1 1 July 2026
2 EMA/185661/2026
3 European Medicines Agency

4 Draft - EMRN Data Standards Framework

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Draft Review - Network Data Steering Group	15 July 2026
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Comments should be provided using this EUSurvey form. For any technical issues, please contact the EUSurvey Support.

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Keywords	Data Standards, Data Governance, ISO, ICH, VICH, HL7, CDSIC,

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See websites for contact details

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

Contents

1. Introduction

The European medicines regulatory network (EMRN) data strategy[3] sets out an agreed vision, principles to be followed and goals to be met to maximise 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, standardised and accessible for consumers of the data. To meet the data strategy vision a specific goal has been included to strengthen the EMRN's coordination of data standardisation.

This framework has been developed to support the Network Data Steering Group's (NDSG) mandate[1] to enable interoperability and exchange of data through using standards and fostering international collaboration, alignment and harmonization by agreeing common international standards.

Data standardisation is the process of taking data or information and representing it in a common format to enable semantic interoperability and exchange. Once developed and implemented, this standardisation then simplifies the process for exchanging, managing, analysing data and use of artificial intelligence (AI).

In most cases data standards include terms, definitions, controlled vocabularies, and logical data models that provide the semantic interoperability that support data use, reuse, and analytics. In addition, the standards may include the message exchange format that is required for technical interoperability.

Standards are normally developed through the involvement of a Standards Development Organisation (SDO) such as ISO, HL7 & CDISC. These organisations have different processes and requirements to participate and develop standards. Standardisation activities needed to be prioritised to manage the work of a limited number of people with the knowledge and experience to develop standards through SDOs.

The time taken and resources used for developing, implementing, and realising business benefits have in the past been greater than expected. The aim of this framework is to make the process more accessible and efficient through enhanced clarity and streamlined workflows.

1.1. Background

This framework document is part of the Network Data Steering Group (NDSG) work plan[2] and is intended to support the EMANS 2028[3] Theme 2 and the goal 1.2: "*Ensure a high level of interoperability, standardisation and quality of data addressing potential biases and ethical considerations and ensure that the network data assets are appropriately managed*."

The Big Data Steering Group and the EU Network Databoard previously co-authored the EMRN Data Standardisation Strategy[4] document that identified areas where data standardisation would bring the most benefit to the EMRN. This framework builds on that strategy document to provide a governance approach that can be followed when data standardisation needs are identified.

[1] NDSG Mandate
[2] NDSG workplan 2026-2028
[3] The European medicines agencies network strategy 2028
[4] European Medicines Regulatory Network Data Standardisation Strategy

1.2. Scope and purpose

The scope of this framework is to manage the process of adoption, creation, updating, and implementation of data standards for use by the EMRN for both human and veterinary medicines regulatory purposes. It is intended to enable the EMRN to manage and govern the process for regulatory data standardisation use cases; however external stakeholders will be able to highlight their own important use case for consideration by the EMRN.

A new streamlined process will be achieved by defining specific roles, responsibilities and objectives for individuals and governance groups involved in the standardisation activities. These together should provide clear governance, oversight and transparency and resolve the previous siloed ad hoc approach to standardisation.

At an individual level, this framework should enable someone with limited knowledge of data standardisation to be able to understand the steps needed to create, adopt and implement data standards. This should contribute to reducing the long implementation timeframes and the disconnection between standards development, IT systems development and business process change management.

The EMRN should also benefit through the strengthening of coordination of data standardisation efforts and engagement with standards development organisations leading to a reduced resourcing requirement for these activities.

The successful outcome of the framework would see a larger number of data standards being implemented, and within a much shorter timeframe.

The effectiveness of this framework will be assessed through capturing lessons learned from its implementation. At scheduled intervals in the NDSG work plan any findings will be used to improve the framework through new versions of the document.

2. Principles

This framework has the following principles to support the EMRN data strategy:

1. Ensure the use of high-quality data standards developed by accredited SDOs in accordance with voluntary and consensus-based processes. Unless not compatible with EU legislation or otherwise impractical, these standards can be used in place of (unique) local or proprietary standards.
2. Ensure that data standards support data sharing & exchange, data protection, and data ethics by design.
3. Leverage collaboration between the EMRN and its stakeholders and be informed by stakeholder needs.
4. Support the use and adoption of open data standards[5].
5. Assess requirements against what has already been implemented, to prevent the use or creation of overlapping and competing standards. The assessment should include both human and veterinary needs so that where possible one standard covering both domains can be used.

[5] Open standards - Are created and maintained by a not-for-profit organisation, and their ongoing development occurs based on an open decision-making procedure available to all interested parties. In addition, the standard specification documents are available either freely or at a nominal charge. It must be permissible to all to copy, distribute and use the standard for no fee.

6. Foster international collaboration, alignment and harmonization through agreeing common international standards
7. Support the use of terminologies already used and available in the EMRN when implementing data exchange standards

3. Review process for data standardisation proposals

The mandate of the NDSG[6] includes fostering international collaboration, alignment, and harmonisation (e.g. ICH, VICH, HL7, ISO, CDISC) on data interoperability, use of standards, data quality, analysis, methods, and data use in medicines regulation. In addition, it has a role in data governance and enabling interoperability through the promotion and use of standards.

The NDSG therefore has the key role in managing the EMRN data standardisation process. In view of this, requests for initiating the development of a data standard from within the EMRN or made externally to the EMRN should be submitted to the NDSG.

The development of a standard should also consider its implementation. The implementation of a data standard implies the need for software tools to receive, process, store and analyse the data. Therefore, to enable quicker implementations, the development of IT systems should be planned from the start of the standards development process.

The NDSG therefore is responsible for reviewing proposals and advises whether to support the development, adoption and implementation of new data standards and the revisions to already existing standards. In addition, during the review the NDSG needs to consider the proposal in the context of already implemented standards to ensure data interoperability between the standards.

The process to review a new standardisation proposal is different depending on where the proposal is coming from, these can be grouped into the following sources:

1. Members of the EMRN or its stakeholders
2. ICH/VICH topic proposals that include data exchange.
3. Standards development organisations work item proposals.

The sections below describe the process to follow for each of sources of proposals.

3.1. Standardisation proposals from the EMRN and its stakeholders

One starting point for EMRN identifying the need for a data standard comes from business groups which identify an opportunity for business process optimisation and/or better regulatory decision making through the analysis of data.

These business groups can be, for example, a scientific committee, a coordination group, a working party, a governance body, a community of practice or a stakeholder community. The template for the proposal provided in Annex 1 -NDSG proposal template of this document should be completed following the guidance provided in subsequent sections of this document. This then provides NDSG with a good understanding of the use cases for the proposal and the expected benefits the standardisation work would bring.

[6] Mandate: Joint HMA-EMA Network Data Steering Group

The proposal should indicate a lead person that would present the proposal to the NDSG and would be expected to lead the standardisation work. The lead person does not need to be an expert in creating standards; however, they should have a good knowledge about the scientific and administrative data that is being proposed to be collected and exchanged.

The proposal should then be provided to the NDSG secretariat for editorial review prior to circulation to the NDSG members for consideration. The NDSG may then add an agenda item for discussing the proposal or follow a written procedure. The review outcome can be one of the following:

- Approved – Standardisation activity recommended to proceed.
- Approved with amendments to the proposal – Standardisation activity recommended to proceed with the amendments provided by NDSG.
- Not approved – Standardisation activity is not recommended to proceed.
- Deferred – NDSG decision to proceed has not been made, additional information will be requested before re-review by the NDSG.

The NDSG review outcome will also include advice on the timing of implementation, for example within one or two years, and be communicated to the lead person.

3.2. ICH/VICH topic proposals

New ICH or VICH topic proposals can be made by ICH or VICH parties and are only known by ICH coordinators. An EU recommended position needs to be provided to EC Europe management committee (MC) members. Where a new topic proposal includes a data standard, the NDSG should review the proposal and advise the EC Europe MC members on the data exchange and standards in the proposal.

Often there is a short period of time between a topic proposal being circulated and for an ICH or VICH decision to proceed or not. Therefore, a quicker review process for NDSG will be needed and it will need to be planned, in collaboration with the ICH coordinators for the EC.

Request for advice from the NDSG will be submitted through the NDSG secretariat who will organise the creation of a NDSG briefing note following the content of the proposal template described in Annex 1 -NDSG proposal template. The NDSG secretariat will reach out to EMRN Standards Development experts, subject matter experts, and business process managers to collect the information needed for the briefing note. As the time for providing NDSG advice may be short, the briefing note may not be as complete as EMRN standardisation proposal.

If the EC Europe decision is for the ICH proposal to go forward it is expected that the NDSG would support and follow the development of ICH guidelines and its related data standards.

The review outcome can be one of the following:

- Recommend the ICH proposal proceeds as described
- Recommend that the ICH proposal proceeds if changes are made to the proposal
- Recommend that the ICH proposal does not proceed

3.3. Standards development organisations work item proposals

SDOs are continuously creating and revising data standards, with their work programmes organised through their own members and management committees. Their work is independent from the EMRN and other medicines regulatory bodies worldwide. The standards produced by SDOs can have direct

impact on medicines regulators in terms of data that can be used for regulatory decision making. If an international data standard that is in active use by the EMRN is being revised, then this revision is likely to have a significant effect on the processing and use of data by the EMRN.

As the SDOs manage a large portfolio of existing data standards and are regularly creating new standards that are not relevant to EMRN use cases, activities within the SDOs need to be monitored and work item proposals triaged for relevance to the EMRN. In addition to creating new standards, SDOs have within their portfolio management processes set periodic reviews of their standards to ensure that they are still relevant and if they need updating. These periodic reviews are important for the standards implemented by the EMRN as the decision to revise an existing standard can have an impact on the EMRN data processes and IT systems that manage data. The EMRN as stakeholders actively using the standards should therefore provide feedback to the SDO to help with the decision to keep the standard unchanged or to support a revision of the standard. If a new SDO work item or a periodic review of an existing standard is relevant to the EMRN it should be escalated by the EMRN SDO experts to NDSG secretariat for NDSG review.

The NDSG secretariat will maintain an SDO activity tracking sheet that will be accessible to NDSG members, and the secretariat will be supported in the tracking by EMRN SDO experts[7] that participate in SDO meetings.

The NDSG secretariat will coordinate the creation of an NDSG briefing note when SDO activities are identified as requiring NDSG review. The content of the briefing note will follow the proposal template described in Annex 1 -NDSG proposal template. The NDSG secretariat will reach out to EMRN Standards Development experts, subject matter experts, and business process managers to collect the information needed for the briefing note.

The review outcome can be one of the following:

- Recommend that an EMRN SDO expert should lead the SDO development work.
- Recommend active participation of EMRN SDO experts in the SDO work.
- Recommend non-active participation, SDO experts would follow and comment on the SDO work but would not be expected to attend SDO meetings.
- No EMRN participation in the SDO work. No EMRN resources assigned to the SDO work.

In the case of a recommendation to be involved in an SDO work item a EMRN lead person would need to be identified so that they can act as the contact point for the topic.

3.4. EMRN data standardisation proposal

The focus of an EMRN data standardisation proposal is on the benefits the standard will bring to EMRN and its stakeholders. This is best documented as specific use cases that will be met and linked to goals identified in published strategic documents (e.g. EMANS). Clearly defined expected business outcomes should be described to enable the assessment and prioritisation process. The proposal should be described at a high-level only, such as using T-shirt sizing for describing effort and costs (S/M/L/XL). The proposal template is provided in Annex 1 -NDSG proposal template.

The proposal should also include the following:

1. Overview of the proposal

[7] Roles and responsibilities for data standardisation

a. Technical aspects: data sharing, data exchange, etc

b. Data protection and ethical aspects

2. Landscape analysis – This should provide a concise overview of:

a. What standards are currently available and if there are their suitability for fulfilling the use case requirements

b. What EMRN IT systems (EMA and NCA) could be impacted to manage, store, and process the data considered in the proposal

c. Which current network data assets may be impacted

3. Standardisation approach of the proposal

a. State if there is an existing standard that is to be adopted or if an existing standard needs to be amended to meet the use case requirements or if no current standard exists

b. Indicate if ICH/VICH, or similar international groups would be included in the standardisation

c. Which Standard Development Organisation(s) or consortium are being considered

4. Engagement plan

a. Provide a list of EU stakeholder groups to be involved (e.g. scientific committees, industry groups, patient, and healthcare groups)

b. Identify international regulators to be included

c. Anticipate potential changes to business and data management processes

5. Proposal sponsors

a. Provide details of organisations and/or committees that are supporting the proposal

6. Resources

a. Identify lead person to manage the standardisation work

b. Identify potential SDO expert(s) to support the work, indicate if contractors would be needed to support the work

c. Identify Subject Matter and business process experts to support the work

7. Pilot implementation details – Where adoption of an existing standard is being considered.

a. Provide details of the proposed pilot including timeframe for running the pilot and when the findings of the pilot would expect to be reported

3.5. NDSG briefing note

An NDSG briefing note will provide an overview of the proposal being made by the external group. The briefing may not contain all the information contained within an EMRN proposal. The following information should be included with the briefing note where available.

1. Landscape analysis – This should provide a concise overview of:

a. What EMRN IT systems (EMA and NCA) could be impacted to manage, store, and process the data considered in the proposal

b. Which current data assets may be impacted

2. Standardisation approach of the proposal

a. Which Standard Development Organisation(s) or consortium are making the proposal

3. Engagement plan

b. List EU and international stakeholder groups to be involved and potential changes to business and data management processes

4. Proposal sponsors

a. Identify international regulators that are participating in the proposal

5. Resources

a. Identify a contact person from the EMRN to provide more information if needed

b. Identify potential SDO expert(s) that are following the proposal

c. Identify Subject Matter and business process experts that can be consulted on the topic

4. SDO collaboration model

Organizations leverage Standards Development Organizations (SDOs) to create open standards that facilitate interoperability, transparency, and broad adoption. CDISC, HL7 and ISO are the main SDOs that produce standards for biomedical research and pharmaceutical regulatory procedures. It should be noted that ISO standards often must be bought to get access to them and therefore are not considered fully open standards.

To reduce the risk of developing competing standards for exchanging the same data, the SDOs work together to prevent competing standards, the main group coordinating the work is the Joint initiative council[8].

ICH and VICH* are not SDOs (see Table 1 below), instead they work with SDOs to create standards that fulfil specific regulatory requirements through providing requirements, terms, and definitions to be used in a standard. Typically, ICH and VICH will produce a specific implementation guide for a data exchange standard that sets additional business rules to support interoperability for international data exchange.

The participation within these organisations usually requires membership and the rules for membership are different for each of them. The Table 1 below summarises the information about the main SDOs used for medicines regulation data standards.

[8] http://www.jointinitiativecouncil.org/council.asp

Table 1 Standards Development Organisations

SDO	Focus	Membership	Standard accessibility	Main type of data standards
ISO	**Market-driven**, initiated by stakeholder demand and governed by national bodies	Personal through national member Body (DIN, NEN, etc.)	Paid for	Logical[9] and conceptual[10] data models
HL7	**Community-driven**, with a flexible, iterative process and strong tooling support	Personal or organisational membership	Openly available standards	Electronic exchange formats
CDISC	**Domain-specific**, focused on drug development	Personal or Organisational membership	Openly available standards	Data models & Electronic exchange formats
ICH / VICH*	**Regulatory process-driven**, with a strong focus on harmonisation across regions.	Nomination to an EWG through a regulatory authority (EU EC)	N/A	Implementation guides for standards created by SDOs

The NDSG will maintain a list of EMRN SDO experts that hold membership to the above organisations that can support the development of standards.

As explained in the section Standards development organisations work item proposals

the NDSG will advise on the level of participation the EMRN will provide into an SDO process to develop or create a standard. In addition, to EMRN staff participating as SDO experts in the SDO processes it is also possible for contractors to the EMRN to participate on behalf of the EMRN. The participating EMRN SDO experts and contractors' work will be coordinated by the Data Standardisation Lead appointed by the NDSG.

[9] A logical data model is a structured, platform-independent blueprint that defines data elements, their attributes, and the relationships between them. It acts as a bridge between abstract business concepts and the actual database implementation, ensuring data integrity

[10] A conceptual data model is a high-level visual blueprint that maps out core business concepts and how they relate to each other. It focuses entirely on what data is important to the business rather than how it will be stored, making it completely independent of any technology or database system

The SDO experts are expected to provide regular feedback to the Data Standardisation Lead and to receive input from the identified EMRN subject matter experts. The status updates reported by the SDO experts will be captured in the SDO activity tracking sheet that will be accessible to NDSG members. The NDSG secretariat will contact the SDO experts at regular intervals to ensure that information captured in the tracking sheet is up to date

In the situation where EMRN is requesting an SDO to amend an existing standard or create a new one the SDO experts will need to follow the SDO's specific process for making the proposal.

The SDO experts also have the task of monitoring new work item proposals under discussion at SDOs and inform the NDSG secretariat when EMRN relevant topics are identified. The NDSG secretariat will maintain a tracking sheet to support the monitoring activity.

Collaboration of the SDO experts and the NDSG secretariat with existing data science communities of the EMRN such as the methodology European specialised expert community[11] should be considered. Such collaborations will serve as a platform for information exchange, discussion and Subject Matter Expert input.

For ICH/VICH topic proposals the EU/EC Management Committee members can reach out to the NDSG secretariat to coordinate the creation of a briefing note and NDSG guidance.

5. Interaction between data standardisation and network portfolio

When a data standardisation proposal is adopted by the NDSG the relevant network portfolio value stream owners should be informed by the data standardisation lead. A review of the potentially impacted IT systems should be conducted and planning for future implementation should follow the network portfolio processes. The intention is that data standardisation should not be conducted unconnected to the IT systems and business processes that will manage the data that will be collected and analysed.

The process for standardisation can take many years, however the involvement of the value stream owners early on in the standardisation process is important for the following reasons:

1. Supports knowledge transfer between data standardisation experts and IT system developers.
2. Value stream owners can be involved in reviewing and testing the standard as it is developed and provide technical input before the standard is finalised.
3. If contractors are to be involved for the data standardisation SDO process, the network portfolio process is needed to manage the contracts.
4. Development of IT systems to incorporate data standards can be planned.
5. Planning for change management of business processes can be made in advance of the standard being finalised and implemented.
6. The development of EU implementation guides for the standards can be done with support of the technical and business process leads.

In the situation where an existing standard has been recommended to be adopted a pilot or prototype can be used to test the implementation of the standard to help develop the processes for data

[11] Methodology European Specialised Expert Community | European Medicines Agency (EMA)

management and gain experience with the analysis of new data. IT systems will be required to support such pilots and prototypes; therefore, network portfolio would be required to manage them.

6. Roles and responsibilities for data standardisation

The process to adopt, develop and implement data standards requires a multidisciplinary approach to successfully achieve their implementation. Having individuals and groups with well-defined roles and responsibilities simplifies the task. The table below lists the key roles and their responsibilities.

Party	Description	Responsibilities
Data Standardisation Lead	NDSG appointed person from the EMRN that leads the standardisation work for the network.	Responsible to update the standardisation activity tracking sheet. Provides updates to NDSG upon request. Escalates issues to data standardisation community such where the subject matter experts are unable reach a consensus position. Consults with subject matter experts to get consensus positions for the standard's development and implementation. Keeps technology owner(s) updated and collects their input to the technical documents developed by the SDOs
Data Trustee	NDSG appointed person from the EMRN that acts as the trustee for a data asset or data product that will be affected by the standard	Follows the development of the new standard, provides subject expert input and plans for future change management and data migration activities.
Subject Matter Expert	A person from the EMRN that has a detailed understanding of a specific scientific, regulatory, or technical area that is the focus of a standardisation activity.	Makes a data standardisation proposal to NDSG. Provides support to the Data Standard Lead Follows the development of the new standard. Is responsible to review and commenting on technical documents and information circulated by the Data Standard Lead

Party	Description	Responsibilities
NDSG Secretariat		Manages the data standardisation tracking sheet. Manages the EMRN SDO experts list Tables briefing notes and standardisation proposals to the NDSG Supports the data standardisation lead
SDO expert	A person that has a detailed understanding of creating a data standard through the processes of one or more standards development organisation. Can be either someone working directly for the EMRN or a person contracted by EMRN to conduct the SDO development activities.	Keeps their details in the directory of Standards Development Expert up to date. Monitors for new SDO work items relevant to the EMRN and informs NDSG secretariat Is part of the data standardisation community In liaison with the data standards lead they can represent the EMRNs position and provide technical input into Standards Development Organisations' drafting committees.
IT product owner	Network portfolio assigned person responsible for managing the development of a specific network IT system	Is responsible for implementing data standards in a specific IT system. Is responsible for ensuring change management activities related to implementing a standard are addressed. Should follow the development of a standard to be able to understand the changes that will occur to the IT system under their responsibility
NDSG		Reviews and prioritises data standardisation proposals coming from the EMRN, SDOs or ICH. Nominates a EMRN data standardisation lead. Advises the Network Portfolio
Network portfolio		Implements adopted standards into IT systems. Manages business process changes connected to the IT system updates

Party	Description	Responsibilities
ICH coordinator	EMRN representative at the ICH management committee who coordinates all ICH topics for the EMRN	Identifies ICH/VICH proposals with a data standard component and contacts NDSG secretariat

List of abbreviations

CDISC	Clinical Data Interchange Standards Consortium
EC	European Commission
EMA	European Medicines Agency
EMRN	European medicines regulatory network
HL7	Health Level 7
HMA	Heads of Medicines Agency
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ISO	International Organization for Standardisation
NDSG	Network Data Steering Group
SDO	Standards Development Organisation
VICH	The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

Annex 1 -NDSG proposal template

Data standard name: …					
Lead person	**[name]**	**Proposer**	VICH / ICH / SDO / EMRN	**Priority at NDSG**	
Value stream owner	**[name]**	**SDO expert**	**[name]**	**Proposed start**	**Qx 20YY**

Connection to the European medicines agencies network and data strategies

The implementation of this data standard will bring value to this EMRN Data Strategy:
List here the data strategic goals this proposal helps to reach (prioritised list if more than one): **NDSG workplan 2025-2028**

Adopt (existing), Adapt (revise existing), Develop (new standard):
Select the appropriate category and describe interdependencies with other data standards.

Stakeholder involvement needed for adoption/implementation of this data standard?
Engagement required for (e.g. research community, drug developers, healthcare providers, scientific committees – specify which ones).

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Business Outcomes

- Improved automation capacity: …
- Operational efficiency: …
- Improved data quality: …

Expected Benefits

- [Measurable performance indicator 1]
- …
- [Measurable performance indicator n]
- Increased user [EMA, NCA] satisfaction: …

Landscape analysis

- Existing data standards: …
- Expected impact on IT systems: …
- Expected impact on data assets: …

Engagement plan

- Involvement of International regulators
- Proposal for an ICH or VICH topic (yes/no)
- Identification of EU stakeholder groups
- Resource requirements for data standardisation and implementation (T-shirt size S/M/L/XL)