ISO/IDMP Initiative: Maturing Structure and Standardization with the Healthcare Ecosystem

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ISO-IDMP Standards and Technical Specifications

Identification of Medicinal Products (IDMP)
Each Standard defines data elements and structures for unique identification and exchange of a certain aspect of a medicinal product.
Implementing a global standard regionally

ICH harmonisation for better health

IDMP spins out of ICH to support improved patient safety to establish data foundation for ICSR

ISO

ISO assumes ownership of (ISO) IDMP and defines standards and implementation guidelines for the global implementation (2010-2018)

FDA

Regional authorities implements in different initiatives based on legislation (2018 →)

EUROPEAN MEDICINES AGENCY

SPOR, xEVMPD, CESP

SPL, PQ/CMC
IDMP Drivers – Pharmacovigilance

Pharmacovigilance – Supported by the concept of Unique Identifiers

Product Level

- Substance
- Pharmaceutical Product
- Primary Packaging
- Secondary Packaging
- Medicinal Product
- Packaged Medicinal Product

Unique Identifiers

- SID
- PHPID
- BAID_2
- BAID_1
- MPID
- PCID

Adverse Events Detection

Taking Measures

- Individual Case Safety Reports (ICSRs)
- Periodic Reports & Analytics

Packaging Leaflet

Recall

Alert
IDMP Drivers – Efficiency

*Improve and unify the exchange of data between the pharma companies and authorities*

Different authorities, same XML structure.

What eCTD is to documents, FHIR is to structured data!
"...the harmonization of global IDMP implementation is a process whereby regulatory recommendations across different countries or regions become aligned over time using international guidance documents, consensus standards, policies, and procedures.”

**FDA Notice 2023-D-0266-0001**

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**Mapping of Data IDMP to CMC – As Applicable**

**CANADA**
- Confirmed commitment to implement IDMP as appropriate in alignment with SPM and adoption of Controlled Vocabularies
- In June 2021, HC initiated Phase II: full production on voluntary basis for XML Structured Product Monographs (SPM), Timeline for mandatory transition under development. Following HL7 SPL and HC CVs

**USA**
- FDA is taking a Modular Approach
- FDA and EMA started a new GIDWG (Global IDMP working group) with WHO-UMC to tackle the problems with global implementation of IDMP – e.g. PhPID and Substance identification
- FDA testing Data Exchange Standards across modules, with alignment to ISO IDMP as appropriate: Module 3 PQ/CMC, Module 4 SEND, Module 5 ICSR E2B(R3), CeSHarP initiative using the Fast Healthcare Interoperability Resources (FHIR) messaging for exchange

**EU**
- EMA is taking an agile approach to IDMP implementation
- The eAF form approach will be aligned with SPOR databases, SIAMED, IRIS, and xEVMPD
- RMS and OMS rolled out and being used, SMS progressing, PMS UAT in progress

**JAPAN**
- Actively participating and the interest is also driven by the connection to the E2B(R3) standard in Pharmacovigilance
- Adoption of ICH Approach to Data Standards and Application

**SWITZERLAND**
- Swissmedic will follow EMA's approach closely, regarding both requirements and timelines

**AUSTRALIA AND SINGAPORE**
- Part of the ACSS consortium
- Following Switzerland and Canada
Key Elements

SPOR Controlled Vocabularies

IDMP is implemented by the EMA through SPOR.

• The SPOR data management services will provide centralized management of master data and controlled vocabularies that comply with the ISO IDMP standards.

• Industry will use the SPOR services and processes for submitting and maintaining master data.

The standardized language for IDMP.

Substance Management Service (SMS)
MDM setup for SUBSTANCE DATA

Product Management Service (PMS)
MDM setup for PRODUCT DATA

Organizations Management Service (OMS)
MDM setup for ORGANIZATIONAL DATA

Referentials Management Service (RMS)
MDM setup for REFERENTIALS or CONTROLLED VOCABULARY
Data compliance journey

*Reference: “Enterprise Ontology” – Theory and Methodology, by Jan Dietz*
Explosion in collected datapoints but inefficient use

The drug development landscape is subject to rapid change, introducing an increasing amount of data sources.

To unlock the full potential of data and automated data flow, it is vital to ensure “data health” by implementing measures that preserve the integrity of the data that is collected.

Simplified representation of data flow through disparate R&D systems.
Industry Vision: Documents to Data – Structured Content

**Current Data Flow** vs **Future Data Flow**

<table>
<thead>
<tr>
<th>Current Data Flow</th>
<th>Future Data Flow</th>
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<tbody>
<tr>
<td>Data generated / received</td>
<td>Data generated / received</td>
</tr>
<tr>
<td>Data captured and updated in multiple documents</td>
<td>Data captured in <strong>databases</strong></td>
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<tr>
<td>Data stored in various systems</td>
<td>Documents are populated from data</td>
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<tr>
<td><strong>Outcome:</strong> a high percentage of data elements remains in documents.</td>
<td><strong>Outcome:</strong> data centric processes enhance data quality and provide a foundation for <strong>large scale analytics and content reuse.</strong></td>
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Example Use Cases for Content Reuse

- Components are reused across different projects and document types
- Components can be edited collaborated on prior to approval
- Change history captures the lifecycle of the component
- Traceability reports are generated to determine “where used” impact across the Content Repository
Example Use Cases for Content Reuse

Content Repository

USPI Negotiation: New Indication

USPI Negotiation: Safety Supplement

Current Approved USPI

FDA Structured Product Label (SPL)

Health Canada Structure Product Monograph (SPM)

EMA electronic Product Information (ePI)

Structured Data Submission (HL7/FHIR): IDMP, PQ/CMC
Data enablement – Empower those who change lives

Enable your R&D data and achieve real business outcomes

<table>
<thead>
<tr>
<th>Enablers</th>
<th>Outcomes</th>
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<tr>
<td><strong>Technology</strong></td>
<td><strong>Informed Decision-Making</strong></td>
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<td>Empower the business</td>
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<td>with the right tools</td>
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<td>and technologies</td>
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<td>to leverage trusted</td>
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<td>data for value-adding</td>
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<td>decision making</td>
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<td><strong>Automate</strong></td>
<td><strong>Inspection readiness</strong></td>
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<td>Automate end-to-end</td>
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<td>processes to breakdown</td>
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<td>silos, increase</td>
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<td>efficiency and reduce</td>
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<td>manual work</td>
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<td><strong>Advanced Analytics</strong></td>
<td><strong>Faster time to market</strong></td>
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<td>Utilize advanced</td>
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<td>analytics to drive</td>
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<td>data causality and</td>
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<td>gain deeper data</td>
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<td>insights</td>
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<td><strong>Predictive Modelling</strong></td>
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<td>Enable predictive</td>
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<td>modelling to optimize</td>
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<td>including outcome</td>
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<td>prediction and resource</td>
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<td>planning</td>
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Unlock the business benefits of data and accelerate the use of emerging technologies

The business benefits can be categorized into three categories; **run the business, grow the business and transform the business.**

- **Run the business**
  - Better decision-making and greater business agility
  - Reduced cost and time savings
  - Improved compliance with regulatory requirements
  - Trustworthy data ensure operational stability
  - Clear data ownership and accountability
  - Breaking information silos

- **Grow the business**
  - Value-adding work only
  - Better reporting
  - Better decision-making and greater business agility
  - Optimized business processes end-to-end
  - Unlocking new markets and business potentials

- **Transform the business**
  - Paperless operations / digitalization
  - Automation and RPA
  - Data hub and data sharing technologies (data lakes, data warehouses)
  - Digital MDM catalog
  - Low-code GxP Apps (Powerplatform)
  - Machine Learning
  - AI
  - NLP
  - Blockchain
  - Software as Medical Device / Digital Biomarkers
  - Data visualization
  - Business Intelligence
  - IOT and sensors
  - HoloLens
Recap

- Global Collaboration
- Product Identification and Safety
- Data and Enterprise Ontologies
- Data from Content within Context
- Easier Adoption of Technology Advancements
Thank You

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