research institution and networks

Institutions

Real-World-Evidence, IQVIA NL

Netherlands
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Institution
ENCePP partner
Other

Multiple centres: 24 centres are involved in the study

Contact details

Study institution contact
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Primary lead investigator
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Study timelines

Date when funding contract was signed
Planned:
13/12/2021
Actual:
13/12/2021

Study start date
Planned:
01/07/2022
Actual:
01/07/2022

Date of final study report
Planned:
23/01/2023
Actual:
21/03/2023

Sources of funding

- EMA

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:
Other

Study topic, other:
Disease/Epidemiology study

Study type:
Not applicable

Scope of the study:
Other

If ‘other’, further details on the scope of the study
Propose a methodology to grow the EU catalogue of real-world data sources in a sustainable manner and catalogue an initial set of 24 data sources.

Data collection methods:
Combined primary and secondary data collection

Main study objective:
To establish an EU catalogue of sources of real-world data, characterised by a common set of metadata and data quality measurements.

Population studied

Short description of the study population
N/A

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
Not applicable

Data management

Data sources

Data source(s)
Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)
Pedianet network
PedNet Haemophilia registry
Hospital Episode Statistics
National Prescribed Drugs Register / Läkemedelsregistret
Danish registries (access/analysis)
European network of population-based registries for the epidemiological surveillance of congenital anomalies

Data sources (types)
Administrative data (e.g. claims)
Disease registry
Drug dispensing/prescription data
Electronic healthcare records (EHR)

Other

Data sources (types), other
Prospective patient-based data collection

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