Network data strategy: Data Quality Management & Interoperability

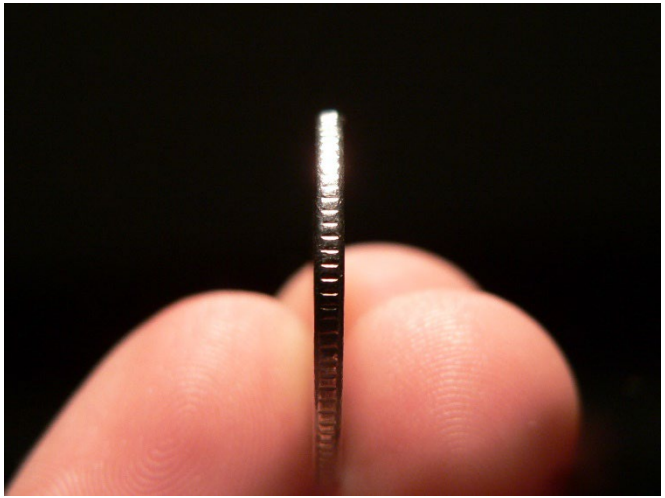
28 November 2024

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

Presented by Isabel Chicharo, Head of Regulatory Data Management, EMA

Why Data Quality & Interoperability is important?

Data Quality ensures that the **information used to make key business decisions** is reliable, accurate, and complete.



Interoperability enables that data can be easily shared and **understood** between systems, teams can work together more **effectively** and helps eliminate redundant procedures, saving time and reducing costs.

Best decisions are accurate and timely!

Data Quality Management

Strategic Objective: Data Quality (DQ) Management

Strategic Objective	Objectives
Data Quality Management Ensuring fitness for purpose in meeting users' needs for business processes, research, policy making.	**Objective 3 – Data Quality Framework, aligned with EU best practice is commonly used across the Network.** Sets out the principles for data quality objectives applicable across all EMRN data assets and systems, while recognizing and aligning the good practices that already exist.
	Objective 4 – Network Data Assets Quality is improved Applying the Data Quality Framework to key data assets.

Goal/Benefits

Ensuring data managed by EMRN is reliable, trustworthy so it can add value and enable automation.

Delivering Data Quality (DQ) Management for the Network

Assessments, gaps, mapping

- Look at what we have …
  - Build on the existing **DQ Framework** and UPD DQ Framework
  - Build on existing EU best practices (e.g. work done in SPOR/PMS and UPD)
- Prioritise/focus on critical data assets (e.g. **Product master data**)

Implementation

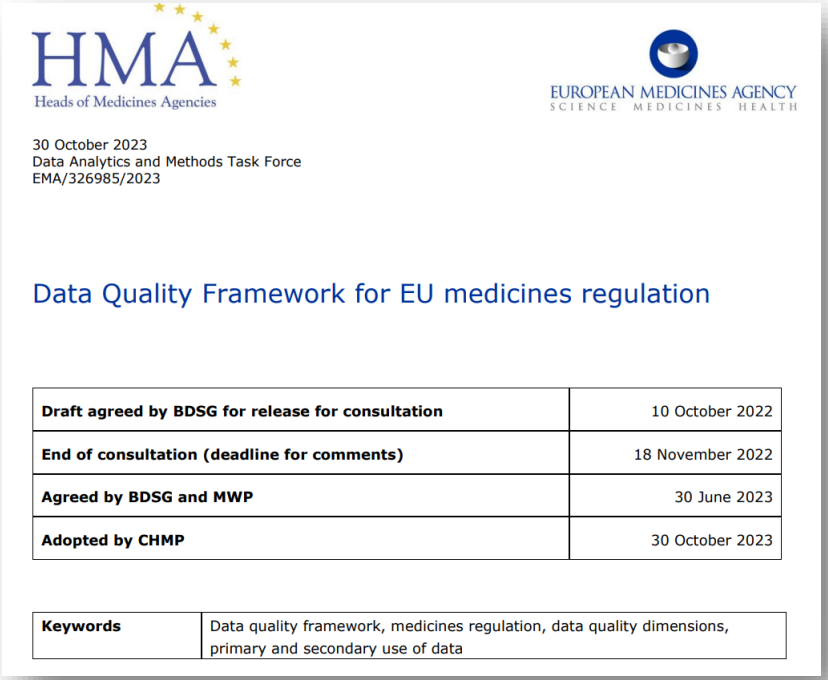
- Update **DQ Framework**
- Develop DQ **maturity assessment**
- Ensure appropriate data governance for data quality is in place
- Increase the data quality in **Product master data** to be useful in other systems for different use cases

Monitoring

- **Clear plans for data reconciliation, synchronisation, and integration with Master Data Systems** (such as SPOR)
- Establish processes for handling **EMA-NCA data discrepancies**

Data Quality Framework for EU medicine regulation

- Drafted under the co-sponsorship of BDSG and MWP – adopted by CHMP
- The document encompasses considerations related to data quality for a wide range of datasets pertaining to medicine regulation
- The Data Quality Framework is intended to lay the groundwork for building specific applications to datasets of interest:
  - Real-World Data
  - Adverse Drug Reaction reporting
  - Consolidating EMA internal procedures surrounding data quality (as part of data governance activities and data strategies)
  - **(…) many more in the future**
    - **OPPORTUNITY to develop data quality rules for key network data assets**



HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 October 2023
Data Analytics and Methods Task Force
EMA/326985/2023

Data Quality Framework for EU medicines regulation

Draft agreed by BDSG for release for consultation	10 October 2022
End of consultation (deadline for comments)	18 November 2022
Agreed by BDSG and MWP	30 June 2023
Adopted by CHMP	30 October 2023

Keywords	Data quality framework, medicines regulation, data quality dimensions, primary and secondary use of data

Interoperability

Strategic Objective: Interoperability

Strategic Objective	Objectives
Interoperability Efficient movement and consolidation of data within and between data stores, applications, and organizations.	**Objective 5 – EMRN is a recognised leader in international standardisation efforts.** Enhancing interoperability through the adoption of international open data standards & best practices.
	Objective 6 – Majority of EMRN IT initiatives include requirements for interoperability to achieve higher levels of maturity. Enhancing interoperability through alignment with the European Interoperability Framework and recognizing Master data management as a cornerstone of data integration and interoperability efforts.

Goal/Benefits

Create a seamless data ecosystem that supports the network's mission in medicines regulation, while also aligning with broader EU interoperability initiatives.

Key enablers for interoperability

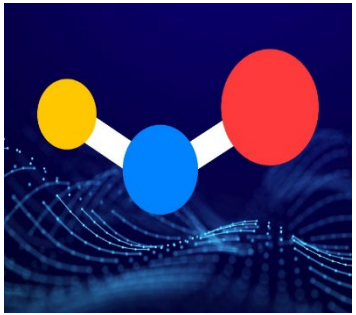
European Interoperability Framework

Provides **principles** and **best practices** to develop cross-border solutions.

Interoperable Europe Act

Provides **transparency to interoperability aspects** (legal, organisational, semantic, technical) in a systematic manner and introduces some **mandatory obligations** to develop cross-border solutions.

International data standards



Ensure data can be **shared, combined, exchanged, and understood** by different users

- ISO IDMP standards and their Technical specifications
- HL7 messaging standards (FHIR, V3 message,...)
- CDISC (BRIDG, SEND, ...)
- ...

Master data

Substance, Product, Organisation. Referentials **(SPOR) master data services** implement the ISO IDMP standards and deliver **processes, technology and data** to the Network.

Interoperable Europe Act in a nutshell

What? Digital public services and their systems

All services requiring interaction across Member States' borders by means of their network and information systems

- SPOR
- Union Product DB
- XEVMPD
- Clinical Trials Information System
- EudraCT
- EudraVigilance H, V
- European Shortage Monitoring Platform
- PSUR Repository
- EudraCommonDirectory
- EudraLink

How? Key obligations

- Appointment of an Interoperability Coordinator
- Mandatory Interoperability Assessments for new and modified cross-border digital public services, covering technical, semantic, organizational, and legal interoperability aspects.
- Public Interoperability Assessment Reports either on the EMA website or on the Interoperable Europe portal.
- Sharing and Reuse of Interoperability Solutions with Union entities and public sector bodies if requested.
- Interoperable Europe Board composed of Member States, with ENISA and the European Cybersecurity Competence Centre (ECCC) as observers.

Interoperable Europe Act in a nutshell

Helps EU and Member State administrations to deliver connected digital services to citizens and businesses across Europe

Who? Union entities and public sector bodies

All entities that provide or manage digital public services

Why? Better public services

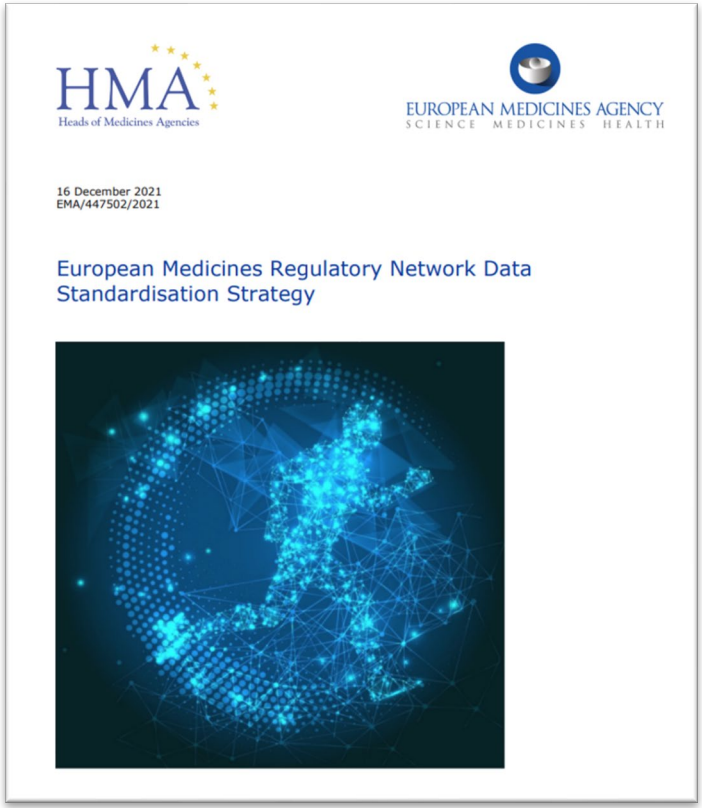
By making people think about interoperability before they take decisions having impact on it

When? Entry into force in April 2024

Application after 3 months, except for **Article 3** and 17 where application is after 9 months

Data Standardisation Strategy

- Drafted under the co-sponsorship of BDSG and EUNDB – adopted by HMA
- The strategy sets out the **principles** used to guide data standardisation efforts and the adoption of data standards by the EMRN.
- The strategy provides **recommendations for the development and adoption of standards** and organizes the recommendations into four domains
  - Medicinal Product
  - Healthcare & study data
  - Safety & risk management
  - Submissions



Master Data

ISO IDMP standards

ISO IDMP standards provide the description and **identification of medicinal products** for **human use.**

SPOR Master data services

Substance, product, Organisation. Referentials **(SPOR) master data services** implement the ISO IDMP standards and deliver **processes, technology and data** to the Network

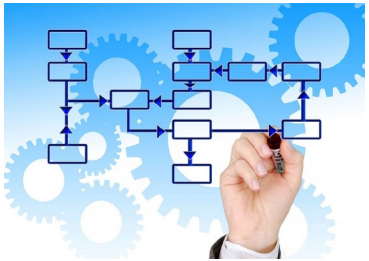
SPOR applies to **Human & Veterinary domains**

OMS and RMS were delivered in **2017**. RMS implemented ISO 11129 and 11240 standards.

SMS phase 1 was delivered in **2019** and European Substance Reference System (**EU-SRS**), ISO 11238 compliant, was delivered in **2022**. Substance cleansing is ongoing.

PMS data migration/transformation into ISO 11615 compatible format completed in April **2024**, PMS User Interface (UI) and Application Programming Interface (API) rolled out throughout 2024.

Integration into regulatory processes



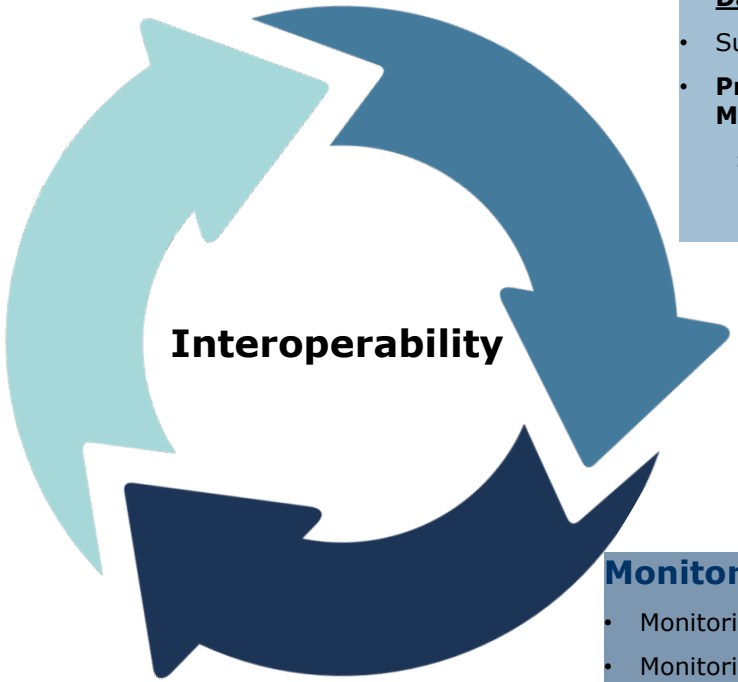
Most EU regulatory processes are already using **data from SMS, OMS, RMS.**

In 2024 **PMS product data** is/will be used for electronic application forms (**eAF**), electronic Product Information (**ePI**), CAP regulatory procedure management (**RPM**), shortages (**ESMP**) and antimicrobials sales and use (**ASU**)

Delivering Interoperability for the Network

Assessments, gaps, mapping

- Look at what we have …
  - EU contributions to SDO work -> **European Medicines Regulatory Network Data Standardisation Strategy**!…
- Prioritise/focus on
  - **EU interoperability framework and Interoperable Europe Act obligations**
  - **NCAs/EMA readiness for IDMP/ medicinal products data implementation**



Implementation

- Update **European Medicines Regulatory Network Data Standardisation Strategy**
- Support/lead relevant SDO activities
- **Progress with Implementation of IDMP/ Medicinal Products in EU**
  - **Roadmap** for implementation and a **Target Operating Model** to **harmonise and use** medicinal product/SPOR data in Europe .

Monitoring

- Monitoring SDO work
- Monitoring on **Implementation of IDMP/ Medicinal Products in EU**
- Compliance with **Interoperable Europe Act** and **EU interoperability framework**

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