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The European Medicines Agencies Network Data Strategy (draft)

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

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1. Introduction

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 European medicines regulatory network (EMRN). To seize these opportunities and address these challenges effectively, a coordinated approach to data management and utilization 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 draft 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 organizations, 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 (EMRN) in order 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 ISO 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.

Getting the full value from the data requires the data to be of good quality, well documented, and accessible for possible consumers of the data. This strategy sets out the agreed EMRN vision, principles to be followed and objectives to be met to maximize the value of the data managed by the EMRN.

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 EHDS and it is closely linked to business strategies such as the overarching European medicines agencies network strategy to 2025 that will be updated to 2028.

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 optimizing 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 underutilization 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 important areas to be developed.

A significant challenge is the varying levels of organizational 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 organizations.

Data sharing and analysis are further complicated by privacy concerns and the rapidly evolving landscape of artificial intelligence and big data analytics. These factors present both opportunities and challenges for the EMRN in terms of data governance, standardization, and ethical use in regulatory processes.

Key Challenges:

- Varying levels of organizational 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 like ISO IDMP
- Inconsistent data quality levels and standardization of legacy regulatory data
- Limited use of advanced analytics and AI in regulatory assessments
- 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. 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.

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, data in scope of this strategy concerns:

- **Regulatory data:** Data submitted to, created by or controlled within regulatory procedures throughout the lifecycle of human and veterinary medicinal products. This includes master data essential for the network's interoperable operations and product shortage and safety monitoring, regulatory submissions, and procedure data
- **Data supporting evidence on medicines:** Data used to generate evidence on the use, safety, quality or efficacy/effectiveness of medicines. This includes clinical trial raw data, pooled clinical

trials data, real world data such as electronic health records, registry data and claims data, datasets from spontaneously reported suspected adverse drug reaction, and genomics, proteomics and metabolomics datasets. This may also include non-clinical data, chemistry, manufacturing and controls (CMC) data, and supply data.

This strategy applies to data that fulfil at least one of the following criteria:

1. Data that are received, collected, created, enriched and distributed by organisations in the EMRN
2. Data that are handled in order to carry out the legally mandated tasks of the EMRN
3. Data that are shared within the network or with external stakeholders

Data from the regulatory business are made available to the health care sector where they can use it as master data by the health care sector. 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 utilised.

Regarding processes, the EMRN can oblige itself to follow the principles described in this strategy. 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 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
Increasing the value of data for the benefit of public and animal health

While the vision of this data strategy focusses on shared data that drives the core public and animal health work of the EMRN, the principles can be optionally applied to organisational or national data that is not shared externally by that organisation.

The following **goals** are key to materialising EMRN's data vision for 2028:

- Data about medicinal products is harmonised by all members of the EMRN according to the ISO IDMP standards
- SPOR databases are established as the data hub in the EMRN supporting all regulatory processes
- The EMRN has implemented Artificial Intelligence for maximising evidence generation, increasing productivity, data insights and strengthened decision-support.
- Ensure that data are fit for purpose: of good quality, representative, protected, safe and secure.
- Enable **reliable and consistent data management, data governance** and **practical use** of data.

- Ensure **findability and reusability** of data, minimising the need for data replication via uninterrupted accessibility.
- Maintain traceability and audit of data input, modification, and integration/transfer.
- Provide stakeholders, in and outside EMRN, with the levels of **access** to data appropriate to their role and needs, to support the use of data e.g. in product lifecycle management.
- Contribute to the creation and use of international **data standards** for existing and new business processes in the EMRN to facilitate data **interoperability**.
- Enable state of the art **data analytics**, **self-service analytics** [1] including **dashboards** and **visualisations**, as well as **advanced analytics,** using **artificial intelligence (AI)** [2] and **predictive modelling**.
- Contribute to European and international initiatives such as the European Health Data Space,

The strategy delivers 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.
- Manage the 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 incl. leveraging past regulatory decisions and experience (scientific memory) to inform future decision making.

3. Data Principles

Data held within the EMRN should be understood and valued as much as 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) 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. The following data principles underpin the EMRN's data strategy.

3.1. Principle 1 – Data are an asset

Statement:

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

Rationale:

Information represents a valuable corporate resource, with actual and measurable value. Data are the basis of the decision-making process. Therefore, it must be carefully managed and

[1] Self-service analytics describes the use of technology and data by business users and stake holders to perform analysis without requiring substantial support.
[2] As defined in the Artificial Intelligence Act (Regulation (EU) 2024/1689)

governed to ensure constant awareness of its location, reliability of its accuracy, and access whenever and wherever necessary.

Implications:

- This is one of three closely related principles regarding data: data are an asset; data are shared; and data are easily accessible. The implication is that there is an education task to ensure that all organizations within the EMRN understand the relationship between value of data, sharing of data, and accessibility to data.
- Managing and govern data as an asset requires resourcing; otherwise, data will degenerate.
- EMRN needs to have the means to ensure:
    - data are clearly defined.
    - data can be properly accessed.
    - data are appropriately controlled.
- Data need to be governed with defined roles and responsibilities throughout the EMRN.
- Policies, processes, procedures and tools have to be put in place in the EMRN to support data management, monitor and ensure 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 in order to improve the quality and efficiency of network procedures and to external stakeholders in order 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.

Implications:

- This is one of three closely related principles regarding data: data is an asset; data are shared; and data are easily accessible. The implication is that there is an education task to ensure that all organizations within the EMRN understand the relationship between value of data, sharing of data, and accessibility to data.
- 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 must be consistently defined, and the definitions agreed upon across the EMRN, shared and made available to all users to prevent misinterpretation of data.
- Data must be protected from unauthorized use and disclosure. Processes, procedures, and automated methods must 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:

- This is one of three closely related principles regarding data: data are an asset; data are shared; and data are easily accessible. The implication is that there is an education task to ensure that all organizations within the EMRN understand the relationship between value of data, sharing of data, and accessibility to data.
- To enable data sharing we must 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 must be interoperable at all levels to enforce sharing. EMRN data has to be interoperable in accordance with the EU Interoperable Framework (EIF)[3] for usage of EMRN qualified data in national, European and international data initiatives, e.g. EHDS
- Data must be standardized 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 must comply with information security / data access policy requirements. Under no circumstances must the data sharing principle cause confidential data to be compromised.
- Shared data must be of sufficient, pre-defined and of agreed quality.
- Common methods and tools for creating, maintaining, and accessing the data shared across the EMRN must 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.

[3] 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[4] and a data steward. 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.
- It is essential to identify the true source(s) of the data in order that the data governance can assigned responsibilities to a trustee.
- 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, must then recognize the importance of this trusteeship responsibility.

3.5. Principle 5 - Common Vocabulary 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 must 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.

Implications:

- Significant additional resources must 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.

[4] 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 standardization and definition tasks. A data trustee may delegate actives and responsibilities for the data steward to carry out on their behalf.

- The Network must establish an agreed common vocabulary to facilitate interoperability.
- Data management for common vocabularies must follow consistent process across their lifecycle (from identification of need, collection, creation, quality assurance, maintenance, use, reuse and to archiving or destruction) and it is consistently used across business processes and domains.
- Common vocabularies are shared and used inside and outside the Network to facilitate interoperability.
- Multiple data standardization initiatives need to be co-ordinated.
- Administration responsibilities for common vocabulary and definitions must 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 must comply with information security policies following recognised standards, such as ISO 2700x and in force in 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. pre-decisional, decisional, classified, sensitive, or proprietary data).
- The lifecycle of the data according to the classification shall be defined.
- The appropriate controls must be determined 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 must 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 harm towards individuals or the community must be the paramount consideration for any governance policy.

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

- **Accountability** – consideration must 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 must be in place to ensure that data accuracy and authenticity is maintained and any tampering with data is averted.
- **Benefit-Risk Balance** – balance societal benefits and individual rights, ensuring that data use brings tangible benefits to individuals and the community while minimizing 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 anonymized.
- **Consent** – in principle, an individual has ownership over their personal information. Whenever feasible, the collection and processing of data from individuals should be based on an informed consent.
- **Fairness** – Ensure that data practices are free from discrimination and bias, promoting equality 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 standards.
- **Transparency** – it must be made clear how data are collected, generated, used and shared e.g., foundation models should be made available and evaluation criteria must be transparent.
- **Purpose limitation** – the risks associated with the collection of data without a purpose, like data breaches, privacy violations or data that are unfit for a later purpose should be carefully weighed against possible benefits.
- **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.
- **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.

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

4. Strategic Objectives

This Data Strategy provides the foundation for achieving EMRN's vision for data using a framework[5] for data management as its basis. 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 objective areas and related activities that needed to be completed to fulfil the strategic vision & goals, as well as realising the benefits, these objectives are described in the sections below.

[5] https://www.dama.org/cpages/body-of-knowledge

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 or specific data categories, such as personal data, and 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.

Two groups lead on data governance at network level: the Network Data Board and the joint HMA/EMA Big Data Steering Group. These groups lead on 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 liaise with other organisations and groups at national, EU and international level in relation to data.

In line with the Interoperable Europe Act, 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.

Objective 1 – Operational EMRN Data Governance Framework aligned with EU Interoperability Initiatives, Supporting Data Sharing and Evidence Generation

Objective 2 – Data Governance integrated into IT Network Product Delivery across the network.

4.2. Data Quality Management

Data quality is defined as the fitness for purpose of data in meeting users' needs for business processes, research, 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 for EU medicine regulation and aligned with relevant EU data quality initiatives, including the Union Product Database (UPD) Data Quality Framework. 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, synchronization, 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 organization.

To characterize 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.

Objective 3 – Data Quality Framework, aligned with EU best practice is commonly used across the Network.

Objective 4 – Network Data Assets Quality is improved.

4.3. Interoperability

There is an inherent need to support the need for 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 organizations.

The EMRN is committed to enhancing interoperability through the adoption of international open data standards, best practices, and alignment with the European Interoperability Framework. This approach addresses semantic, organizational, 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 to create a seamless data ecosystem that supports the network's mission in medicines regulation, while also aligning with broader EU interoperability initiatives.

Objective 5 – EMRN is a recognized leader in international standardisation efforts.

Objective 6 – Majority of EMRN IT initiatives include requirements for interoperability to achieve higher levels of maturity.

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 utilization of data assets across the network. Effective metadata management provides essential context about data purpose, generation, sources, processing steps, and lineage, enhancing the value and usability of EMRN's data resources.

A robust data cataloguing framework 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 standardized 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 (EHDS), while meeting the specific needs of the medicines regulatory network.

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

4.5. Knowledge and change management

Knowledge, skills and adoptability are essential to the successful implementation of the EMRN data strategy. This encompasses, targeted capability and capacity building, and proactive alignment with evolving EU, 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. This includes 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.

Objective 8 – Network Data Strategy Capacity building programs are available for EMRN.

Objective 9 – EMRN is ready for implementation of EU legislation on data and interoperability.

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** is 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 **modern self-service data analytics** and **data visualisation** capabilities.
- Extracting **insights** from **structured and unstructured** data.

- Leveraging advanced analytics (including AI) to deliver benefits to business process and public health.

Objective 10 – Additional business value is generated by using and interconnecting EMRN data assets.

Objective 11 - Value from information and data available in unstructured sources is generated.

Objective 12 – Tools for analysis are available for the EMRN to enrich and improve scientific, regulatory, and corporate processes.

5. References

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EHDS (European Health Data Space) Proposal
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EU Interoperability Act
https://commission.europa.eu/publications/interoperable-europe-act-proposal_en

European Veterinary Big Data strategy 2022- 2027
https://www.ema.europa.eu/en/documents/other/european-veterinary-big-data-strategy-2022-2027_en.pdf

FAIR Principles
FAIR Principles - GO FAIR (go-fair.org)

List of metadata for Real World Data catalogues
https://www.ema.europa.eu/en/about-us/how-we-work/big-data#metadata-list-describing-real-world-data-section