

Network data strategy: Data Governance, Data Cataloguing and Metadata Management

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Session 4 of the HMA/EMA Big Data Stakeholder Forum: Unlocking the value of data with the EMRN data strategy

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NDB Group member

Data Governance, Data Cataloguing, and Metadata Management

Data Governance

- Definition and Importance
- Objectives of Data Governance
- Key Components of Effective Data Governance
- Data Governance Principles

Data Cataloguing

- Overview and Purpose
- Objectives for Data Cataloguing

Metadata Management

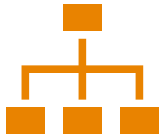
- Definition and Benefits
- Key Aspects of Metadata Management

Integration and Conclusion

- Integrating Data Governance, Cataloguing, and Metadata Management

Data governance

Data Governance - Definition and Importance



Definition of Data Governance

Framework for managing and controlling data across the EMRN



Ensures Data Consistency, Quality, Security and Ethical use

Maintains high standards in regulatory processes



Supports Compliance

Adheres to legal and security standards in data sharing and usage

Objectives of Data Governance as in the draft European Medicines Agencies Network Data Strategy

- Obj. 1 – Operational EMRN Data Governance Framework aligned with EU Interoperability Initiatives, Supporting Data Sharing and Evidence Generation
- Obj. 2 – Data Governance integrated into IT Network Product Delivery across the network

Key Components of Effective Data Governance



Defined Roles and Responsibilities

Essential for data management provide strategic direction, planning, oversight and quality control measures over the management and use of data.



Governance Groups

Network Data Steering Group (NDSG)



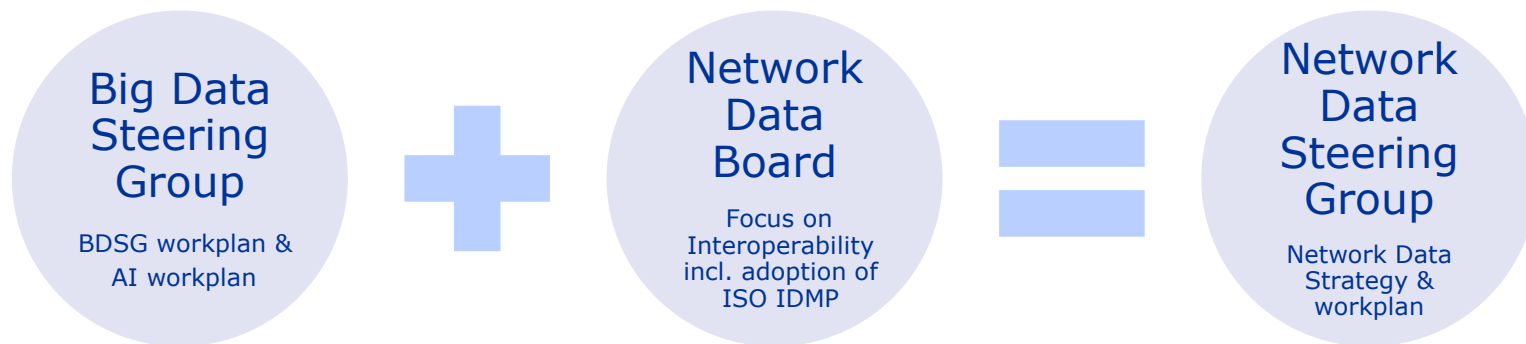
Collaboration with EU and national Bodies

e.g. European Health Data Space Board

One Network Strategy, one Network Data Strategy
work plan → one governance group to oversee the
implementation



Source: ronstik/Shutterstock.com



A unified Network data governance

- **Role:**
 - **Strategic advisory group** established to maximise data interoperability, exchange and use across the EU network, the access to data and generation of evidence, and the beneficial utilisation of AI.
 - Advise Heads of Medicines Agencies and EMA Management Board
 - Work to be guided by structured workplan and to be adopted in early 2025
 - The group will be appointed until end of 2028, in line with EMANS to 2028
- **Scope:**
 - **Regulatory data:** Data submitted to, created by or controlled within regulatory procedures throughout the lifecycle of human and veterinary medicinal products, e.g. master data, regulatory submissions, and procedure data.
 - **Data supporting evidence on medicines:** Data used to generate evidence on the safety, quality or efficacy/effectiveness of medicines ,e.g. clinical trial raw data, real world data such as electronic health records, registry data and claims data, genomics....



Data Governance

Advisory reference point for data related matters; Ensuring proportionate data governance for managing EMAN data assets; Proposing and agreeing EMAN strategies and related implementation plans, recommendations, positions; Contributing to implementation of relevant EU legislative initiatives; Fostering international collaboration, alignment and harmonization; Support Network IT Portfolio; Horizon Scanning

Interoperability

*Enabling effective management and use of high quality data;
Enabling high levels of interoperability and exchange of data through the use of standards, terminologies and master data*

Data analytics

*Maximising evidence generation via access to data/analysis of RWD (DARWIN EU), CT raw data, other type of data (i.e. patient experience data, genomic data...);
Piloting new analytical approaches*

Artificial Intelligence

Overseeing the work to realise the EMAN vision to harness AI capabilities for personal productivity, process automation and systems efficiency, data insights and strengthened decision-support.

Change Management

Network guidance, reflection papers, Big data training, Stakeholders' events (workshops, forum, webinars, masterclass, deep dive...), learnings and integration with business processes

Ethical use of Data

Accountability/Accuracy-authenticity-integrity/Benefit-Risk-Balance/ Confidentiality-
Privacy/Consent/Fairness/Lawfulness/Transparency/Purpose Limitation/Sustainability/AI and trustworthiness

Data are an
asset

Data has
value to the
EMRN and is
managed and
governed
accordingly

Data are
accessible

Data are
accessible
across
business
functions and
processes
inside the
EMRN

Data are
shared

Data are
shared within
the EMRN for
users to
perform their
duties as part
of an effective
and efficient
regulatory
network

Data are
managed

Each data
asset has
clearly
defined data
management
roles
established
such as a
trustee and a
data steward

Common
Vocabulary
and
Definitions

Data is
defined
consistently
throughout
EMRN

Data
are safe
and secure

Data are
protected
from loss,
damage,
unauthorized
access,
corruption,
theft and
unauthorized
disclosure
throughout its
lifecycle

Metadata Management and Data Cataloguing

Metadata Management -Definition and Benefits

- Definition of Metadata Management
 - Management of metadata to describe, structure, and contextualize data: “data about data”
 - Categories of metadata are:
 - Descriptive Metadata: Information like titles, authorship, creation date
 - Structural Metadata: How different parts of a dataset relate to each other
 - Administrative Metadata: Information about access rights, ownership, etc.
- Benefits of Metadata Management
 - Ensures data is easily understood, traceable, and usable across EMRN
 - Contributes to data quality by capturing data lineage and processing history

Key Aspects of Metadata Management



Standardized Metadata Schemas

Use standards when available, applied across EMRN



Data Interoperability and Integration

Facilitates e.g. European Health Data Space and other use



Efficient Regulatory Analysis

Supports decision-making with accessible data

Data Cataloguing- Overview and Purpose

- Purpose of Data Cataloguing
 - **Improve data discoverability and access across the network**
- Enables Regulatory Stakeholders
 - **Locate and understand data assets**
- Helps in Regulatory Decision-Making
 - **Provides context, source, and lineage of data**

Objective for Data Cataloguing as in the draft European Medicines Agencies Network Data Strategy

Objective 7 – Dataset Catalogues are established and provide a clear way to discover EMRN Data Assets



Establish Clear and Accessible
Dataset Catalogues

Ensure datasets are easily discoverable
and usable



Align with EU Metadata
Standards

Enhance interoperability across
different systems



Develop a Structured
Cataloguing Framework

Standardize data documentation
processes

Data Asset – Identification and cataloguing

List of EMRN data assets (non-comprehensive) for potential inclusion in the catalogue:

- **EudraVigilance Human and Vet**
 - 10 potential Data assets identified
- **Substance Product Organisation Referential (SPOR) database**
 - 4 potential Data assets identified
- **Union Product Data Base**
- **Clinical Trials Information System**
 - 5 Potential Data assets identified
- **European Shortage Monitoring Platform**
 - 1 Potential data asset identified

HMA-EMA Real-World Data Catalogues

230
registered RWD sources



81.7%
in the EU
(n = 188)

35

New data sources
added since February
2024 (go-live)



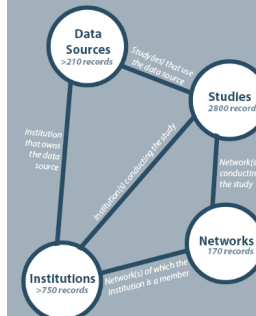
HMA EMA | RWD Catalogues

Facilitating data sources discoverability to support research and regulatory decision making

The HMA-EMA RWD Catalogues serve as repositories of metadata that describe and contextualise real-world data (RWD) sources and studies utilising such data to generate real-world evidence (RWE). They help pharmaceutical companies and researchers identify and utilise RWD in investigating the use, safety, and effectiveness of medicines.



Launched in February 2024



- Facilitate RWE utilisation in regulatory decision making
- Help identify relevant data using 'FAIR' data principles
- Advanced user-friendly platform
- Promote transparency in observational research
- Simplify the integration and analysis of real-world data
- Search and filtering functionalities
- Public access to metadata
- Studies linked to data sources v.v.
- Encourage collaboration
- Streamlined identification of data sources for research questions
- Data interoperability and integration with other catalogues

Explore and populate the RWD Catalogues

- 1 Increase visibility and utilisation of your data source in relevant research
- 2 Based on your research interests, search for relevant data source and studies
- 3 Assess a study report and interpret the study results by understanding the suitability of the utilised data source
- 4 Respond to the EU open call via the RWD Catalogues

National Data Catalogues, connected through a centralized EU infrastructure is ensuring interoperability & secure communication between Member states.

Use of standards (e.g. healthDCAT AP) and quality and utility labels ensure reliability.

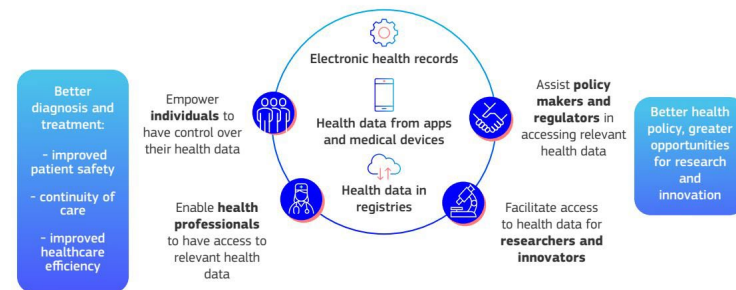


Image Source: [The European Health Data Space \(EHDS\)](#)

Sources: https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en#latest-updates-and-documents

<https://healthdcap.github.io/>

<https://www.lnds.lu/european-health-data-space-an-introduction-to-the-ehds/>

Integrating Data Governance, Metadata Management and Data Cataloguing

- **Seamless Data Management**
 - Integration of data governance, cataloguing, and metadata management
- **Reliable and Accessible Data**
 - Ensures data reliability, accessibility, and usability across the EMRN network
- **Support for EMRN Goals**
 - Facilitates data-driven regulation and public health protection

Thank you for listening

Further information

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is
an agency of the European Union



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