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The European Medicines Agencies Network Data Strategy

Increasing the value of data for the benefit of public and animal health

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

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1. Introduction

This strategy sets out the agreed European medicines regulatory network (EMRN) vision, principles to be followed and goals to be met to maximize the value of the data managed by the EMRN. Getting the full value from data requires the data to be of good quality, well documented, and accessible for consumers of the data. This strategy is to guide the network and to inform stakeholders of the activities that the network will be undertaking to realise its vision for data.

The strategy is set in the overall context of general EU requirements for data protection (EUDPR, GDPR), data sharing and interoperability (EU Data Act, EU Interoperability Act) as well as domain specific initiatives like the European Health Data Space (EHDS) and it is closely linked to business strategies such as the overarching European medicines agencies network strategy to 2028.

The rapid evolution of digital technologies, coupled with the growing volume and complexity of data in medicines regulation, presents both opportunities and challenges for the EMRN. To seize these opportunities and address these challenges effectively, a coordinated approach to data management and utilisation across the network is essential.

This EMRN data strategy establishes a comprehensive framework to maximize the value of regulatory data while ensuring its quality, security, and ethical use. The strategy aligns with and supports the broader objectives outlined in the European medicines agencies network strategy to 2028, particularly in advancing data-driven decision-making and strengthening the network's digital capabilities.

Success in implementing this strategy relies on effective collaboration with a diverse ecosystem of stakeholders who both contribute to and benefit from EMRN data, including healthcare professionals, patients and their organisations, the pharmaceutical industry, academia, health technology assessment bodies, and policymakers. Through this collaborative approach, the strategy aims to enhance the network's ability to protect public health while fostering innovation in medicines development and regulation.

Data are received, collected, created, updated, and enriched every day by organisations in the European medicines regulatory network to serve as the basis for their decision making and as a necessary step in fulfilling their legally mandated tasks and other obligations.

Data should be shared within the network to improve the quality and efficiency of network procedures. Data should be shared with the health care sector, the life science industry, academia, and policy makers to allow them to improve the quality and efficiency of their processes.

New technologies, standardisation initiatives like International Organisation for Standardisation (ISO) for the identification of medicinal products (IDMP) and controlled terminologies offer new ways of getting value from data, either for well-known purposes or for entirely new ones. These developments make it important to look beyond the immediate purpose for which data are processed to ensure that they are as suitable as possible for future uses.

1.1. The need for the network level data strategy

The EMRN strives to maintain an effective and efficient regulatory system that protects public health in the EU by coordinating the efforts of national regulatory authorities and the European Medicines Agency (EMA). Effective data management is essential for the EMRN to fulfil this mission. However, the network faces several challenges in optimising its use of data, which impacts regulatory decision-making and overall efficiency.

The EMRN's data landscape is characterized by different operational approaches, data fragmentation, inconsistent quality levels, and underutilisation of advanced analytics. Regulators put a lot of effort to

gain a comprehensive view of product lifecycles and regulatory activities across the network due to data silos and interoperability issues between EMRN systems. The EMRN's ability to efficiently exchange data, make data-driven decisions, identify data related trends, and optimize resource allocation have been highlighted as key areas to be developed.

A significant challenge is the varying levels of organisational maturity, skills, and technical readiness across the network. These differences, coupled with financial limitations, affect the speed at which data management improvements can be implemented and adopted uniformly. This disparity creates obstacles in achieving consistent data practices and leveraging advanced technologies across all member organisations.

Data sharing can be complicated by privacy concerns and the need to adhere to legislation. In addition, data analysis is a rapidly evolving area that can be a challenge for organisations to have in place the skills to make use of the latest advances. These factors present both opportunities and challenges for the EMRN in terms of data governance, standardisation, and ethical use in regulatory processes.

Key challenges:

- Varying levels of organisational maturity, skills, and technical readiness across the network.
- Financial limitations affecting the speed of improvement implementation.
- Lack of interoperability.
- Slow adoption of new data standards such as ISO IDMP.
- Inconsistent data quality levels and standardisation of legacy regulatory data.
- Privacy and security concerns in cross-border data sharing.
- Adaptation to evolving EU data regulations and initiatives.

Addressing these challenges is crucial for the EMRN to maximize the value of its data assets and increase the use of advanced analytics and Artificial Intelligence (AI) in regulatory assessments. By enhancing data integration, interoperability, quality, and accessibility, while considering the diverse capabilities of its members, the network can improve processes, accelerate scientific assessments, and strengthen its ability to protect public health across the EU. This strategy aims to provide objectives for overcoming these obstacles and transforming the EMRN into a data-driven regulatory ecosystem that promotes innovation, efficiency, and better coordinated decision-making among national authorities and the EMA.

This strategy provides the foundation for achieving EMRN’s vision for data by outlining the principles underpinning the data strategy and setting out the strategic goals which enable the fulfilment of its strategic vision. The strategy also discusses the high-level implications of the principles and sets out the required steps to achieve the strategic goals.

A detailed operationalisation of the required steps, specifying roles and responsibilities of all involved stakeholders and envisaged timelines, is beyond the scope of this strategy – this will be provided in a separate implementation plan.

1.2. Scope of the strategy

The EU Data Act defines ‘data’ in the following way: ‘data’ means any digital representation of acts, facts or information and any compilation of such acts, facts, or information, including in the form of sound, visual or audio-visual recording.

As defined in the Joint HMA-EMA Network Data Steering Group mandate, the European medicines regulatory network handles a wide spectrum of data that is received, processed, generated, managed

and analysed to ensure that decisions on medicines are well-informed and evidence based. Such data include:

- **Regulatory submissions data** – sent by marketing authorisation holders or applicants to demonstrate the safety, efficacy, and quality of a medicine.
- **Substance, product, organisation and referential (SPOR) master data** - essential for the network's cross operations including the monitoring of medicines' safety and shortages.
- **Real-world data** such as electronic health records, patient registry data or datasets from spontaneously reported suspected adverse drug reactions to complement the evidence from clinical trials and fill knowledge gaps regarding a medicine.

Data from the regulatory business are made available to the health care sector where they can use it as master data e.g. Product Management System (PMS). Data from the health care sector can be used to generate evidence and support regulatory business, academia, and policy makers. The secondary use of health care data is further enhanced if the regulatory master data has been used.

Regarding processes, the EMRN can oblige itself to follow the principles described in this strategy. This strategy is intended for the members of the EMRN and will help clarify the roles and responsibilities of the members that manage network data assets on behalf of the EMRN. For data created by external stakeholders, the EMRN will set general requirements, validate the quality and the format of the data, and the accompanying documentation. Existing requirements for the processes applied by external stakeholders to create and manage the data the EMRN receives are not affected by this strategy.

2. EMRN's Data Vision

A vision for data will drive the EMRNs mission to foster scientific excellence in the evaluation and supervision of medicines and medical devices, for the benefit of public and animal health and the environment in the European Union.

EMRN's Data Vision
Trusted medicines by unlocking the value of data

This strategy will bring the following **benefits**:

- Maintains the EMRN as an international leader in the use of data for public health decision making.
- Build trust from stakeholders by making trusted data accessible for review and analysis.
- Share and use data for innovation and improved access to and availability of medicines and veterinary medicinal products.
- Improve the management of data to enable better quality, safety, and efficacy of medicinal products throughout their life cycle.
- Make data available for analysis allowing improved efficiencies in processes and the quality of outcomes.
- Enable continued digitalisation and improvement of data quality.
- Increase scientific, regulatory, and corporate knowledge by leveraging past regulatory decisions and experience (scientific memory) to inform future decision making.

3. Data Principles and Ethical use

Data held within the EMRN should be understood and valued in the same way as for other assets such as people, financial resources, and technology. It is important to note that the full value of data lies not just in its original purpose, but also in its potential to be reused for other purposes. Data are expected to be FAIR (findable, accessible, interoperable, and reusable)[1] and machine-readable as humans increasingly rely on computational support to deal with data because of the increase in its volume, complexity, and creation speed. Access to data also needs to be managed to protect the personal and commercially sensitive data. The data principles described bellow underpin the EMRN's data strategy and are all closely linked together. It will be an education task to ensure that relationships between these principles are understood by the EMRN.

3.1. Principle 1 – Data are assets

Statement:

Data are an asset that has value to the EMRN and is managed and governed accordingly.

Rationale:

Information represents a valuable EMRN resource, with actual and measurable value. Data are the basis of the decision-making process. Therefore, it should be carefully managed and governed to ensure constant awareness of its location, reliability of its accuracy, and access whenever and wherever necessary.

Implications:

- Govern data as an asset requires resourcing; otherwise, data will degenerate.
- Data need to be governed with defined roles and responsibilities throughout the EMRN.
- Policies, processes, procedures, and tools need to be put in place in the EMRN to support data management, monitor and to ensure applicable data quality.
- Data needs to be managed throughout its life cycle, from identification of need, collection, creation, quality assurance, maintenance, use, reuse and to archiving or destruction once the data has ceased to be useful or because of legal requirements.

3.2. Principle 2 – Data are accessible

Statement:

Data are accessible across business functions and processes inside the EMRN to improve the quality and efficiency of network procedures and to external stakeholders to allow them to improve the quality and efficiency of their processes.

Rationale:

Wide access to data leads to efficiency and effectiveness in decision-making and affords timely response to information requests and service delivery. Staff time is saved, and consistency of data is improved.

[1] FAIR Principles - GO FAIR (go-fair.org)

Implications:

- Access to data should be performed through appropriately defined interfaces to ensure the proper understanding and use of the data.
- Access to data does not constitute understanding of the data. Therefore, data should be consistently defined, and the definitions agreed upon across the EMRN, shared and made available to all users to prevent misinterpretation of data.
- Data should be protected from unauthorised use and disclosure of personal and commercially sensitive data. Processes, procedures, and automated methods should be used to ensure the security of data.

3.3. Principle 3 – Data are shared

Statement:

Data are shared within the EMRN for users to perform their duties as part of an effective and efficient regulatory network. Data are also shared outside the network e.g. health sector and academia, for the benefit of public and animal health.

Rationale:

Shared access to accurate and timely managed data, improve the quality and efficiency of decision-making.

Implications:

- To enable data sharing we should develop and abide by a common set of policies, procedures, and standards governing data management and access.
- Clear roles and responsibilities that are needed to support management of EMRN data governance needs to be identified and put into play.
- Data should be interoperable at all levels to enforce sharing. EMRN data has to be interoperable in accordance with the EU Interoperable Framework (EIF)[2] for usage of EMRN qualified data in national, European and international data initiatives, e.g. EHDS.
- Data should be standardised across various levels to enforce interoperability and consistency. EMRN uses widely accepted standards (e.g., published by ICH, ISO, HL7, VICH) and common vocabularies (e.g., MedDRA, EDQM, VEDDRA) whenever available, legally appropriate, affordable, and relevant to EMRN's mission.
- Data sharing should comply with information security / data access policy requirements. Under no circumstances should the data sharing principle cause confidential data to be compromised.
- Shared data should be of sufficient, pre-defined and agreed quality.
- Common methods and tools for creating, maintaining, and accessing the data shared across the EMRN should be developed and adopted throughout the network.
- To be able to exploit the new ways of getting value from data that new technologies offer, either for well-known purposes or for entirely new ones, it is important to look beyond the immediate purpose for which data are processed in order to ensure that they are as suitable as possible for future uses.
- Data sharing requires a significant cultural change to move away from traditional data silo approaches.

[2] EIF is a set of the principles and recommendations to deliver cross-border data services. The legal interoperability defines rights and obligations to manage data; organisational interoperability focuses on business processes to manage data; the semantic interoperability ensures that all parties have shared understanding of data; the technical interoperability defines interfaces to access and modify data.

3.4. Principle 4 – Data are managed

Statement:

Each data asset has clearly defined data management roles established such as a trustee[3] and a data steward[4]. The appointed people manage the data on behalf of the EMRN in line with EMRN data governance practices.

Rationale:

As the degree of data sharing grows and business rely upon common data, it becomes essential that data are managed effectively. Since data will increasingly be shared between organisations the reliance on that data will increase, the data trustee will have responsibility for maintaining data quality and integrity.

Implications:

- Real trusteeship avoids data "ownership" issues and allows the data to be available to meet all users' needs. This may require a change of a perception of data "ownership" to data "trusteeship".
- The data trustee will be responsible for meeting quality requirements levied upon the data for which the trustee is accountable.
- It is essential that the trustee can provide user confidence in the data.
- Effective data governance requires data source identification which enables the assignment of responsibility to trustees.
- Information should be captured electronically once and immediately validated as close to the source as possible. Quality control measures should be implemented to ensure the integrity of the data.
- As a result of sharing data, the trustee is accountable and responsible for the accuracy and currency of their designated data asset(s) and, subsequently, should then recognize the importance of this trusteeship responsibility.

3.5. Principle 5 – Data are described using common vocabularies and definitions

Statement:

Data is defined consistently throughout EMRN, and the definitions are understandable and available, inside and outside the network.

Rationale:

The data that will be used inside and outside EMRN should have a common definition throughout the network to enable semantic interoperability. A common vocabulary (business glossary) will facilitate communications and enable dialogue to be effective. In addition, semantic interoperability is required to enable the interfacing of systems and data exchange. It is a prerequisite for use of data in different contexts.

[3] A data trustee is different to a data steward - a data trustee is responsible for accuracy and currency of the data, while responsibilities of a steward may be broader and include data standardisation and definition tasks. A data trustee may delegate actives and responsibilities for the data steward to conduct on their behalf.

[4] A data steward is responsible for the management of a data asset ensuring data quality, integrity, accuracy, and consistency. They are subject matter experts of their data and follow data management requirements set by the data trustee and data governance.

Implications:

- Significant additional resources should be committed to achieve this task. It is key to the success of efforts to improve the data environment to facilitate data sharing and data-driven decision-making.
- To facilitate interoperability the network needs to establish agreed common vocabularies.
- Data management for common vocabularies should follow consistent processes across their lifecycle (from identification of need, collection, creation, quality assurance, maintenance, use, reuse and to archiving or destruction) and should be consistently used across business processes and domains.
- Common vocabularies are shared and used inside and outside the network to facilitate interoperability.
- Multiple data standardisation initiatives need to be co-ordinated.
- Administration responsibilities for common vocabulary and definitions should be assigned.

3.6. Principle 6 – Data are safe and secure

Statement:

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

Rationale:

As data are an asset (see principle 1) the actions performed on this asset, such as receiving, storing, modifying, and accessing should comply with information security policies following recognised standards and legislation, such as ISO 2700x, EU Cybersecurity Act[5] and in force across the network. This shall ensure the protection and the security of the data.

Implications:

- The data need to be catalogized and a clear *trusteeship* needs to be defined.
- The data need to be classified according to sensitivity (e.g. ISO 27001:2013 lists the following categories: confidential, restricted, internal, and public).
- The lifecycle of the data according to the classification shall be defined.
- The appropriate controls should be determined and applied according to the classification of the data.
- Those essential controls are access controls, encryption, data loss prevention, data backup and recovery, network security controls and endpoint protection, but can be extended where necessary.
- Appropriate training of the personal managing and working with data shall be ensured.
- Regular data security risk assessments and security audits need to be conducted.

3.7. Ethical use of data

While ethical principles are already implemented in the human and veterinary medicine domains, the increasing quality, quantity and availability of data, the implementation of new technologies and analytical tools and the development towards a data-driven regulatory network require that data ethics and ethical data management need to be deeply embedded in any framework.

Overall, the development, implementation, and application of the EMRN data strategy should be guided by the principle that the health and safety of all individuals have the highest priority. Where insights derived from data have the potential to impact on the integrity of the individual, the prevention of

[5] EU Cybersecurity Act is a regulation (EU) 2019/881

harm towards individuals or the community should be the paramount consideration for any governance policy.

The following pillars are meant to guarantee an ethical data framework:

- **Accountability** – consideration should be given to the legal responsibility including the obligation to report, justify, and be answerable for resulting consequences, with an additional focus on generative AI systems.
- **Accuracy and integrity –** measures should be in place to ensure that data accuracy and authenticity is maintained and any tampering with data is averted.
- **AI and trustworthiness** - Inform users about AI intervention, control biases, and provide explainability for AI results to the greatest extent possible. Build and maintain trust through ethical data practices, ensuring reliability, integrity, and transparency in all data management activities.
- **Benefit-Risk Balance** – balance societal benefits and individual rights, ensuring that data use brings tangible benefits to individuals and the community while minimising risks.
- **Confidentiality and Privacy** – Uphold the right to privacy and ensure that data subjects' information is protected from unauthorized access and misuse. Wherever possible, data should be anonymised.
- **Consent** – in principle, an individual has control over their personal information. Whenever feasible, the collection and processing of data from individuals should be based on an informed consent. If other legal bases than consent are used (such as public interest) at least the information of individuals should be maintained.
- **Fairness** – Ensure that data practices are free from discrimination and bias, promoting equality, equity and fairness in all data-related activities.
- **Lawfulness** – Adhere to all relevant legal and regulatory frameworks, setting legislative requirements as the baseline for ethical data management and striving for higher ethical standards.
- **Purpose limitation** – the risks associated with the collection of data without a defined purpose, like data breaches and privacy violations should be carefully weighed against possible benefits. The risk that data become unfit for a later purpose should also be explicitly considered.
- **Sustainability** - Commit to eco-responsible data practices, including minimizing the environmental impact of data processing and storing and promoting the re-use and recycling of data infrastructure.
- **Transparency** – it should be made clear how data are collected, generated, used, and shared e.g., foundation models should be made available and evaluation criteria should be transparent and easy to find.

A continuous re-evaluation of systems and governance is essential to keep pace with rapid digitalisation and transformation. This ensures that relevant ethics principles remain at the forefront of practices and are consistently adhered to at the highest standards.

4. Strategic Goals

This data strategy provides the foundation for achieving EMRN's vision for data using a framework[6] for data management as its basis using the principles as guidance. The framework defines the relationships between data and the business and technical context in which EMRN operates, the outcomes EMRN aims to achieve from successful implementation of this strategy and the capabilities and culture that EMRN needs to develop to realise these outcomes.

The EMRN has identified key areas and related activities that needed to be completed to fulfil the strategic vision, as well as realising the benefits, these goals are described in the sections below.

4.1. Data Governance

Network data governance provides strategic direction, planning, oversight, and quality control measures over the management and use of data. It enables standardisation and harmonisation in a data-driven network in ensuring practices exist for the network to meet its business objectives and specific legal and security requirements concerning shared data including special categories of data, such as personal data, and to align with broader European interoperability initiatives.

The data governance organisation agrees common policies, key processes, and standards and ensures appropriate training and communication on data-related matters. It also defines common roles and responsibilities that are needed to perform and support data management and business intelligence across the network. This also includes influencing IT developments to be in line with the agreed objectives.

The Network Data Steering Group (NDSG) leads on the development of data governance at network level. This group is responsible for the discussions and collaboration required to develop European and international data strategies and standards and EU policy initiatives relevant to the medicines regulatory domain and consults with other organisations and groups at national, EU and international level in relation to data e.g. HMA Regulatory Optimisation Group (ROG)[7] and Network Portfolio governance[8].

In line with the Interoperable Europe Act[9], the EMRN aims to work with designated digital health authorities and participate in relevant European governance structures, such as the European Health Data Space Board. This collaboration ensures that EMRN data governance aligns with broader EU interoperability goals while meeting the specific needs of medicines regulation.

Goals	How this will be achieved
1. Operate data governance that enables reliable and consistent data management and practical use of data.	• IT Network Portfolio delivery integrates data governance. • Strengthen EMRN data governance.
2. Support stakeholders, within and outside EMRN, with the levels of access to data appropriate to their role and needs, to support the use of data.	• Support data trustees in publishing access rules and requirements for EMRN data assets.

[6] https://www.dama.org/cpages/body-of-knowledge
[7] Heads of Medicines Agencies: Regulatory Optimisation Group (ROG)
[8] Network Portfolio | European Medicines Agency (EMA)
[9] Regulation (EU) 2024/903 Interoperable Europe Act

4.2. Data Quality Management

Data quality is defined as the fitness for purpose of data in meeting users' needs for business processes, research and policy making.

Data quality should be a fundamental consideration from the start of data collection and generation processes. Proactive quality management, supported by robust master data and reference data systems, is crucial for ensuring data reliability, trustworthiness and enabling automation.

The EMRN data strategy should be guided by the principles outlined in the Data Quality Framework (DQF) for EU medicine regulation[10] and aligned with relevant EU data quality initiatives. These principles should form the foundation for data quality objectives applicable across all EMRN data assets and systems.

Data quality management should be an integral part of all data system proposals and improvements. This includes clear plans for data reconciliation, synchronisation, and integration with master data systems (such as SPOR) and related data ecosystems. Responsibility for data quality should be shared among business data owners, users, and technical teams, fostering a culture of quality across the organisation.

To characterise data quality for specific data entities, measures and metrics will be developed for different quality dimensions such as reliability, extensiveness (completeness and coverage), coherence, timeliness, and relevance.

Goals	How this will be achieved
1. Improve the quality of network data assets to ensure reliability for their intended purpose.	• Define data management roles and responsibilities for data stewardship. • Publish data quality measures, identified critical data elements, and validation requirements for data assets.
2. Enable data quality monitoring across the EMRN's data assets.	• Conduct data quality maturity assessments for critical datasets.
3. Support harmonised implementation of master data within the network.	• Support a community of good practice on use of master data. • Leverage experience from current operational use. • Support use of regulatory data in EHDS.
4. Advance international collaboration on data quality.	• Monitor for opportunities for international regulatory alignment on data quality. • Contribute to harmonized data quality methodologies to improve global regulatory acceptance. • Align with EU-funded initiatives on data quality enhancement.

[10] Data Quality Framework for EU medicines regulation

4.3. Interoperability

There is an inherent need to support partners in the EMRN to be creators, contributors, and users of datasets at the same time. This results in the need for interoperability measures to ensure an efficient flow of trustworthy data.

Interoperability encompasses the processes for efficient movement and consolidation of data within and between data stores, applications, and organisations.

The EMRN is committed to enhancing interoperability through the adoption of international open data standards, best practices, and alignment with the European Interoperability Framework[11]. This approach addresses semantic, organisational, and technical interoperability, ensuring that data can be effectively shared and understood across systems and processes.

Master data management is recognized as a cornerstone of data integration and interoperability efforts. By enabling the linkage of multiple data sources, master data enhances the value of information through improved business intelligence and analytics. Its effective use across internal and external-facing systems increases efficiency, reduces duplication, and enables more effective reporting and monitoring of business data and processes.

The focus for the strategy is on semantic interoperability to create a seamless data ecosystem that supports the network's mission in medicines regulation, while also aligning with broader EU interoperability initiatives.

Goals	How this will be achieved
1. Strengthen EMRN's coordination to data standardisation.	• Coordinate EMRN contributions to standardisation efforts (e.g. ICH, ISO and HL7). • Define systematic engagement processes for EMRN members within standards development organisations.
2. Enable trusted data exchange across EMRN and other stakeholders.	• Revise and update EMRN's data standardisation strategy. • Support implementation of the European Interoperability Framework for regulatory data flows.
3. Embed interoperability as a core design principle in EMRN IT and data projects.	• Identify best-practices for interoperability impact assessments in IT and data projects. • Promote API-first architecture. • Drive the adoption of FHIR-based structured data exchange.

[11] The European Interoperability Framework (EIF)

4. Align EMRN regulatory data strategies with broader EU health data initiatives.	• Support the implementation of EHDS. • Strengthen partnerships with EU-funded initiatives to enhance regulatory data exchange.

4.4. Data Cataloguing and Metadata Management

Data cataloguing and metadata management are critical components of the EMRN's data strategy, enabling efficient discovery, access, and utilisation of data assets across the network. Effective metadata management provides essential information about data purpose, generation, sources, processing steps, and lineage, enhancing the value and usability of EMRN's data resources.

A robust data cataloguing approach is fundamental to maximizing the potential of EMRN's data assets. It ensures that data can be easily located, understood, and appropriately used in regulatory decision-making processes. By implementing standardised metadata schemas and processes, the EMRN can significantly improve data discoverability, interoperability, and overall data governance.

The EMRN is committed to developing a comprehensive approach to data cataloguing and metadata management that aligns with broader EU initiatives, such as the European Health Data Space[12], while meeting the specific needs of the European medicines regulatory network.

Goals	How this will be achieved
1. Establish a comprehensive data catalogue for EMRN.	• Develop a centralised EMRN data assets catalogue with clear metadata schemas. • Align dataset cataloguing with EU-wide initiatives (e.g., EHDS) to enhance cross-border regulatory data discoverability. • Define metadata management and standardization for interoperability where appropriate (e.g., Health DCAT-AP, ISO 11179).
2. Enable efficient discovery and reuse of Real-world data.	• Maintain EMRN HMA catalogue of Real-World data.

4.5. Knowledge and Change Management

Knowledge, skills, and adaptability are essential to the successful implementation of the EMRN data strategy. This encompasses, targeted capability and capacity building, proactive alignment with evolving EU and international data initiatives and comprehensive change management.

The EMRN is committed to promote a data-driven culture across its network, ensuring that all stakeholders are equipped with the necessary skills and knowledge to leverage data assets effectively and unlock the value of the data through analytics, including interpretation of evidence. This includes

[12] European Health Data Space Regulation (EHDS) - European Commission

developing tailored training programs, providing ongoing guidance, and facilitating knowledge sharing among network members.

Furthermore, the EMRN recognizes the importance of staying ahead of legislative and regulatory changes in the data landscape. By actively monitoring and preparing for new EU and international initiatives, the EMRN will maintain its position as a leader in data-driven medicines regulation.

Goals	How this will be achieved
1. Network data strategy capacity building programs are available for EMRN.	• Perform a survey to identify knowledge training needs across the network. • Create targeted training on priority topics for managing and utilising data.

4.6. Value of data through analysis and use of tools

Advanced analytics, warehousing and business intelligence solutions should provide the EMRN with a consistent, trustworthy, applicable, and reliable set of capabilities to support the needs of the EMRN and where appropriate external stakeholders.

Business and technical decisions related to business intelligence and data analytics should be based on the principles outlined in the present data strategy, including:

- A set of data analytics tools are available, such that data can be viewed and analysed using the tool which best fits the needs.
- All stakeholders are empowered to independently consume data assets according to their access rights.
- Data access and movement are controlled and traceable.

Business intelligence and data analytics solutions enable data-driven decision-making by:

- Integrating data silos into an interconnected and interoperable data network.
- Providing fit for purpose self-service data analytics and data visualisation capabilities.
- Allowing extract of insights from structured and unstructured data.
- Leveraging advanced analytics (including AI) to deliver benefits to business process and public health.

Goals	How this will be achieved
1. Enable modern data analytics, self-service analytics including dashboards and visualisations, as well as advanced analytics, using AI and predictive modelling.	• Agree and implement a network data analytics strategy.
2. Realise value from information and data available in unstructured sources.	• Identify opportunities for extracting information from unstructured sources, such as dossiers and documents, using tools such as AI.

List of abbreviations

AI	Artificial Intelligence
EDQM	European Directorate for the Quality of Medicines & HealthCare
EHDS	European Health Data Space
EMA	European Medicines Agency
EMRN	European medicines regulatory network
EUDPR	European Union Data Protection Regulation
FAIR	Findable, Accessible, Interoperable, and Reusable
GDPR	General Data Protection Regulation
HMA	Heads of Medicines Agency
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IDMP	Identification of Medicinal Products
ISO	International Organization for Standardization
MedDRA	Medical Dictionary for Regulatory Activities
SPOR	Substance, Product, Organisation and Referential master data
VEDDRA	Veterinary Dictionary for Drug Regulatory Activities
VICH	The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products