Consultation on the EU Network data strategy

Fields marked with * are mandatory.

Introduction and instructions.

The European Medicines Regulatory Network (EMRN) data strategy aims to provide a vision, principles and objectives for implementing effective data management so that the EMRN can be transformed into a data-driven regulatory ecosystem that promotes innovation, efficiency, and better coordinated decision-making among national authorities and the EMA.
The scope of the strategy is for data assets maintained by and within the EMRN.

Stakeholders are invited to review and provide comments on the draft strategy, the EMRN would also like to collect ideas on what actions could be undertaken by the Network to achieve the strategic objectives.

Data Protection statement

In this survey EMA does not collect or process personal data. Therefore, please make sure that you do not reveal your identity or include other personal data in the free text answers. The survey is designed to collect the answers only in an aggregate and anonymous format. The responses will only be evaluated and the results shared in an aggregate way.
For the collection of data in this Survey EMA relies on the EU Survey external system. For more information on how EU Survey processes personal data, please see: https://ec.europa.eu/eusurvey/home /privacystatement
The EU Survey external system uses:
Session "cookies" in order to ensure communication between the client and the server. Therefore, user's browser must be configured to accept "cookies". The cookies disappear once the session has been terminated. Local storage to save copies of the inputs of a participant to a survey in order to have a backup if the server is not available during submission or the user's computer is switched off accidentally or any other cause.

☑ Please confirm that you have read and understood the data protection statement above.

Administrative information

*Please select stakeholder group you represent.
- ◉ Patients
- ◉ Consumers
- ◉ Pharmaceutical industry
- ◉ Medical Device industry

○ Contract Research Organisation

○ Academia

○ Researchers

○ Healthcare Professionals

○ EU Institution (EC, EU Agency...)

○ National Competent Authority

◉ Other

* Please state the name of organisation you represent.

100 character(s) maximum

International Society for Pharmaceutical Engineering (ISPE)

Consultation

Provide comments on a section of document

☑ Introduction

☑ EMRN's Data Vision

☑ Data Principles

☑ Ethical use of data

☑ Strategic Objectives

☐ References

☑ Other

* add your comments on EMRN's Data Vision section

500 character(s) maximum

144 Please clarify what "all regulatory processes" means. Consider clarification of expectations for manufacturing and quality data from industry day-to-day operations - refer to "CMC and supply data" in Lines 113 and 119

146 "Artificial Intelligence": refer to the appropriate rules or regulation for AI in the network.

165-175 Kindly amend this section to read as benefits.

* add your comments on Introduction section

500 character(s) maximum

Industry already shares information with regulatory authorities. Full clarity is required of extent of data sharing in the network, and of security and confidentiality measures applied. Some member states already have information shared between industry and regulators for drug shortage prevention. For efficiency EMRN should build on this experience. Harmonisation and interoperability are critical for this project. ISPE suggests an implementation road map is drafted.

* add your comments on Data Principles section

500 character(s) maximum

2

266-289 Management of data requires more clarification. ISPE recommends that two roles are considered across the whole network – Governance (e.g. policies, processes, hardware, validation policy) and Content (e.g. correctness of data, nomenclature) After line 332, consider adding in "Data Principles" add an additional section for "Representative Data".   Text should explain the strategy that data reflect real-world diversity and be regularly assessed for biases within the intended use.

*add your comments on Ethical use of data section

500 character(s) maximum

Consider repeating the point about the need for 'representative data."

*add your comments on Strategic Objectives section

500 character(s) maximum

As important to the strategy, consider making ISO 2700x series standards mandatory across the network and, potentially with other stakeholders who connect to EMRN.
High levels of data control and prevention from cyber-attacks are an essential strategic objective.

*add your comments on Other section

500 character(s) maximum

87 Key challenges:add "Connection to existing company management, business strategies and data structures" 103 Scope:clarify if all companies should comply e.g. for all (review and inspection) CMC data. Please provide a reason as well. Some companies may have to develop policies and infrastructure. 113-118: mention scope is wider than current expectations for regulatory data. Please include text explaining the scope of data relating to inspection and drug shortage prevention.

Do you wish to submit any additional comment(s)?

500 character(s) maximum

A further principle could be "Lifecycle of data". Text should explain that data has a lifecycle and this should be managed.

Please provide suggested actions that should be undertaken by the EMRN to achieve the objectives given in the strategy.

- ☐ 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.
- ☑ Objective 3 – Data Quality Framework, aligned with EU best practice is commonly used across the Network.
- ☐ Objective 4 – Network Data Assets Quality is improved.
- ☑ 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.
- ☐ Objective 7 – Dataset Catalogues are established and provide a clear way to discover EMRN Data Assets.
- ☐ 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.
- ☐ 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.

* add your suggested action for Objective 3

500 character(s) maximum

> Objective 3: Data Quality Framework, aligned with EU best practice is commonly used across the Network. Suggest clarifying that there is a single management organisation in charge of supervision and assessment of good data management practices across all stakeholders.

* add your suggested action for Objective 5

500 character(s) maximum

> Objective 5: ISPE suggests having this platform interoperable as a critical objective in a world where other platforms operate and are supported by NCA's or Europe such as Google. Interoperability with the emerging ICH PQKM platform is required.

Do you wish to submit any other proposals for actions?

500 character(s) maximum

> None

Thank you for your participation!

Contact

Contact Form