IDMP Ontology
Collaborative Implementation in Pharma

Community of Interest

July 11th, 2023
Sheila Elz, Bayer
Heiner Oberkampf, Accurids
Max Fink, Boehringer Ingelheim
Karsten Quast, Boehringer Ingelheim
Agenda

1. Intro & Recent Highlights
2. Progress Update: IDMP-O Release v0.4
3. Demo: IDMP-O Implementation at Boehringer Ingelheim
4. Outlook Q3: Towards v1.0
5. Open Discussion
   (10 min at the end)
The Problem: Diverging IDMP implementations create more silos and are a risk for envisioned standardization benefits of IDMP for drug safety, innovation and operational efficiency.
The IDMP Ontology provides a universal implementation of the IDMP product data model as a common language to effectively bridge the gap between people, processes, and systems.
Our agile governance framework ensures effective industry alignment.

### IDMP Ontology Executive Advisory Board

**Strategic guidance on long term roadmap (1 every 2 months)**  
Senior executives from founding pharma companies and key industry or regulatory stakeholders.

### Project Steering Team

**Provide direction and make strategic decisions on quarterly project priority tasks** (at least quarterly)  
Sponsoring organizations: Novartis, Roche, Merck, GSK, Boehringer Ingelheim, Johnson & Johnson, Amgen, AstraZeneca, AbbVie, Pfizer, ...  

### Project Core Team

**Collaborate and deliver on project scope and target results** (bi-weekly)  
People assigned from the Steering Team + WS team leads + selected key experts.

### Interested Parties

**Regulatory Agencies**  
G-SRS, EULS, European Medicines Agency (EMA), BfArM, ANVISA, Health Canada, MedWatch, ...  

**Standards Development Organizations**  
SNOMED CT, ISO, CIC, WFIS, ICSH, ...  

**Government Initiatives**  
PH Trade Associations, Projects, ...  

**Not-for-profits**  
Vendors: E.g., Veeva

### Project Community of Interest

**Present project results and insights for a discussion in an open forum of innovators** (every 6 weeks)  
Whole team with an open list of interested people from any organization.

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<tr>
<th>Stream</th>
<th>Project Area</th>
<th>Description</th>
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<td>Ontology Governance &amp; Hosting</td>
<td><strong>EDMCouncil</strong></td>
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<td>Use Case Implementation</td>
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<td>Value Capture &amp; Use Case Specification</td>
<td><strong>OSTHUS</strong></td>
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### Project Lead & Management

Gerhard Noelken, Sheila Elz, Heiner Oberkampf, Jan Kroh, Ivana Miljkovic

Pistola Alliance

Agile Project Organization  
Marketing Communication  
Stakeholder Management
Recent Highlights

1. Release IDMP-O v0.4 including first concepts around Therapeutic Indication and significant augmentations of the substance and medicinal product module

2. ISO/AWI TS 21405 “Health Informatics — Identification of Medicinal Products — Methodology and Framework for the Development and Representation of IDMP Ontology” – with project leads Sheila Elz, Vada Perkins

3. IDMP-O presentation at DIA Global, Boston
Ontology Progress Report
With each iteration, the IDMP-O covers more of the ISO IDMP standards, can answer more competency questions, is tested across more data (examples, public data, private data) and has been reviewed by more experts.
IDMP-Ontology use cases ... drive the coverage of ISO IDMP

- **Substance Identification and Roles**
  Active moiety, ingredient strength & chemical groupings

- **Regulatory and Manufacturing**
  Enabling interoperability between manufacturing (bottom-up) and IDMP/labelling (top-down) perspective

- **Therapeutic Indication**
  Linking medication to clinical particulars

- **Jurisdiction-agnostic Medicinal Products**
  Global Medicinal product that industry can refer to without any regulatory-specific data

- **Falsified Medicines Directive**
  Integrated data for mandatory EMA reporting

- **Pharmacovigilance**
  Global Impact Assessment of Safety Risks Across the Product Life-Cycle

- **Clinical and Regulatory**
  Enabling interoperability between ClinOps and Regulatory incl. reference to CDISC

**July 11, 2023**

The IDMP Ontology | Community of Interest
Ontology Development Progress

**Version**

**New concepts, patterns**

- Therapeutic indication, contraindications etc.
- Medical conditions
- Link to MedDRA
- Pharmaceutical dose forms
- EDQM terminologies
- Completed coverage of ISO 11238 Annex L

**Refinements of concepts and patterns**

- Substance
  - significant additions for non-chemical substances
  - Substance classifications based on defining characteristics
  - Substance relations, e.g., isotopes
  - molecular representations
- Complete set of ingredient roles
- Packaged and authorized medicinal product

**Release v0.4**

July 10, 2023

*Release Notes: [https://wiki.edmcouncil.org/display/IDMP/Release+Notes+0.3.0](https://wiki.edmcouncil.org/display/IDMP/Release+Notes+0.3.0)
Coverage of ISO Standards today and potential for v1.0 in 2023

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<tr>
<th>Ontology Module</th>
<th>Ontology-relevant terms in ISO IDMP*</th>
<th>Coverage July 2023 IDMP-O v0.4</th>
<th>Potential Coverage Dec 2023 IDMP-O v1.0</th>
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<td><strong>Ontology Foundation:</strong> Basic patterns</td>
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<td><strong>Substance:</strong> ISO-11238, TS19844, Annex L</td>
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<td><strong>Ph. Dose Forms:</strong> ISO-11239</td>
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<td><strong>Harmonized Datatypes:</strong> ISO-21090</td>
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<td>100%</td>
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<td><strong>Augmentations:</strong> e.g., Manufacturing</td>
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<td>n.a.</td>
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*Note that there are several terms which are defined in multiple of the ISO standards. These terms are increasing the count for each of the standards where they appear. In IDMP-O the term may be covered only once and reused by other modules.
Getting Started with the IDMP Ontology


Wiki with Infor on IDMP Ontology and Releases:
[https://wiki.edmcouncil.org/display/IDMP/](https://wiki.edmcouncil.org/display/IDMP/)
[https://wiki.edmcouncil.org/display/IDMP/IDMP+Ontology+Releases](https://wiki.edmcouncil.org/display/IDMP/IDMP+Ontology+Releases)

**IDMP Ontology Viewer:** Public Reference Browser
[https://spec.edmcouncil.org/idmp/ontology](https://spec.edmcouncil.org/idmp/ontology)

**Git Repository:** Public IDMP Ontology source files
[https://github.com/edmcouncil/idmp](https://github.com/edmcouncil/idmp)

**Accurids:** IDMP Data Registry to answer competency questions by business users
[https://pistoiaalliance.dev.accurids.com/](https://pistoiaalliance.dev.accurids.com/)
IDMP Knowledge Graph: IDMP Ontology + IDMP Data Graph

Testing the ontology along concrete use cases and data

IDMP Ontology

Formal semantic definition of concepts, relationships and attributes from the ISO IDMP standards.

- A few hundred concepts
- Need accurate and agreed patterns

IDMP Data Graph

Any data object that are described by the concepts of the IDMP Ontology

- Many millions of objects
- Our test data

Enable business users to answer questions

What substances have a common active moiety?
Which products contain titanium dioxide?

YOUR USE CASE
Implementation of IDMP-O at Boehringer Ingelheim X IDMP-O
Outlook Q3

• Support further pharma implementations and use of IDMP-O for
  – Jurisdiction-agnostic Medicinal Products
  – Falsified Medicines Directive

• Completion of the use case 3 on Therapeutic Indication

• FHIR / IDMP-O interoperability PoC for 3 FHIR resources
  SubstanceDefinition, AdministrableProductDefinition, Ingredient

• Alignment of additional public data sources to IDMP-O

• Enhancement of IDMP-O documentation

• Alignment on priorities and scope for Phase 3 in 2024
Upcoming In-Person Events

**F2F Project Workshop**  
September 5th, Aachen, Germany

**GPRAS Conference**  
October 23-25th, Brussels, Belgium

**Pistoia Alliance, Annual Meeting**  
November 14-15th, Boston, US
How to get involved?

Open invitation to everybody to collaborate

1. Reach out and schedule an intro call: melih.tuzunoglu@pistoiaalliance.org
2. Connect to 11 pharma companies, health regulators and tech providers
3. Get feedback on your own IDMP use case to evaluate how the solution fits your needs
4. Join the project and implement IDMP-O in your organization
Discussion
IDMP Ontology
Collaborative Implementation in Pharma