An update on European data standards activities

CDISC US Interchange: Regulatory Topics

Presented by Dr. Marcia Rueckbeil on 26 October 2022
Data Analytics and Methods Task Force, European Medicines Agency (EMA)

Meet the speaker

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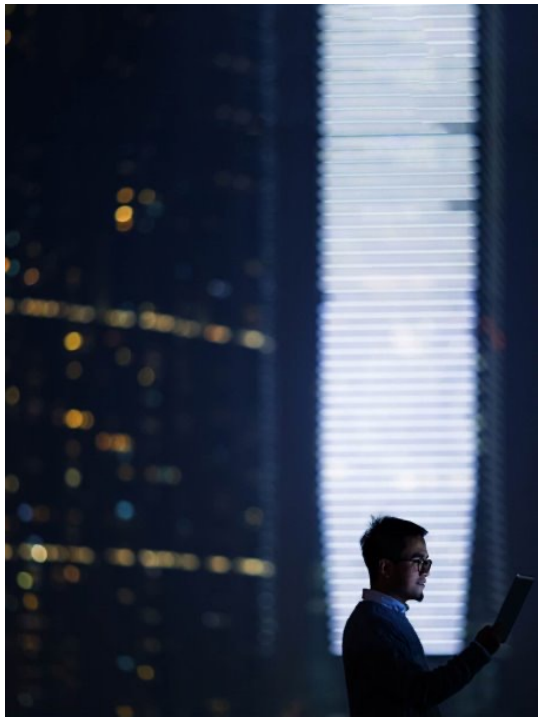
Organisation: European Medicines Agency - Data Analytics and Methods Task Force

Disclaimer

The views expressed in this presentation are my personal views and may not be understood or quoted as being made on behalf of or reflecting the position of the European Medicines Agency or one of its committees or working parties.

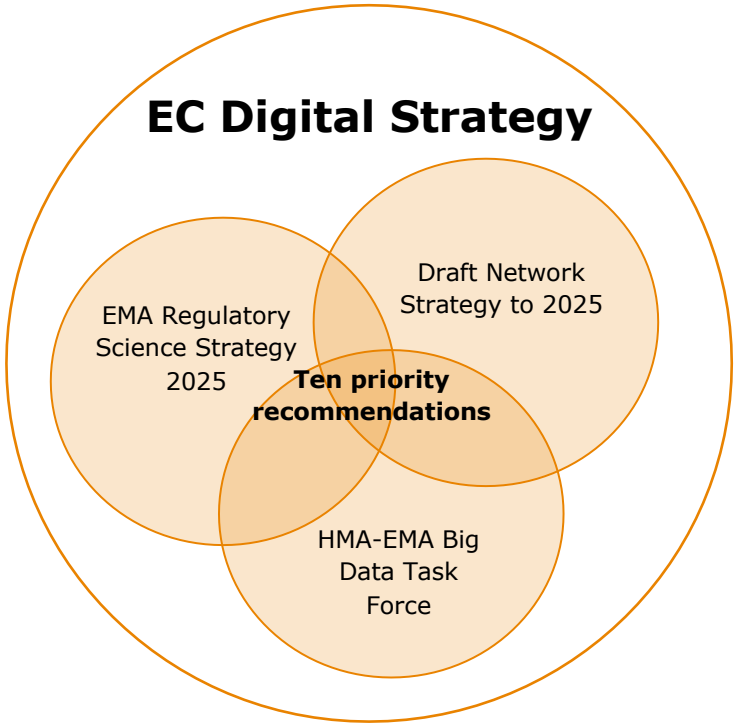
Outline

- Update on selected European data standards activities
  - Governance Framework
  - Data Standardisation Strategy incl. structuring clinical trial protocols
  - Submission of individual patient data from clinical trials
- The way ahead…



The timing is now…

- Key initiatives referred to the Commission digital strategy **"European health data space"** (EHDS):
  - **European Medicines Regulatory Network Strategy to 2025** (data & digital pillar)
  - **EMA Regulatory Science Strategy to 2025**
  - **Joint HMA-EMA Big Data Task Force;** and
  - resulting **priority recommendations**
- Synergies with the following initiatives:
  - **Pharmaceutical strategy for Europe**
  - **European Health Union**



Vision: innovate to turn data into decisions on medicines that create a healthier world

HMA-EMA Big Data Task Force Priority Recommendations

- Data quality & representativeness
- Data discoverability
- EU Network skills
- EU Network processes
- Network capability to analyse
- Delivery of expert advice
- Governance framework
- International initiatives
- EU stakeholder implementation forum

Adopted in July 2022

HMA Heads of Medicines Agencies

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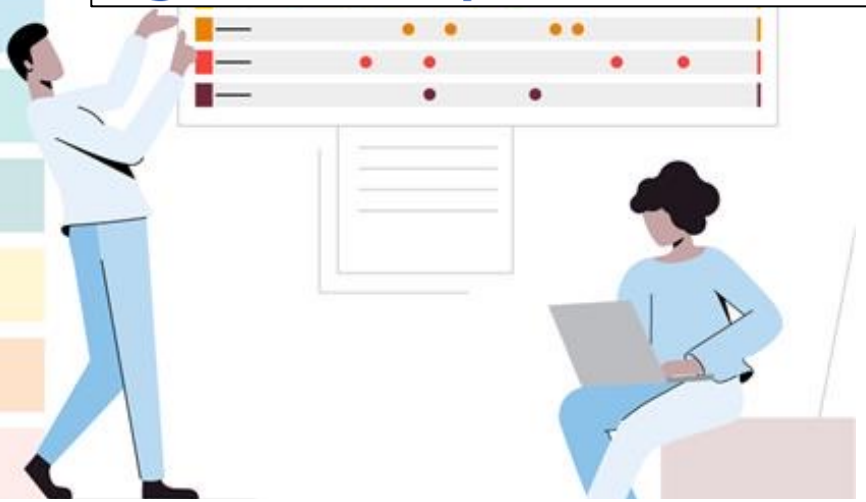
Big Data Steering Group

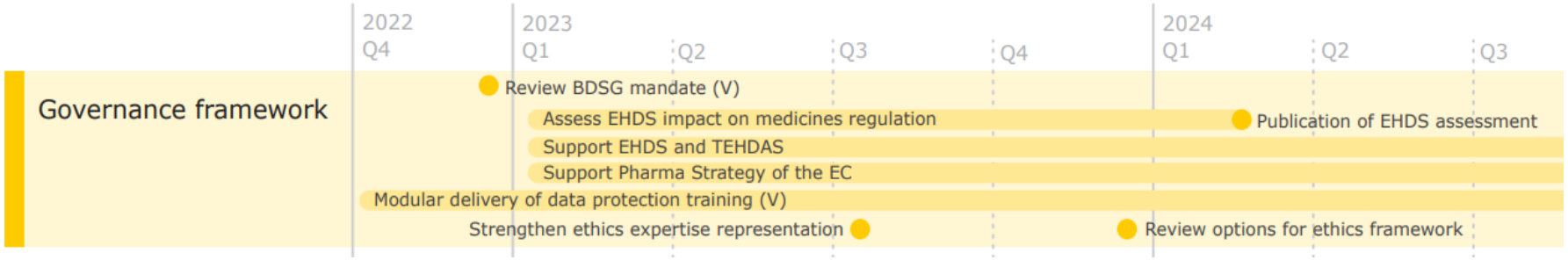
Big Data Workplan 2022-2025



Big Data Workplan and Governance framework

Governance framework

- Review of the **Big Data Steering Group** (BDSG) and the **EU Network Data Board** (EUNDB) **mandates**
- Ensure data are managed and analysed within a **secure and ethical governance framework**
- Continue alignment with **Towards A European Health Data Space** (TEHDAS)

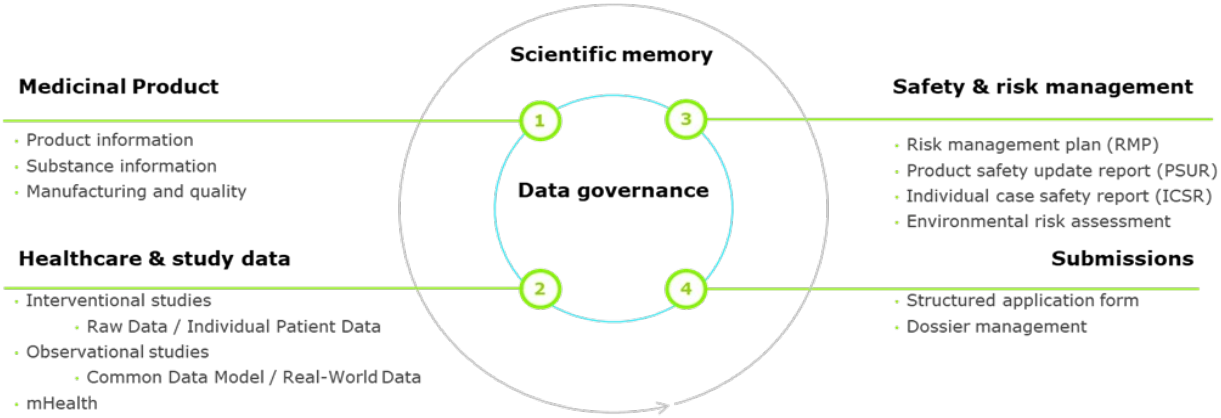


EMRN Data Standardisation Strategy

International initiatives

European Medicines Regulatory Network (EMRN) **Data Standardisation Strategy** (DSS) (link)

DSS recommendations:



EMRN Data Standardisation Strategy: Scope & Aim

- Adopted by the **BDSG** and the **European Network Data Board**, aligned with the **EMRN Strategy to 2025**.
- Will be **maintained overtime** to reflect changes in priorities and additions of new requirements.
- The aims are to:
  - enable **quicker adoption of international data standards** across the EMRN;
  - support **adaptation of existing** and **development of new data standards**;
  - **improve data quality**;
  - **enable data linkage and data analysis** to support medicine regulation.

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16 December 2021
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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 www.hma.eu
European Medicines Agency www.ema.europa.eu

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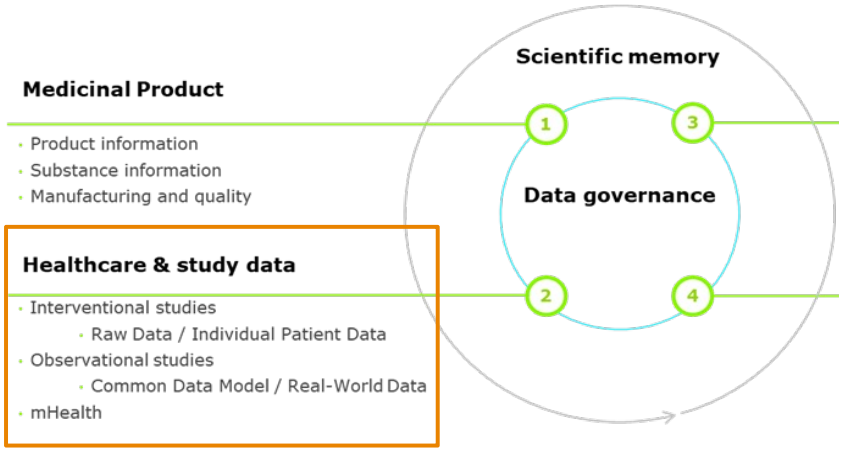
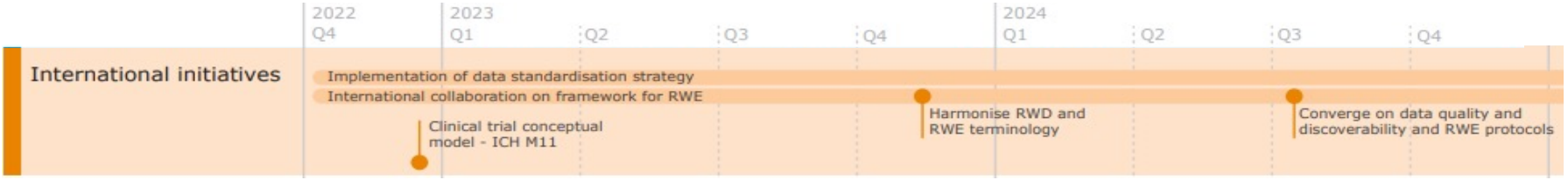
EMRN Data Standardisation Strategy: Next steps

- Continue supporting development of **ICH M11** (structured clinical protocol)
  - Will simplify submission process & support **accessibility** of data
  - Synergy with **EMA project** on efficient **interrogation of scientific information** submitted and created at the EMA

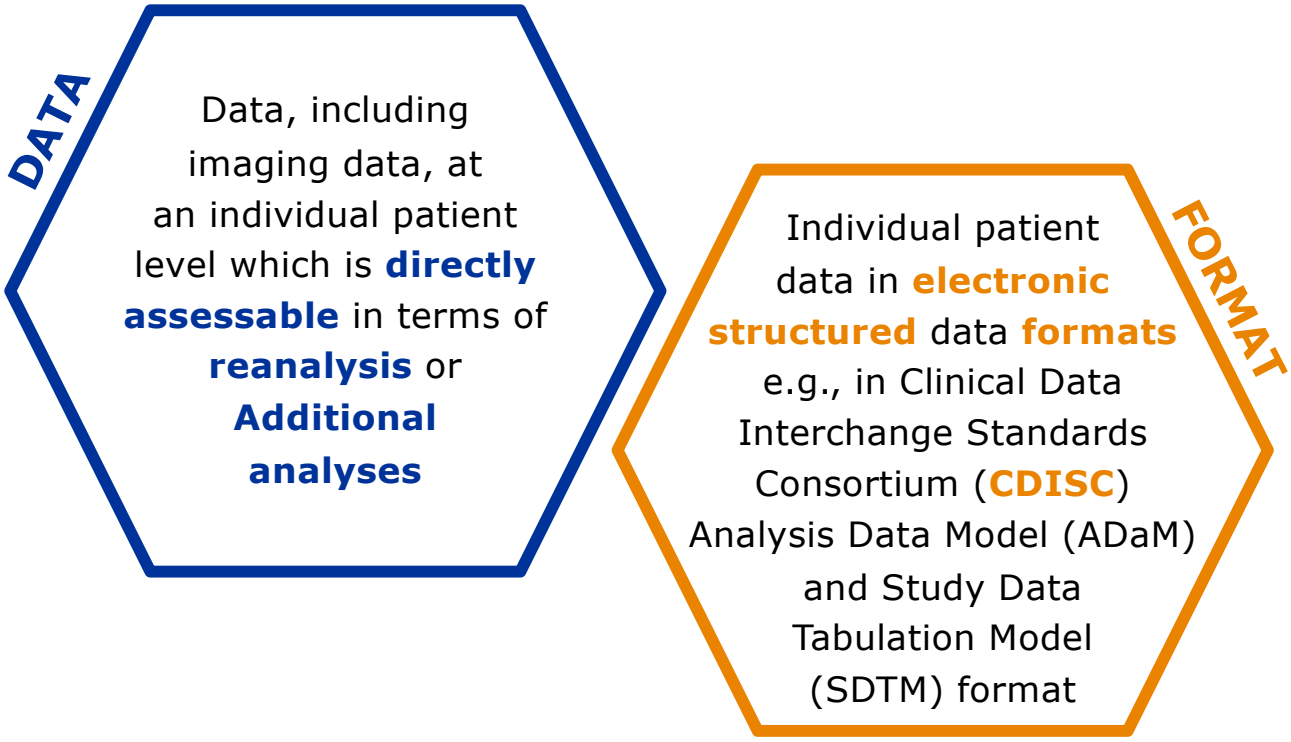


- **Implementation** of the EMRN data standardisation strategy



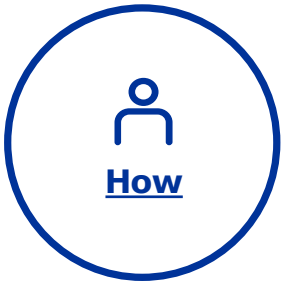
Definition of 'raw data' / individual patient data

Network capability to analyse



EMA's Raw Data project and raw data pilot

- Determine **regulatory benefit of access to raw data** before coming back with **recommendations** to the **Committee for Medicinal Products for Human Use** (CHMP).
- Ultimate aim is for **Network to understand and take informed decisions** on the place of analysis of **raw data for future regulatory submissions.**



- **Put in place procedures and safeguards to process clinical trial raw data** in accordance with data protection legislation.
- **Establish an Advisory Group on Raw Data** (multi-disciplinary group with members from CHMP, EMA Working Parties, patients' and healthcare professionals' representatives)
- **Perform a proof-of-concept pilot** in order establish the value of raw data and to build, step by step, capacity to analyse raw data.
- **Foster stakeholders' engagement** through a communication plan.

Raw Data Pilot: In a nutshell

- **Timeline:** Approx. **10 regulatory procedures over 2 years** from September 2022 (interim report after 12 months).
- **Scope: Initial marketing authorisation applications** and **post-authorisation applications**. Focus on data from **clinical trials**.
- **Participation:** Procedures will be selected based on **voluntary participation of CHMP Rapporteur teams** and **companies**.
- **Usage:** Analyses to inform the assessment of the underlying dossier. Information on methods and results will be **shared with the company** and the company will be asked to **replicate the analyses**.
- **Resources:** Three **resourcing scenarios for who is doing the analysis** will be explored: the CHMP Rapporteur team, EMA staff or EMA contractors.

Raw Data Pilot: Data access and analysis

SUBMISSION	Via **eSubmission Gateway** (no change)
DIALOGUE	**Data submission meeting** and **feedback** on participation Main communication via **existing procedural channels**
SOFTWARE	**SAS**, **R** and **SAS JMP Clinical** to be explored (not exhaustive)
STANDARDS	Data packages for **other intl. regulators** in general accepted Raw data to follow **CDISC standards** (SDTM, ADaM)

Upon completion of the pilot, feedback on adoption of relevant CDISC standards for the submission of raw data will feed into the **EMRN Data Standardisation Strategy's implementation plan**

The way ahead…

Data Standardisation Strategy - Implementation

- Stepwise approach to support NCAs, Network systems and effective change management
- Support collaboration & coordination within the EMRN
- Support work with international regulators on common requirements by clearly setting out the EMRN needs and direction

Submission of structured data in eCTD

- Assess learnings from raw data pilot in 2024
- Quality and manufacturing structured data
- Combine submission data with external RWD

Any questions?

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Back-up slides

Data Standardisation Strategy Recommendations

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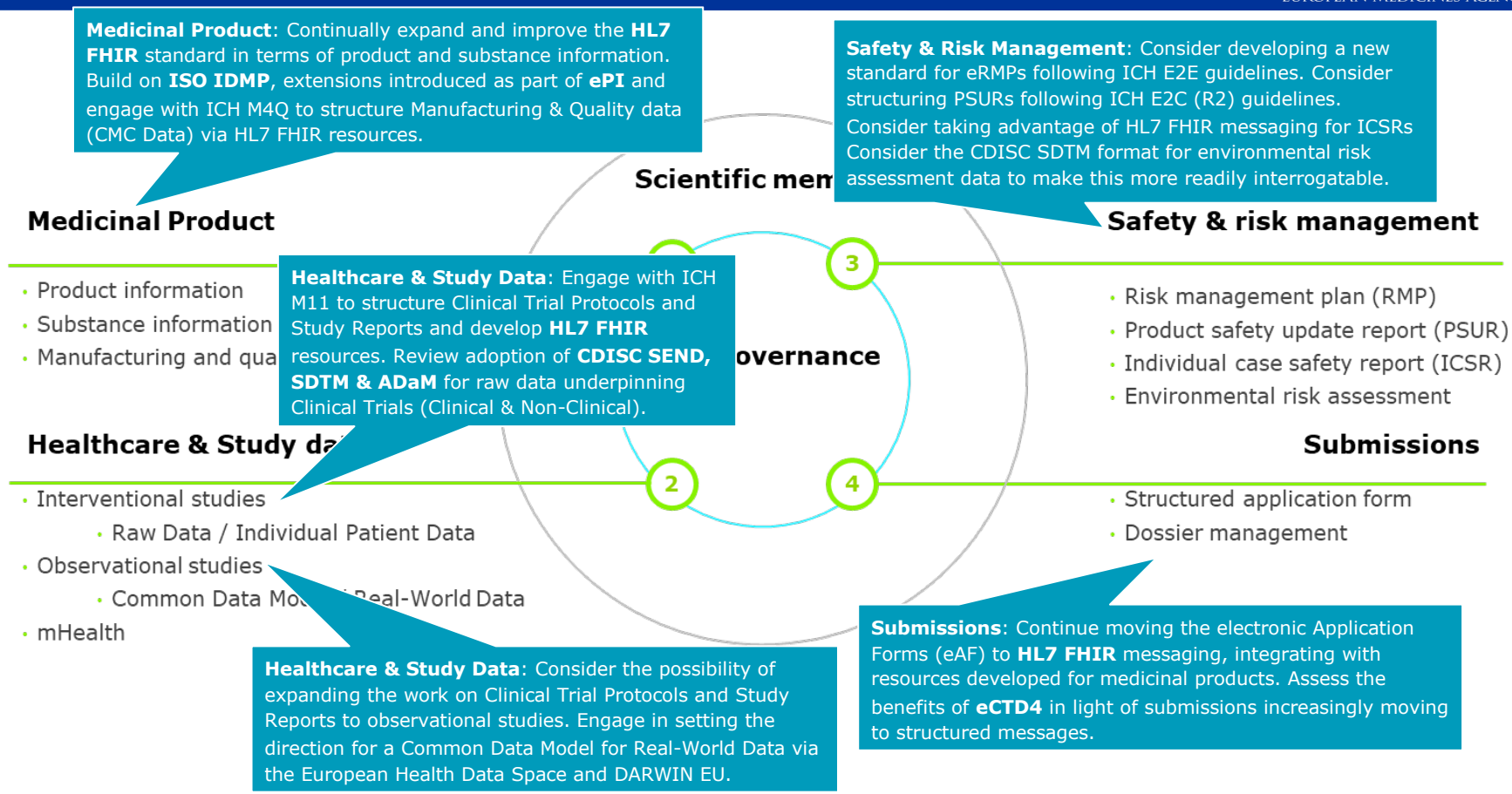

Structured protocol reporting and DSS


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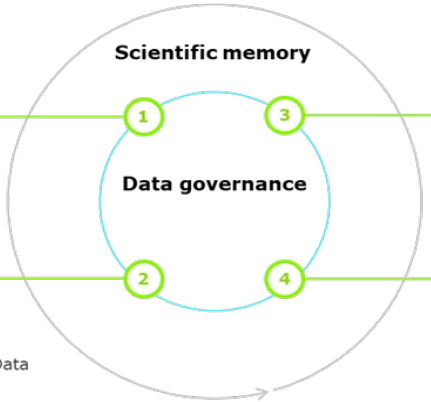
DSS recommendations:

Medicinal Product

- Product information
- Substance information
- Manufacturing and quality

Healthcare & study data

- Interventional studies
  - Raw Data / Individual Patient Data
- Observational studies
  - Common Data Model / Real-World Data
- mHealth



Safety & risk management

- Risk management plan (RMP)
- Product safety update report (PSUR)
- Individual case safety report (ICSR)
- Environmental risk assessment

Submissions

- Structured application form
- Dossier management

Interventional Studies → Structured protocol and reporting

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