Strengthening Use of Real-World Data in Medicines Development: Metadata for Data Discoverability and Study Replicability (MINERVA)

First published: 03/02/2021

Last updated: 16/12/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49345

EU PAS number

EUPAS39322

Study ID

49345

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Czechia
- [ ] Denmark
- [ ] Estonia
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Slovenia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

Study description

Identification of appropriate data sources is becoming an increasing need for regulatory decision making. Metadata are descriptive data that characterise other data to create a clearer understanding of their meaning and achieve greater reliability and quality of information. Access to a standard and electronic set of complete and accurate metadata information can contribute to identifying the datasources that are most suitable for a specific study, describe the datasources planned to be used in a study protocol or research proposal, and contribute to assessing the evidentiary value of the results of a multidatabase observational study submitted in a study report or publication. The objective of this study is to define and collect a set of metadata for a selected number of real-world (RW) datasources. The study consists in the preparatory step for the development and population of a publicly available catalogue of sources of RW data characterised with a common set of metadata.

The catalogue will serve as a proof of concept for a metadata inventory with searchability, dynamic dashboards, visualisation capabilities, and integration of different levels of access (public vs. confidential information). Specific objectives of this study are:

1. Define a list of criteria to identify relevant RW datasources from which the datasources to be included in this study will be selected.
2. Identify a list of a minimum of 10 datasources for this study.
3.Define a set of metadata that should be collected from RW datasources.
4.Conduct an in-depth stakeholders' consultation on the metadata identified.
5.Define a process to collect the set of metadata for the datasources in the study.
6.Collect the defined set of metadata for datasources in the study.
7.Develop a tool enabling access to the metadata collected.
8.Draft a good practice guide with the description of the metadata defined and recommendations on its use for the purpose of identifying RW datasources for specific studies.

Study status

Finalised

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)

- ☐ France
- ☐ Spain
- ☐ Sweden

United Kingdom

United Kingdom (Northern Ireland)

United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution | Not-for-profit | ENCePP partner

Electronic Health Records (EHR) Research Group, London School of Hygiene & Tropical Medicine (LSHTM)

United Kingdom

First published: 19/04/2010

Last updated: 30/10/2024

Institution | Educational Institution | ENCePP partner

Division of Pharmacoepidemiology & Clinical Pharmacology (PECP), Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University

Netherlands

First published: 01/03/2010

Last updated: 23/05/2024

Institution | Educational Institution | ENCePP partner

Health Services Research and Pharmacoepidemiology Unit (HSRP Unit) FISABIO

Spain

First published: 30/11/2023

Last updated: 30/11/2023

Institution | Other | ENCePP partner

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

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

First published: 24/03/2010

Last updated: 23/04/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/02/2023

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

University of Tartu

Estonia

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

Agenzia regionale di sanità della Toscana (ARS)

Italy

First published: 01/02/2024

Last updated: 12/03/2024

Institution | EU Institution/Body/Agency | ENCePP partner

Agencia Española de Medicamentos y Productos Sanitarios (Spanish Agency for Medicines and Medical Devices, AEMPS)

Spain

First published: 01/02/2024

Last updated: 04/09/2024

Institution | EU Institution/Body/Agency | Not-for-profit | Regulatory Authority | ENCePP partner

European Society for Blood and Marrow Transplantation (EBMT)

European Union

First published: 20/02/2024

Last updated: 20/02/2024

Institution

University Medical Center Groningen (The Netherlands), The Spanish Working Group on

Chron’s Disease and Ulcerative Colitis (GETECCU) (Spain), University of Ljubljana Faculty of Pharmacy (Slovenia), Institute of Genomics (Estonia)

Networks

The SIGMA Consortium (SIGMA)

- [ ] Denmark
- [ ] European Union
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

First published: 10/02/2013

Last updated: 16/12/2024

Network **ENCePP partner**

EU Pharmacoepidemiology and Pharmacovigilance (PE&PV) Research Network

Netherlands

First published: 01/02/2024

Last updated: 26/11/2024

Network

Contact details

Study institution contact

Susana Perez-Gutthann

Study contact

sperez@rti.org

Primary lead investigator

Susana Perez-Gutthann

Primary lead investigator

ORCID number:

0000-0001-5798-3691

Study timelines

Date when funding contract was signed

Planned: 04/01/2021

Actual: 23/11/2020

Study start date
Planned: 31/05/2021

Actual: 01/03/2021

Date of final study report
Planned: 15/12/2021

Actual: 10/01/2022

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:

Infrastructure and guidance development

Study type:

Not applicable

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

Definition and description of metadata, visualisation catalogue proof of concept tool and development of a good practice guide

Main study objective:

To define the set of metadata that should be collected from RW data sources and to collect the metadata for at least 10 data sources for the future development & population of a public catalogue with searchability, dashboards, visualisation capabilities, and integration of different levels of access

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)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Study design details

Data analysis plan

Not applicable

Documents

Study results

MINERVA_GoodPracticeGuide_10Jan2022.pdf(1.8 MB)

Study report

MINERVA_D4_WorkshopReport_Final.pdf(764.56 KB)

MINERVA_DataSourceSelection_Final_26March2021.pdf(1.17 MB)

Study, other information

MINERVA Full-metadata-list 10Jan2022.pdf(968.07 KB)

MINERVA_D5_Report_v1.1_28June2021.pdf(2.46 MB)

MINERVA_D9_Metadata-catalogue-10Jan2022.pdf(587.5 KB)

MINERVA_DataSourceSelection_Final_26March2021.pdf(1.17 MB)

Study publications

Pajouheshnia, R., Gini, R., Gutierrez, L., Swertz, M., Hyde, E., Sturkenboom, M...

Gini, R., Pajouheshnia, R., Gutierrez, L., Swertz, M., Hyde, E., Sturkenboom, M...

Pajouheshnia R, Gini R, Hyde E, Swertz MA, Sturkenboom M, Margulis AV, Franzoni...

Gini R, Pajouheshnia R, Hall GC, Platt RW, Setoguchi S, Perez-Gutthann S, Willa...

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Danish registries (access/analysis)

PHARMO Data Network

German Pharmacoepidemiological Research Database

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

ARS Toscana

EpiChron Cohort

The Valencia Health System Integrated Database

Système National des Données de Santé (French national health system main database)

Estonian Biobank

Data source(s), other

EBMT; Swedish National Registers, Sweden; Slovenian health data, Slovenia.

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Laboratory tests and analyses

Omics

Population registry

Pregnancy registry

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Not applicable