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

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Administrative details

EU PAS number	
EUPAS39322	
Study ID	
49345	
DARWIN EU® study	
No	
Study countries	
Austria	
Belgium	
Czechia	

De	enmark
Est	tonia
Fra	ance
☐ Ge	ermany
Ita	ly
☐ Ne	therlands
☐ Slo	ovenia
Sp:	ain
Sw	veden veden
Sw	vitzerland
Un	ited 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

ENCePP partner

Institution

Educational Institution

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
Contro for Pharmacoonidomiology, Karolinska
Centre for Pharmacoepidemiology, Karolinska
Institutet (CPE-KI)
Sweden
First published: 24/03/2010
Last updated: 23/04/2024

Institution
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

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 CICNA Consortium (CICNA)
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

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Network

Contact details

Study institution contact

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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

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)

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)

Omics Population registry
Pregnancy registry
Use of a Common Data Model (CDM)
CDM mapping No
Data quality specifications
Yes
Check completeness Yes
Check stability Yes
Yes Check logical consistency

Laboratory tests and analyses