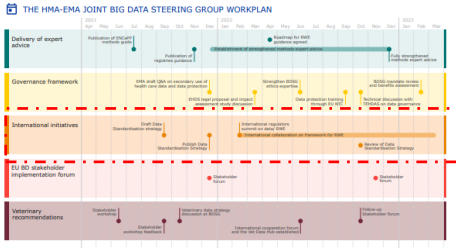
HMA
Heads of Medicines Agencies

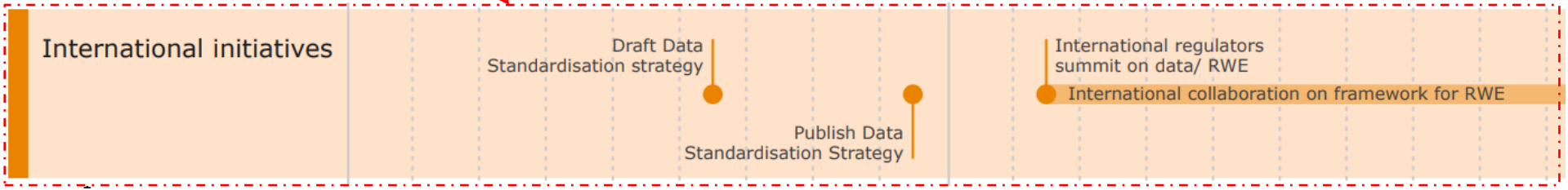
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Current Status on Implementing the Data Standardisation Strategy

Introduction

- Convergence with international partners on standards and guidelines
  - Ensure interoperability and minimize burden on all parties
- Updates of current activities that are addressing the recommendations





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

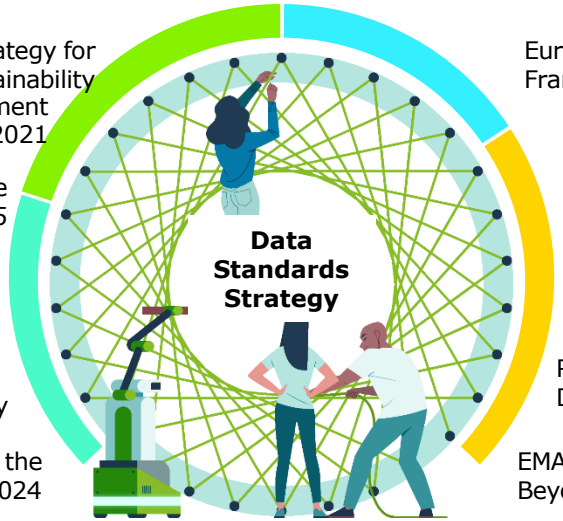
EMA Regulatory Science Strategy 2025

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

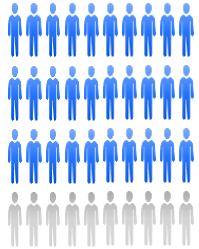
Please note that this is a non-exhaustive overview

Survey & workshop

143 Use Cases

Collected from the survey

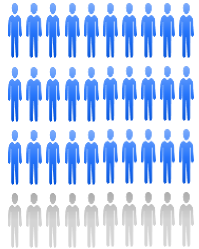
49 organisations responded to the survey



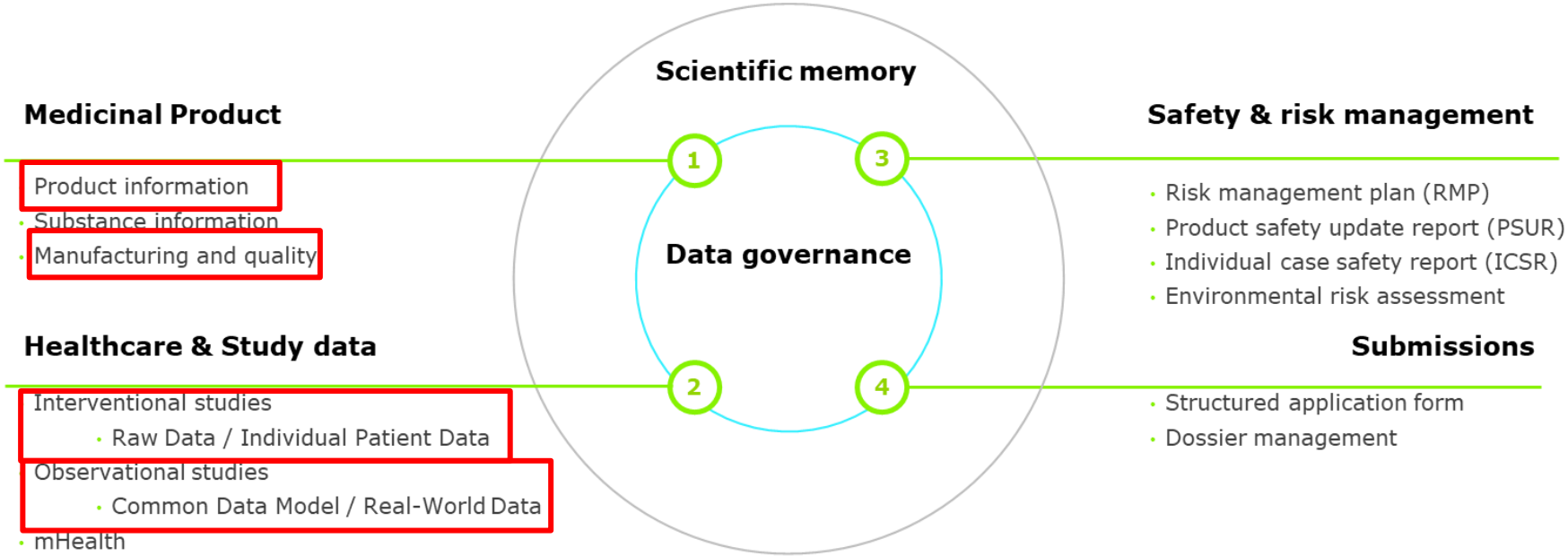
Workshop

4 SDOs presented their work

7 stakeholder groups provided their requirements and priorities



Data Standardisation Strategy



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.

Ongoing EU activity to develop an implementation of the current ePI standard that has been developed with FHIR resources. Following the pilot review further integration with IDMP and SPOR systems will be undertaken following completion of the pilot.

Milestones:

2022 ePI Portal development (12 months)
2023 6-month pilot for ePI submissions
2024 Operationalise ePI submissions for Centrally Authorised Medicinal Products
2025 Review of ePI to integrate with IDMP & SPOR PMS/SMS data

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.

- A proof-of-concept pilot is being established to investigate the benefits of analysing and visualising raw data (patient level data in electronic structured format) from clinical trials to support the assessment and learn about the operational, resource and technological needs when analysing raw data.
- Data standards: CDISC Analysis Data Model (ADaM), CDISC Study Data Tabulation Model (SDTM) as well as the Define-XML and Analysis Results Metadata (ARM for Define-XML). Learnings from the pilot will be assessed by documenting practical learnings, including feedback on adoption of relevant CDISC standards for the submission of raw data.
- The development of the ICH M11 structured protocol is being actively supported and a proof of concept implementing FHIR resources is planned. The proof of concept will provide feedback into the ICH M11 process that will help with the development and finalisation of an ICH electronic exchange specification.

Interventional studies

Milestones ICH M11

Oct 22 EU step 3 consultation of ICH M11 Template, guide and technical specifications

2023 SDO development work for ICH M11 electronic format (HL7 FHIR & CDISC)

2024 Step 3 consultation on draft ICH Implementation guide for Electronic Exchange standard

2024 Step 4 final ICH implementation guide for Electronic Exchange standard

Milestones Raw data

Sep 22 Raw data proof of concept pilot started

2024 Completion of pilot and review

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.

Following the DARWIN EU assessment of Common Data Models the decision to use OMOP was announced in DARWIN EU multi-stakeholder information webinar held in February 2022.

The review of ICH M11 specifications for use in Observational studies will be possible once the work in ICH is published for public consultation.

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.

- ICMRA has published a reflection paper that sets out international harmonisation activities that will be started soon. A number of different groups will be involved in establishing the data standards and guidance to be used for exchanging/sharing this information
- ICH – M4Q(R2) EWG will establish the data elements and standards to be created/adopted for structured product quality submissions (eCTD module 3 data)
- IPRP – (International Pharmaceutical Regulators Programme) Will set out to align Regulatory Assessment and Expectations

Manufacturing and quality

- PIC/s - Inspections PIC/s area – to look at GxP inspection related elements with particular attention to Pharmaceutical Quality Systems (PQS).
  - They will develop a set of specification for a structured data format for inspection reports (to facilitate regulatory reliance and risk/analysis-based oversight).
  - They have already created a proposal paper for the unique dentification of key facility attributes to be captured in structured electronic form. The proposal of the WG on UFI is to collect, verify, and use WGS84 geographic coordinates (geocoordinates) in a specific format, along with name and address of a facility, as well as the existing national identifier, to aide in the identification of global pharmaceutical manufacturing facilities, for both national and third country inspections.
  - https://www.icmra.info/drupal/strategicinitatives/pqkms/joint_reflection_paper

Recommendations

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.

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.

Thank you for listening

Further information

See websites for contact details

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

The European Medicines Agency is an agency of the European Union