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SCIENCE MEDICINES HEALTH

HMA-EMA Catalogues of real-world data sources and studies

Multi-stakeholder webinar – 4 March 2024, 10:00-12:00 CET

Housekeeping rules

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Questions will be **addressed at the end of the webinar** in a Q&A session

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If your **questions are not addressed during this** session feel free to Contact us on the HMA-EMA Catalogues' website

Opening remarks

Peter Arlett (EMA, co-chair BDSG) and Jeppe Larsen (DKMA, co-chair BDSG)

HMA-EMA Catalogues of real-world data sources and studies

One step closer to **data-driven** medicines regulation

Improving **data discoverability** and **research transparency**

Third priority recommendation of the **HMA-EMA Big Data Steering Group workplan**

Objectives of the webinar

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Improving data discoverability
One step closer to more data driven medicines regulation

1. **PROVIDE AN OVERVIEW OF THE HMA-EMA CATALOGUES**
of real-world data sources and studies, including their benefits and significance within regulatory practices.

2. **ILLUSTRATE THE APPROACH**
to using the catalogues, including user roles and responsibilities.

3. **CONDUCT A DEMONSTRATION**
showcasing the key features of the platform.

4. **INFORM ABOUT SUPPORTING DOCUMENTATION**
including user guides and FAQs to optimise the use of the catalogues.

Agenda

1	**Introduction**, BDSG co-chairs Peter Arlett (EMA) and Jeppe Larsen (DKMA)	10:00 – 10:15
2	**HMA-EMA Catalogues of real-world data sources and studies overview**, Ana Cochino (EMA)	10:15 – 10:35
3	**Demonstration of the platform** and **call to action**, Stefania Simou (EMA)	10:35 – 11:10
4	**Resources and user support**, Ana Cochino (EMA)	11:10 – 11:20
5	**Q&A session**	11:20 – 11:50
6	**Closing remarks**, Paolo Alcini (EMA)	11:50 – 12:00

HMA-EMA Catalogues of real-world data sources and studies overview

Ana Cochino (EMA)

Development of Catalogues – activities and preparatory work

MINERVA: Metadata for data dIscoverability aNd study rEplicability in obseRVAtional studies

Strengthening Use of Real-World Data in Medicines Development: Metadata for Data Discoverability and Study Replicability (EMA/2017/09/PE/16)

(**2020**) The Big Data Steering Group (BDSG) – HMA/EMA joint initiative to promote data driven medicine regulation sets up ten priority recommendation. Recommendation 3: Data discoverability

(**2021**) Dedicated data discoverability multistakeholder workshop followed-up by wide-reaching surveys

(**2023**) Migration of ENCePP data sources and studies. Collection of metadata for data sources of interest. development of a new IT system

(**2021**) MINERVA project sets out the foundations of the activity in a one-year preparatory work

(**2022**) Adoption and publication of the List of metadata for data discoverability

Catalogues of RWD sources & studies – scope overview

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Launched 15 February 2024

Catalogue of RWD sources

replaces the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Resources Database

Catalogue of RWD studies

enhances the European Union electronic register of post-authorisation studies (EU PAS Register®)

- The catalogues are primarily aimed at data sources useful in the context of **medicine regulation** and promoting the use of real-world data sources and observational studies in the regulatory process.
- **Freely available access** via the catalogues webpage**,** hosted on EMA public website
- **User-friendly platform** for researchers, regulators, pharmaceutical companies, data source holders and general public
- Facilitation of **search of data sources and studies** related to medicines, ultimately supporting evidence-based decision-making

https://catalogues.ema.europa.eu/

Features overview – better data management

Globally **unique and persistent identifiers** in line with principles set out as **FAIR** (**F**indable, **A**ccessible, **I**nteroperable, and **R**e-usable).

Data management system built-in assisting the data submission (e.g.: data validation of the form, business rules, look-up values)

Integration with EMA's **master data management** system (SPOR) – controlled vocabularies maintained centrally and publicly available, re-usable, facilitating interoperability

Data validation module supporting a **data validation process** conducted by EMA prior to publication – including monitoring of **maintenance** process and updated data

Features overview – better data access and availability

Enhanced search & export functionalities possibility to filter, sort and export search results and records (Excel, pdf)

Link between **data sources and associated studies,** possibility to view information about data sources used in the study and vice versa

Integration with other initiatives and **EMA website content**: studies will be visible in the **relevant medicines overview page,** on the EMA website connection to summary of RMP, EPAR, PI*

**This feature will be released after go-live in a second phase.*

Features overview – registered user functionalities

Secure user management and login through **EU Login** multi-factor authentication service of the European Commission

Data management system built-in ensuring ease of maintenance and **data validation module to ensure reliable data is published**. Integration with EMA's **master data management** system.

New platform enables users to **easily access and manage content**, including the option to **collaborate on records with multiple authors**

E-mail notifications will inform users of the approval/rejection of submitted data, as well as prompting users to update their records*

**This feature will be released after go-live in a second phase.*

Catalogues of RWD sources & studies – available data

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Data Sources currently available (~200 data sources):

- ✓ Data migrated and brought up-to-date from **ENCePP Resource Database**,
- ✓ Resources collected during the **MINERVA** pilot
- ✓ Data sources who expressed interest during the **DARWIN EU open call**
- ✓ EHDEN partners
- ✓ Other data sources directly approached in preparation phase

Studies currently available (~ 3000 studies):

- Studies migrated from the former **EU PAS Register** – post authorisation safety studies and other observational studies submitted on voluntary basis
- Observational studies conducted through the DARWIN EU network, EMA framework contract etc.

Benefits for data source holders and researchers

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The participation in the HMA-EMA Catalogues for data source holders aims to:

Increase the visibility of the data source to the research community funding research

Increase the use of data by regulatory and public health agencies evaluating the benefits and risks of medicines and health care

Facilitate participation in EMA-funded studies and enabling to record a study in the studies catalogue

Increase the **volume of published research** referencing a data source

Guide **research collaboration requests** in being more targeted and suited to the content of a database

Examples of catalogues use cases

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A researcher would like to identify suitable data source(s) for a planned study	The catalogue of data sources offers information (metadata) on the **data source content** (e.g.: capturing of medicinal product information, disease, demographics), availability, contact points to help the choice of data source. It allows benchmarking of different data sources referring to similar population when planning a study.
A study protocol submitted uses a data source. The assessor needs to understand the suitability of the data source proposed	The study can be retrieved using the studies catalogue; the protocol is available. Other **similar studies** can be retrieved using studies structured metadata, and a comparison of **data sources** used in similar research is possible.
An assessor reads a study report for which they need to evaluate the data source(s) used in the study	The study report is available in the catalogue, along with details on the data source used. **Other studies** conducted using this particular data source can be consulted using the catalogues and provide orientation on the suitability of the data. The information on proposed data source used can be easily retrieved and assessed in the same context.

List of metadata | Data sources

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I	II	III	IV	V
Administrative details	**Data elements collected**	**Quantitative descriptors**	**Data flows and management**	**Vocabularies**
• Data source ID • Name and acronym • Data holder (institutions look-up) • Data source contact • Countries & regions • Language • First established date • Time span: first collection – last collection • Website • Publications • Studies conducted using data source • Qualifications • Main financial support (European public funding, industry funding, public-private partnership etc.) • Data source type (e.g., biobank, cancer registry, hospital inpatient..) • Care setting (e.g. GP, community pharmacist, hospital outpatient..)	• Exposure: availability of data on prescriptions and/or dispensing, ATMPs, contraception, vaccines, other injectables, medical devices, procedures, medicinal products and indication, biomarker data • Outcomes: availability of data on hospital admission or discharge, ICU admission, cause of death, clinical measurements, genetic data, patient-generated data, health care utilisation, diagnostic codes, specific diseases, with disease information collected • Disease information • Medicinal product information • Family linkage • Sociodemographic information • Lifestyle factors information	• Population age groups • Estimated percentage of population covered in catchment areas • Description of population in catchment area • Population size (by age groups) • Active population size (by age groups) • Median observation time between first and last available records for all and active individuals	• Governance details: Documents or webpages that describe the overall governance, data capture and management (..) • Biospecimen access • Access to subject details • Description of data collection • Event triggered creation of record • Event triggering registration and de-registration of a person • Linked data sources, names and linkage variable. • Data management including possibility for data validation, data source preservation and approval for publication. • Informed consent for use of data research • Data source refresh and date • CDM mapping & name • ETL process and status	• Medicinal product vocabulary • Cause of death vocabulary • Quality of life measurement • Prescription vocabulary • Dispensing vocabulary • Indication vocabulary • Procedures vocabulary • Genetic data vocabulary • Biomarker data vocabulary • Diagnosis/medical event vocabulary

List of metadata | Studies

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I Administrative details

- EU PAS Register number
- Official study title and acronym
- Study description
- DARWIN EU study: yes/no
- Institution conducting study
- Network conducting study
- Study contact
- Primary lead investigator
- Study timelines
  - Contract signed
  - Study start
  - Data analysis start
  - Interim report
  - Final study report
- Study countries
- Source of funding
- Protocol doc
- Required by EU regulator Yes/No
- Required by RMP?
- Regulatory procedure number
- Other study ID

II Methodological aspects

- Study topic (e.g. disease/health condition, herbal medicine, medical device, medical product/procedure etc.)
- Study type
- Name of medicine (brand name)
- Study drug INN
- ATC Code
- Medical condition
- Population studied
- Age groups
- Special population of interest (e.g. frail, nursing women, pregnant women, hepatic impaired etc.)
- Estimate number of subjects
- Study design
- Study objective
- Setting (persons, place, time period, selection criteria)
- Comparators
- Outcomes
- Data analysis plan (e.g. risk estimation, internal/external validity etc.)
- Summary results incl. study report
- Study publications

III Data management

- ENCePP CoC Yes/No/NA
- ENCePP seal incl. documents
- Data sources (look-up)
- Data source types
- CDM mapping
- Check conformance
- Check completeness
- Check stability
- Check logical consistency
- Data characterisation conducted
- Procedure of data extraction
- Procedure of result generation

Linkage between entities in the RWD Catalogues

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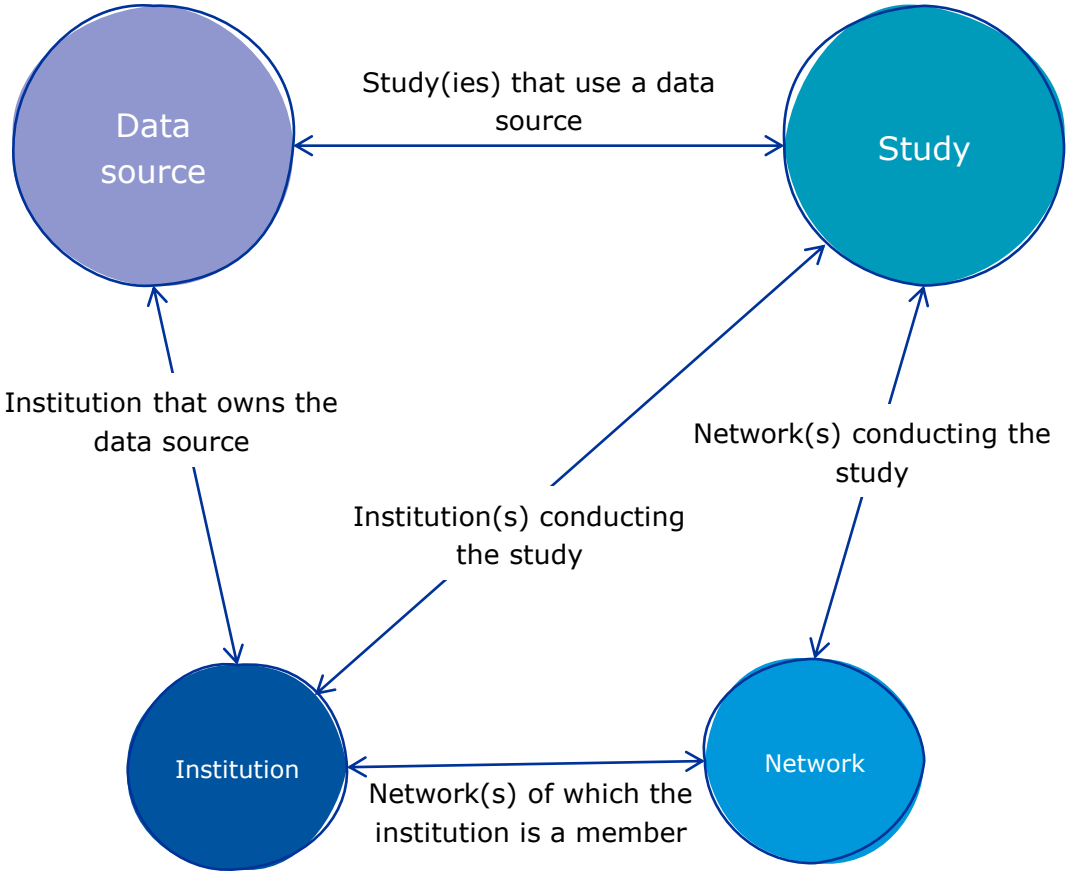
Each record presents information on the **other metadata elements linked** to it.

For example, an institution record would present information about the network of which the institution is a member, the list of studies that the institution had funded/conducted, and the list of data sources that the institution owns.



RWD catalogues – features working towards:

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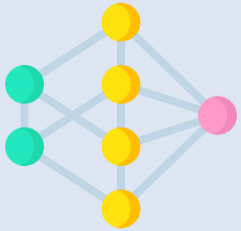
Enhanced Data Visibility and Accessibility

- Modern **user-friendly platform**
- **Easily accessible** on the EMA public website
- **Dynamic pages and search** for real-world data sources and studies
- Streamlined **identification of data sources** for specific research questions

Continuous Improvement and Interoperability



- **Planned ongoing enhancements** and technical improvements – monthly releases to better match user's needs
- **Alignment with advancements** in the regulatory and technological domains
- Promotion of **data interoperability** and integration of data sources
- Collaboration with future **EHDS data source** catalogue

Transparency and Collaboration

- **Public access** to study reports and results
- **Encouraged collaboration** among different actors
- Toward **better-informed decisions** on drug safety and effectiveness
- Contribute to the **collective effort** to advance real-world evidence utilisation

Demonstration of the platform

Stefania Simou (EMA)

Call to action!

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We invite you to populate the catalogue with new data sources!

Submit new records:

1. Create an EU Login account
2. Log in to the RWD Catalogues website
3. Add data source
4. Fill in the form
5. Submit!

Access your existing records:

1. Complete the survey to claim your record
2. Log in to the RWD Catalogues website
3. EMA will assign the records claimed via the survey to your account

Content Moderation Workflow

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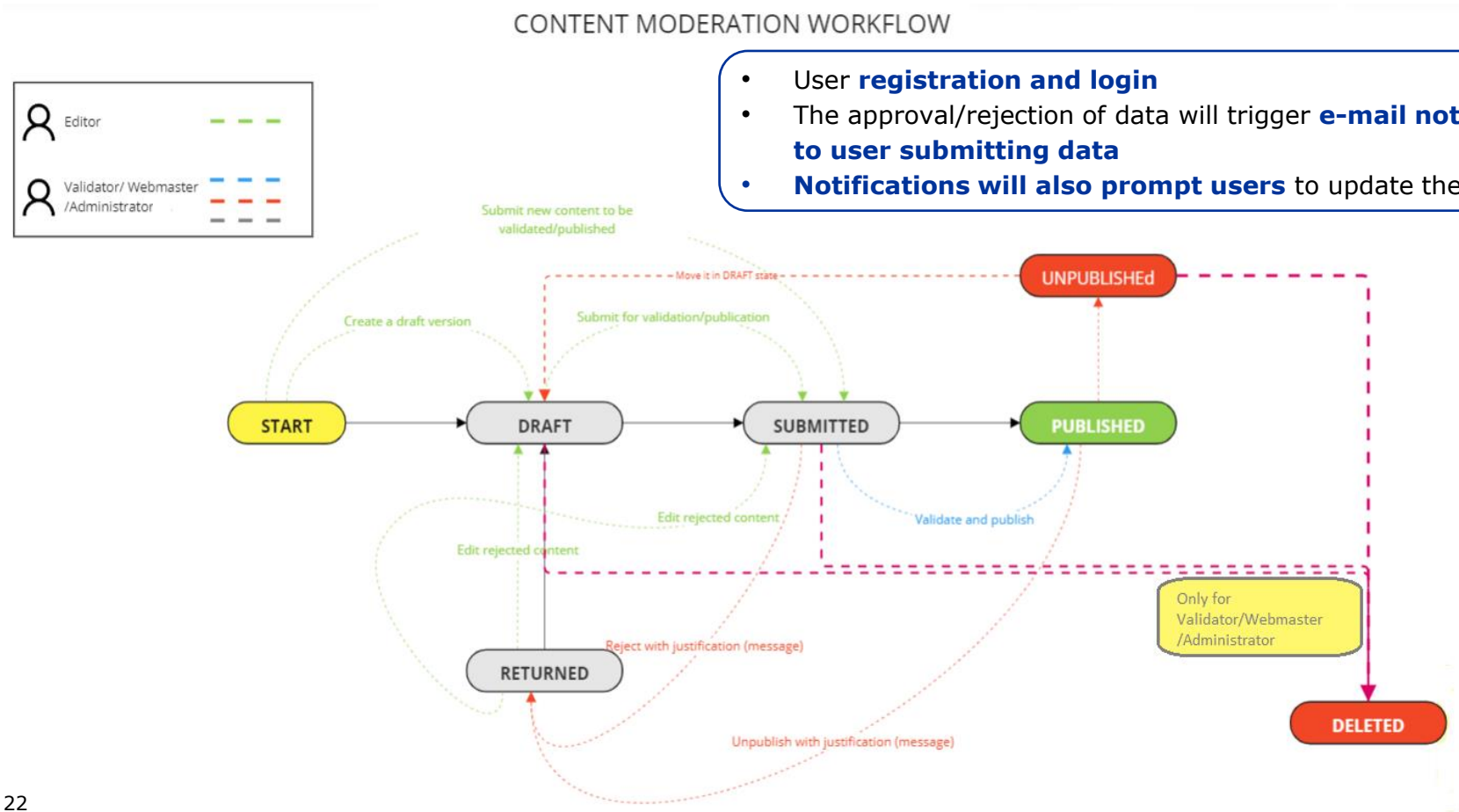
- User **registration and login**
- The approval/rejection of data will trigger **e-mail notifications to user submitting data**
- **Notifications will also prompt users** to update their records



Resources and user support

Ana Cochino (EMA)

Helpdesk support and Frequently asked questions

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User support available via EMA helpdesk – ServiceNow:

- Issues, bugs
- Ownership of information
- Suggestions for improvements

https://catalogues.ema.europa.eu/contact-us

Frequently asked question section covering:

- Studies, data sources submission
- Data entry and maintenance
- Search and export functionalities
- Transfer of records from previous

https://catalogues.ema.europa.eu/support

User support related to creation of an **EU login** account

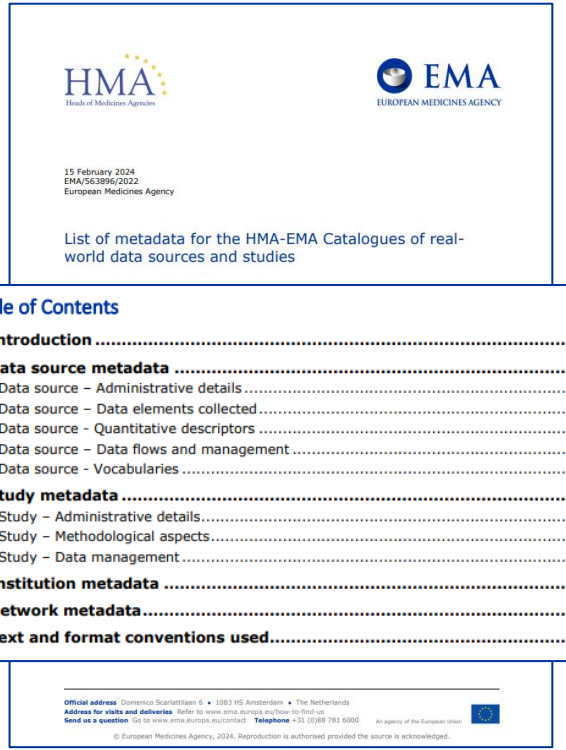
https://webgate.ec.europa.eu/cas/help.html

List of Metadata for Data sources and studies

The EMA and HMA have published the **list of metadata** **for the HMA-EMA Catalogues of real-world data sources and studies**, The metadata elements are tailored to medicines regulation and have been **agreed within the network.**

The main types of defined Metadata are:

Data Sources	Metadata containing information on the data source (e.g., data source countries, data elements collected, etc.)
Studies	Metadata describing studies conducted using RWD sources indexed in the catalogue (or not)
Institutions	Metadata on any contributor to the catalogue, its role and expertise (e.g., institution country, etc.)
Networks	Metadata describing networks/consortia linking to institutions and studies in the catalogue (e.g., network name, website, etc.)



HMA Heads of Medicines Agencies

EMA EUROPEAN MEDICINES AGENCY

15 February 2024
EMA/563896/2022
European Medicines Agency

List of metadata for the HMA-EMA Catalogues of real-world data sources and studies

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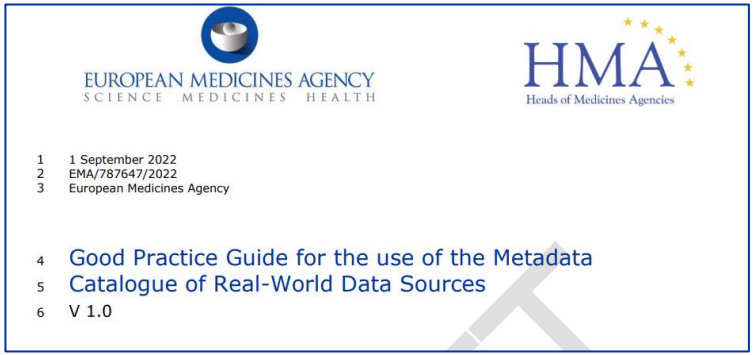
Send us a question Go to www.ema.europa.eu/contact Telephone +31 (0)88 781 6000 An agency of the European Union

Good practice guide for the use of Metadata Catalogue

The EMA and HMA have published the draft **Good Practice Guide** to guide the use of catalogues and description of data elements. An updated version is being developed and due to be published in the next months.



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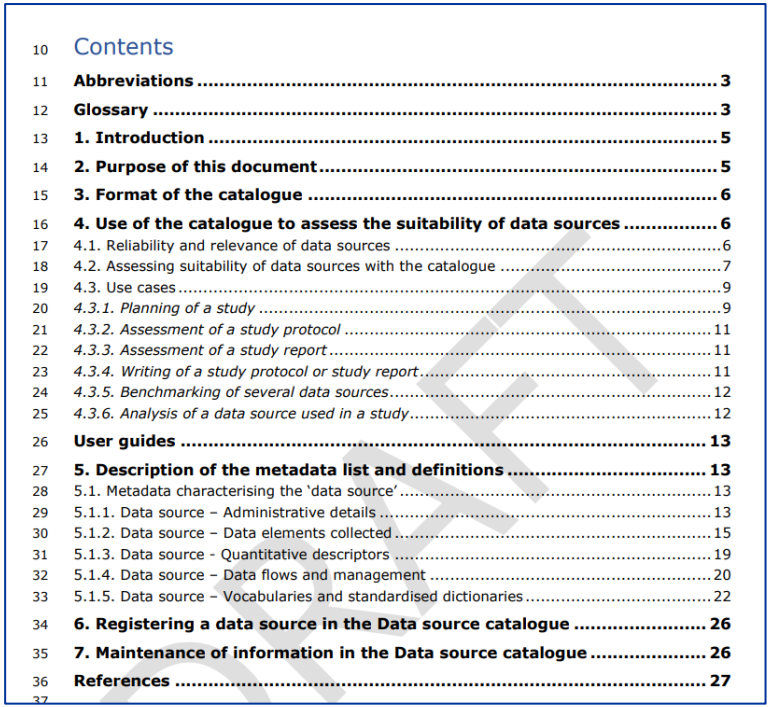
HMA
Heads of Medicines Agencies

1 September 2022
EMA/787647/2022
European Medicines Agency

Good Practice Guide for the use of the Metadata Catalogue of Real-World Data Sources

V 1.0

DRAFT



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DRAFT

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Frequently Asked Questions

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Service desk – ask a question, raise issues/bugs, or propose improvements

Q&A session

Closing remarks

Paolo Alcini (EMA)

Call to action

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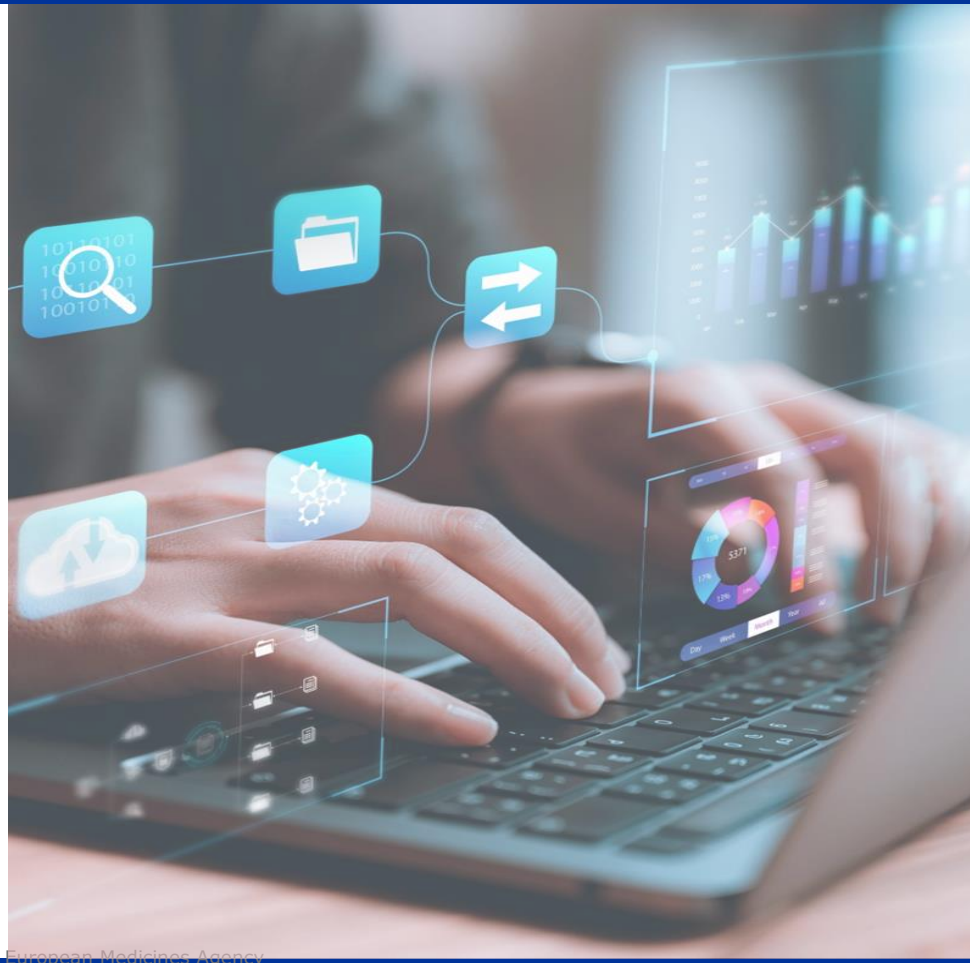
Contribute to data driven medicine regulation by submitting your data source, studies, network, and institutions in the Catalogues

Your contribution matters!

1. Create an EU Login account
2. Log in: https://catalogues.ema.europa.eu/
3. Add your entity (e.g., study, network etc.)
4. Fill in the metadata fields
5. Submit!



Next steps

- *Survey to collect **feedback** on the usability of the RWD Catalogues*
- *Continuous **engagement with stakeholders** to populate the catalogues*
- *Revised draft of the Good Practice Guide publication (Q2 2024)*
- *Monthly releases of **improvements, bug fixes and enhancements***
- *Catalogues **integrated with EMA website** (Q4 2024)*
- *Work towards **interoperability with other systems***

Thank you!

Further information

Contact us | HMA-EMA Catalogues of real-world data sources and studies

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