Background

- The age of Digitalisation is also the age of the Data-driven decision-making. The creation and adoption of data standards supports these activities
- Without data standards the collection, processing and management of large volumes of healthcare and medical product data can be difficult, inefficient and costly. This can then divert finite resources away from data analysis and slows the assimilation of new knowledge.
- The big data taskforce report identified the need for this Data standardisation strategy in order support international collaboration and to work with standardisation bodies.
- Creation of new data standards requires significant time and effort of dedicated experts, therefore careful planning and prisonisation is needed

Data Standardisation Strategy

- This data standardisation strategy document is an important deliverable of the Big Data Steering Group (BDSG) and will be maintained overtime to reflect changes in priorities and additions of new requirements. The strategy has been adopted by both the BDSG and the EU Network Data Board (EUNDB).
- Until now the approach taken to develop and implement data standards has been ad hoc and slow. The creation of a strategy should enable the reduction of effort and a quicker approach to adopting and implementing data standards.
- This strategy sets out the principles used to guide data standardisation efforts and the adoption of data standards by the European Medicines Regulatory Network.
- The document will support the work to create and implement internationally applicable data standards and to support delivering the Network strategy to 2025

Data Standardisation Strategy

Published on the [EMA Big data](#) webpage:

[Direct link](#)

HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINES · HEALTH

16 December 2021
EMA/447502/2021

European Medicines Regulatory Network Data Standardisation Strategy

Adoption by Big Data Steering Committee	16 September 2021
Adoption by European Network Data Board	8 October 2021
Endorsed by Heads of Medicines Agencies	24 November 2021
Endorsed by EMA Management Board	15-16 December 2021

See websites for contact details

Heads of Medicines Agencies
European Medicines Agency

Implementing Data Standards by the European medicines regulatory network (EMRN)

Legal obligation

Having the legal obligation to implement a Standard refers to when the regulatory agencies are obliged to implement a certain Standard (e.g. Pharmacovigilance ISO IDMP)

No obligation, but jurisdiction

For certain parties that have legal obligations, the EMRN can set requirements to adhere to specific standards in the guidelines issued for example by marketing authorization holders, clinical trial sponsors (e.g. data exchange for clinical trial protocols)

No obligation and no jurisdiction

When the EMRN has no jurisdiction over a party, no obligations can be enforced. In such cases the EMRN can get involved in the relevant fora to participate in the decision-making process (e.g. e-health records) for those standards

Data Standards Strategy | Key milestones for its development

Stakeholder Assessment

- Standards developing organizations (SDOs) Landscape Analysis
- Interviews within the Agency

Data Standards Strategy (DSS)

- Identify and align goals & objectives
- Draft DSS document based on input and direction of stakeholders

Communication Plan

- Communication plan and identify appropriate channels for communicating with stakeholders

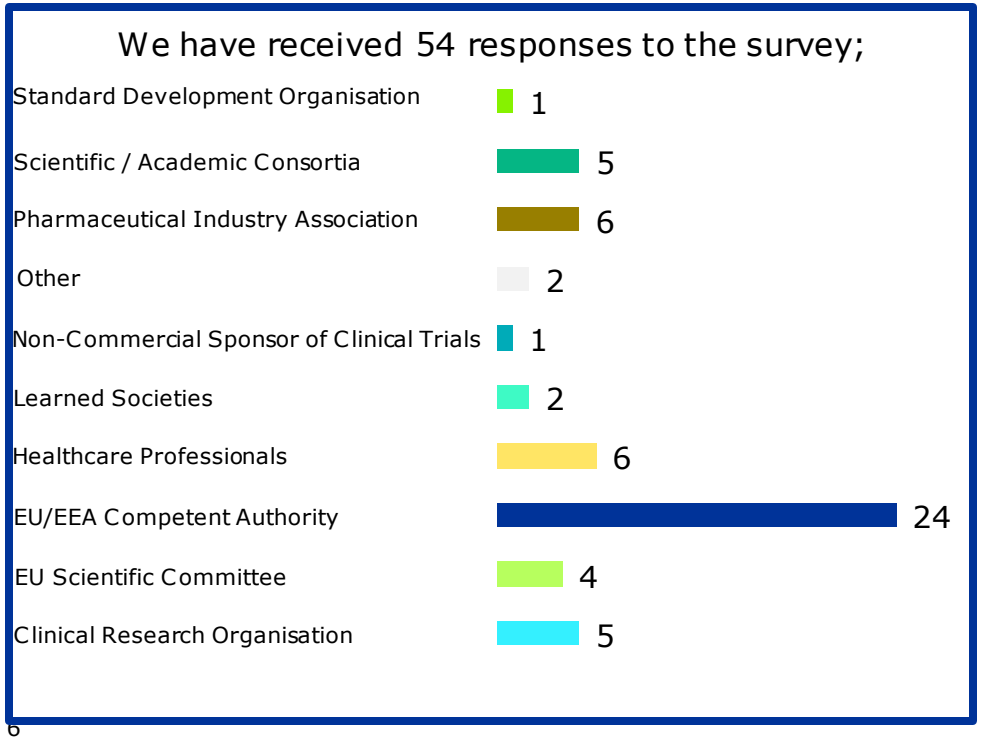
Workshop & Survey

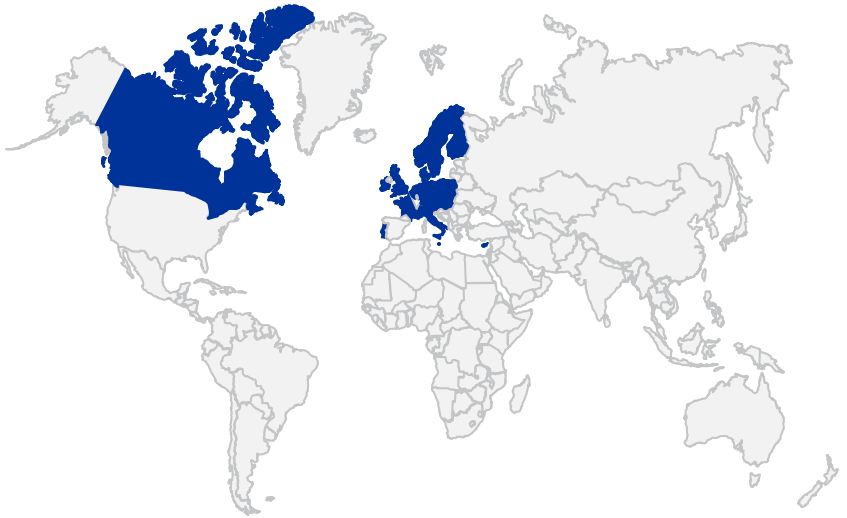
- Present draft DSS findings
- Collect stakeholder feedback

Completion of draft Strategy

- Ready for review and adoption by BDSG and EUNDB

Data Standards Strategy | Survey Results





Data Standards Strategy | Development

From December 2020 an in-depth analysis has been performed on the overall IT, policies and data standards landscape within the EMRN. A Survey was conducted in March/April 2021 followed by stakeholder workshop in May 2021

Background Documents*

Chemical Strategy for Sustainability

Information Management Strategy 2019-2021

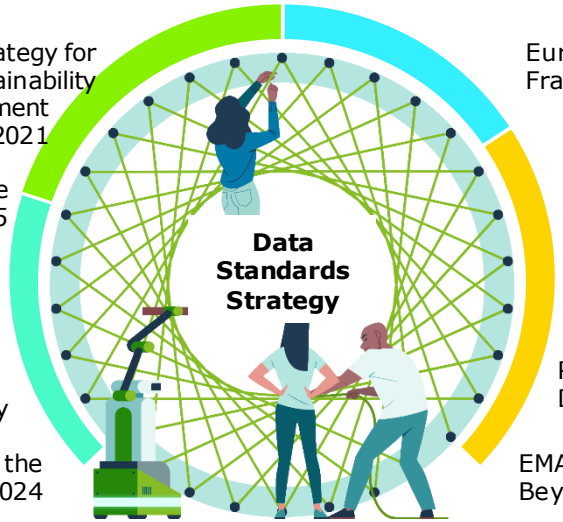
EMA Regulatory Science Strategy 2025

EU Medicines Agencies Network Strategy to 2020

EU Digital Strategy 2025

EU Data Strategy

Political Guidelines of the Commission 2019-2024



European Interoperability Framework

Telematics Implementation Roadmap 2019-2020

EMA Policy Documents & Digital Transformation Tools

EU Policies Human & Vet

Recommendations of HMA-EMA Big Data Task Force

EMA Work Programme(s) 2020-2021 & Beyond

Please note that this is a non-exhaustive overview

Survey & workshop

143 Use Cases

Collected from the survey

49 organisations responded to the survey

Workshop

4 SDOs presented their work

7 stakeholder groups provided their requirements and priorities

Data Standards Strategy | Consultation full results

The information gathered as part of the stakeholder assessment and landscape analysis will be used as input for the Data Standards Strategy

80 internal stakeholders were interviewed throughout **59** interviews.

As a result of the interviews, survey and workshop, more than **330** use cases were collected.

Recurring themes identified revolve around: **ePI, Structured protocol and study design, manufacturing sites, ePSUR, eRMPs**.

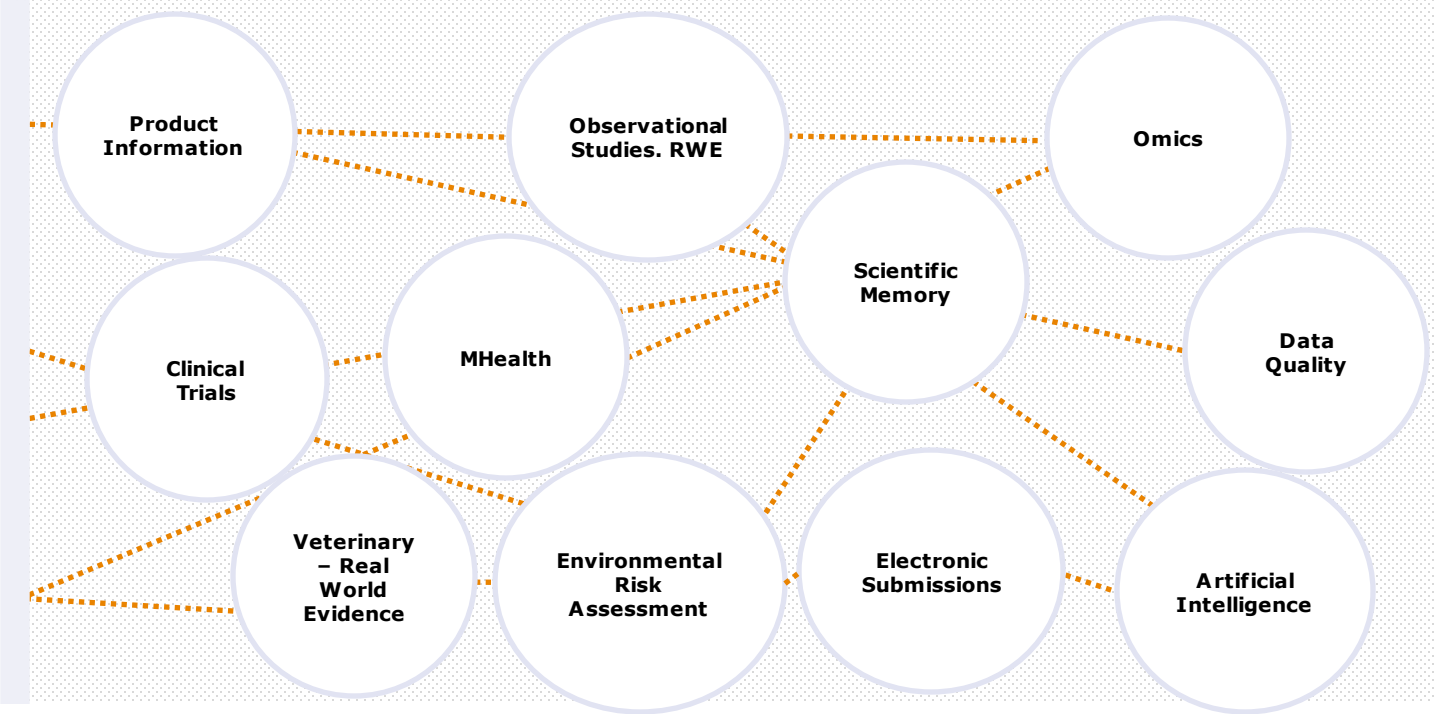
The Landscape Analysis was based on **12 SDOs**, focusing on standards published and under development.

Overall, **+1900** standards were reviewed.

Data Standards Strategy | Themes

Use case received have been grouped as Themes

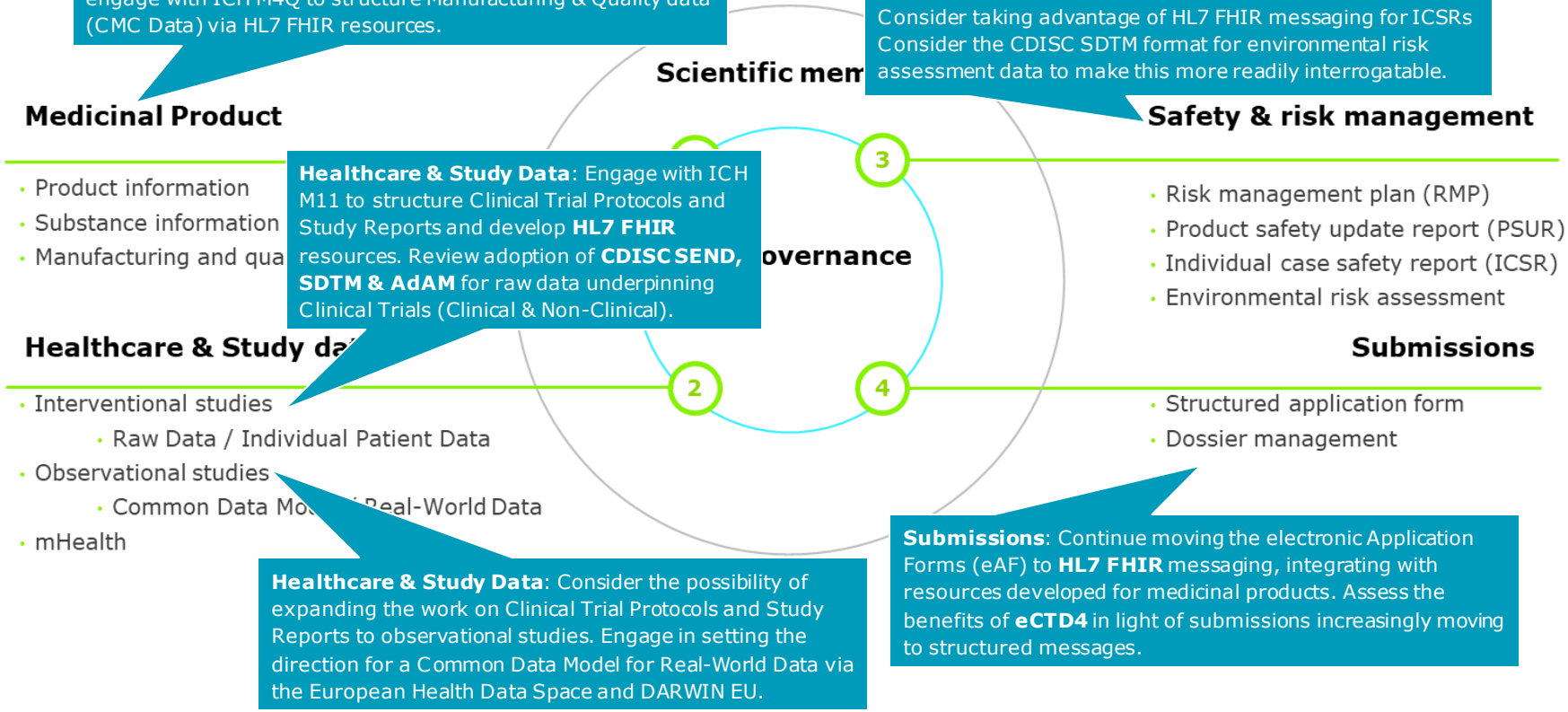
The following themes have been identified



Data Standardisation Strategy Recommendations

Medicinal Product: Continually expand and improve the **HL7 FHIR** standard in terms of product and substance information. Build on **ISO IDMP**, extensions introduced as part of **ePI** and engage with ICH M4Q to structure Manufacturing & Quality data (CMC Data) via HL7 FHIR resources.

Safety & Risk Management: Consider developing a new standard for eRMPs following ICH E2E guidelines. Consider structuring PSURs following ICH E2C (R2) guidelines. Consider taking advantage of HL7 FHIR messaging for ICSRs Consider the CDISC SDTM format for environmental risk assessment data to make this more readily interrogatable.



Healthcare & Study Data: Engage with ICH M11 to structure Clinical Trial Protocols and Study Reports and develop **HL7 FHIR** resources. Review adoption of **CDISC SEND, SDTM & AdAM** for raw data underpinning Clinical Trials (Clinical & Non-Clinical).

Healthcare & Study Data: Consider the possibility of expanding the work on Clinical Trial Protocols and Study Reports to observational studies. Engage in setting the direction for a Common Data Model for Real-World Data via the European Health Data Space and DARWIN EU.

Submissions: Continue moving the electronic Application Forms (eAF) to **HL7 FHIR** messaging, integrating with resources developed for medicinal products. Assess the benefits of **eCTD4** in light of submissions increasingly moving to structured messages.

Recommendations

Product information: Plan further iterations of the electronic product information standard (ePI) to develop additional FHIR resources to support further structuring of information and ensure alignment with the ISO IDMP product and substance related standards.

Manufacturing and quality: To enable the assessments of product quality a group of experts should be tasked with developing a set of requirements for an international standard for raw quality data. In addition, further analysis is needed to determine how manufacturing, supply-chain traceability & inspections data can be standardised.

Recommendations

Observational studies: The standard being developed for clinical trial protocols and study design should be reviewed to see if can be extended to included observational studies. A CDM standard needs to be developed and/or adopted in order to facilitate use real world data (RWD) and metadata obtained from healthcare records and disease registries.

Interventional studies: A structured clinical trial protocol is being developed by ICH M11, this work should be supported by experts from the EU network to progress its development and include study design & reporting study results. Adopting relevant CDISC standards should be considered for collecting raw data.

mHealth: Further analysis is required in order to develop requirements for data standards that respect the accompanying privacy and security considerations. An expert group should perform this analysis.

Recommendations

Risk management plan: A new data standard based on the published ICH E2E pharmacovigilance planning and good vigilance practice module V guidelines should be developed.

Product safety update report: An electronic product safety update report (PSUR) with structured information that follows the ICH E2C (R2) periodic benefit-risk evaluation should be developed.

Environmental risk assessment: The CDISC SDTM standard for data collection of risk assessment data should be reviewed and the adoption criteria be specified taking into account both the human and veterinary domains.

Individual case safety report: The individual case safety report (ICSR) standard could be revised to take advantage of HL7 FHIR based messaging and include patient omics data. Requirements for Omics data would need to be developed by an expert group before such a revision of the ICSR standard is undertaken.

Structured application form: The electronic application form FHIR messages currently being developed should be reviewed to see if they can be extended to support pre-application phase activities and include metadata to run regulatory processes.

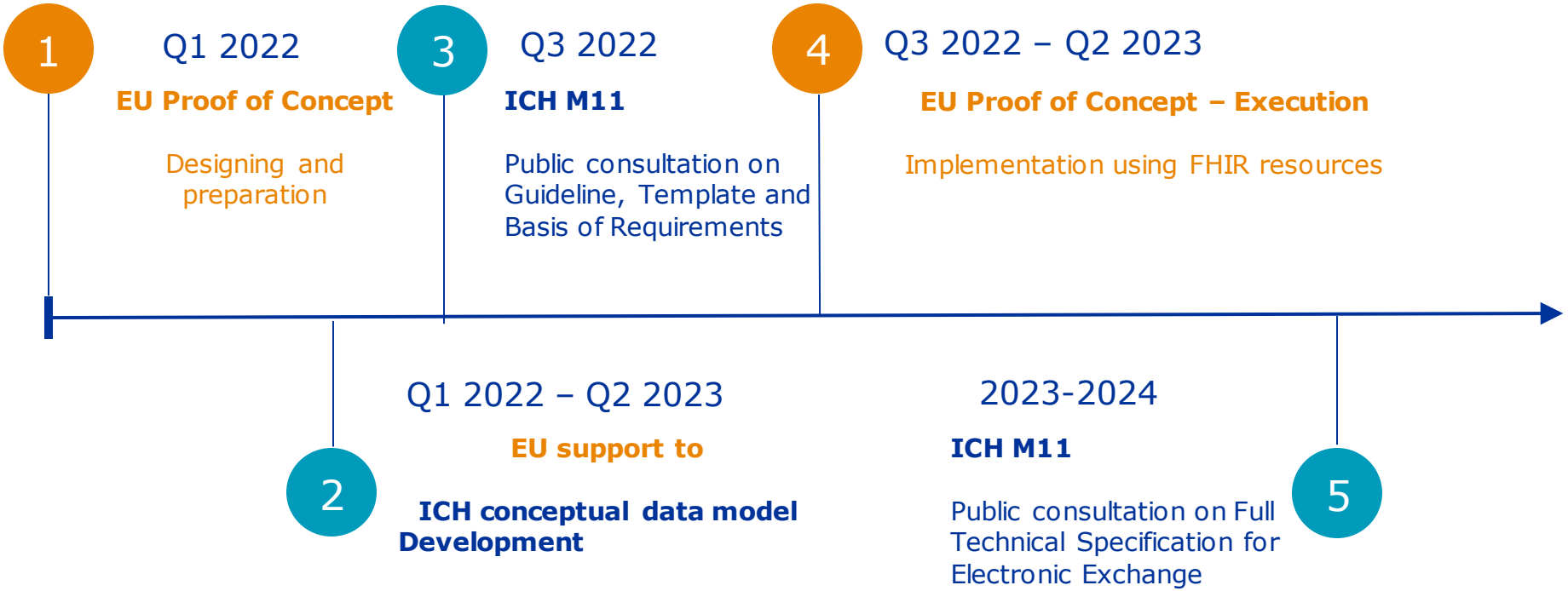
Dossier management: The use of FHIR messaging for regulatory data and document exchange should be reviewed to see if it is the best option for the future.

Structuring clinical trial protocols - EMA

- Efficient interrogation of scientific information submitted and created at the European Medicines Agency
- Increase and ensure quality of scientific output and its accessibility
- Improve the efficiency of the creation of scientific output

- **Synergies with ICH M11**:
  - the work for the ICH M11 Technical Specification is complementary with the HMA/EMA Big Data Task Force recommendation
- Develop a **conceptual data model** based on the ICH M11 template
- Execute a **Proof of Concept** implementation of data exchange and interrogation based on FHIR resources

Structuring clinical trial protocols – EMA timelines



16

Next Steps

- The BDSG & EUNDB are jointly responsible for maintaining the data standardisation strategy document. Additional Veterinary requirements are expected to be added to the strategy in 2022
- In 2022 the BDSG & EUNDB will make proposals for what actions are needed to implement the recommendations for HMA and Management board to consider and adopt
- The implementation of standards will require HMA/MB approval and need to follow a step-wise approach in order to support NCAs, network systems and effective change management
- The document will support collaboration & coordination within the EU regulatory network. In addition, it will support working with international regulatory parties on common requirements by clearly setting out EU needs and direction. The strategy will direct the EU discussions at international fora

Any questions?

Further information

Nick.halsey@ema.europa.eu
Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

Follow us on **@EMA_News**