EMA Data Standardisation Strategy Stakeholder Workshop (EFPIA/EuropaBIO)

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Data Standardisation: Common Data Model (CDM)

Interconnectivity between Different Networks and Data Sources

★ **Standardised Data Structure**

- Alignment with **regional/international** efforts for a mutually agreed upon CDM Framework leveraging open-source, consensus-based standards (interoperability)
  - Universal query and aggregation of results across a formal CDM network
  - Promote global research and analysis across a distributed network
  - Critical for robust data quality and reliability
    - Requirements for **regulatory acceptability/regulatory grade**
      - Data quality and sources from **regulatory**, **HTAs**, and **payer** perspectives

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Interconnectivity between Different Networks and Data Sources

★ **Internationally accepted data standards (CDISC-SDTM, HL7 FHIR, ISO IDMP, others)**

- ➢ **ADOPT/ADAPT**: Avoid developing custom-made/siloed standards
- ➢ **Avoid duplication** across **regulatory authorities** and **standards development organisations**

★ Leverage data standards recommendations from relevant international organisations

Ex: International Coalition of Medicines Regulatory Authorities (e.g., Track & Trace Systems for Interoperability)

- ➢ **General Implementation Considerations**
  - ❖ Utilise compatible open standards for traceability data
    - **ISO IDMP**: Technical enabler to support interoperability for traceability data
      - Falsified medicines, batch recalls, PV, drug shortages

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Data Standardisation Use Case: Clinical Trial Harmonisation Initiatives

Clinical Trial Harmonisation Initiatives:

- ***ICH M11:*** Clinical electronic Structured Harmonized Protocol (CeSHarP)-Comprehensive clinical protocol organization with standardised content
  - Harmonised template w/ common text, data fields and terminologies for data exchange
  - Technical specification for electronic exchange of clinical protocol information

- **ICH E6(R3):** Good Clinical Practice (GCP) to include Annex for **non-traditional interventional clinical trials** & **real world data** sources

- **TranCelerate** Common Protocol Template (CPT) Initiative
  - Harmonised content, structure, & format w/regulator accepted endpoint definitions via therapeutic area libraries

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Data Standardisation Use Case: Real World Data/Evidence (RWD/RWE)

Requirements / Use Cases in Relation to Data Standards

★ **Real World Data/Evidence**

- Ensure alignment with EMRN 2025-*SFA 3.2*, EMA RSS 2025, and EU Telematics Strategy
  - ★ Inclusive **data standards governance model** for all stakeholders
- Awareness of IMI GetReal Institute Initiatives
- IMI Project-European Health Data & Evidence Network (EHDEN)
  - Trusted open science community built for health data research via a European federated network
  - Launched to address current challenges in generation insights and evidence from real-world clinical data

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Data Standardisation Use Case: Real World Data/Evidence (RWD/RWE)

Requirements / Use Cases in Relation to Data Standards

★ **DARWIN EU: Leverage knowledge, expertise, standards from relevant international RWD initiatives**

- US FDA: Common Data Model Harmonization Project, Sentinel Initiative)
- Other ex-EU HA RWD/RWE initiatives

★ **Flexibility: Support multiple formats and stakeholder use cases**

- Evidence generation across **regulatory**, **HTAs**, **payers**, and **healthcare** domain
- International data standards & CDM harmonisation (e.g., DARWIN EU, FDA Sentinel)
  - Open **stakeholder network access** for analysis
    - Patients, ex-EU HAs, Industry, academia, payers, etc.

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Thank You