



IDMP Ontology—Bridging Pharma Efficiency

How to implement an external ontology — factors & scenarios

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AMGEN

IDMP Ontology—Bridging Pharma Efficiency

Efficiency Goals

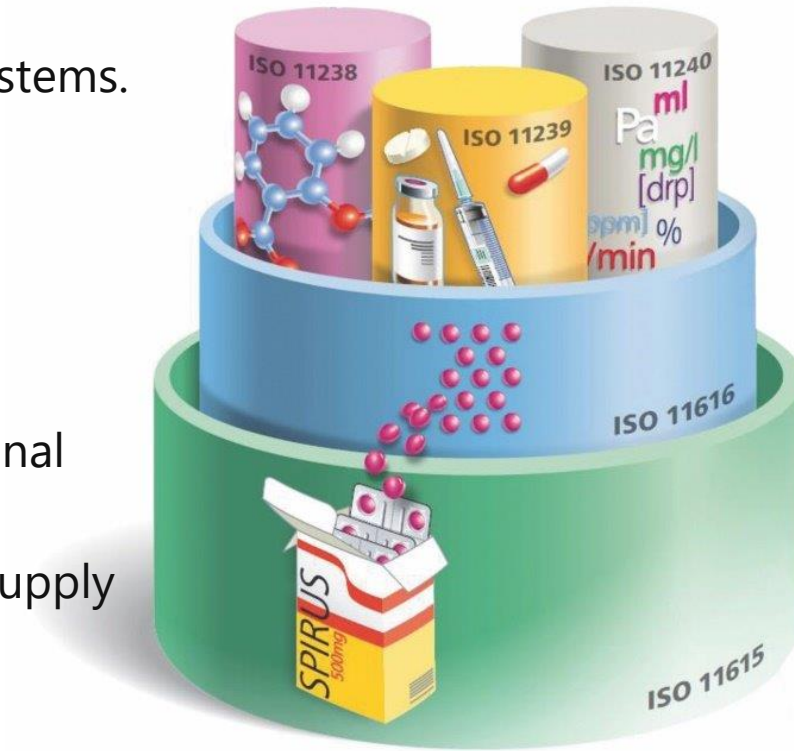
1. Pharmaceutical companies seek ways to optimize their processes.
2. Internally, they are seeking streamlined data consolidation within their systems.
3. Externally, they are seeking efficient exchanges of data with partners, manufacturers, health authorities, and healthcare professionals.

IDMP-O in a Nutshell

1. It's the first semantic framework representing the ISO IDMP standards.
2. It provides a common language—a Rosetta Stone—for describing medicinal products globally.
3. It is the basis for a digital ecosystem where product safety, efficacy, and supply chain transparency converge.

Impact:

1. **Efficiency Boost:** By adopting IDMP-O, we simplify complex processes.
2. **Safety Enhancement:** Clear identification of products prevents errors.
3. **Industry Connectivity:** Collaboration across stakeholders becomes more efficient and timelier.



Identification of Medicinal Products
IDMP

Implementing the IDMP Ontology

What's to consider and be aware of?

Our Quest: *We seek the most appropriate implementation approach — one that aligns with our business use cases and existing data infrastructures and aligns with external standards*



What's to consider and be aware of?

Complexities to Address

- Diverse Internal Data Models: Harmonizing data across departments.
- Regional Variations: Navigating differences in interpretation.
- Alignment with External Standards: Ensuring compatibility with UV-PQ/CMC and FHIR.
- Strategic Approach:
 - We'll delve into strategies that enhance efficiency and promote semantic interoperability.

IDMP implementation isn't just compliance; it's an opportunity for transformation.

Takeaway: *Understanding these complexities will pave the way for successful IDMP adoption.*

Considerations to Guide the IDMP-O Implementation Strategy

Primary Goals: Define specific objectives, use cases, and business needs.

Alignment with Data Strategy: Ensure compatibility with existing data principles and analytics requirements.

Business-Relevant Data Domains: Prioritize data domains most relevant to the business use case.

Ontology Model Compatibility: Assess how existing ontology models align with IDMP-O semantics and structure.

Data Domain Understanding: Understand internal data domains and gaps.

Compliance and Standards: Understand the compliance requirements of IDMP and other external standards.

Data Interoperability: Evaluate how IDMP-O can enhance data interoperability.

Scalability: Plan for data architecture growth.

Impact on Data Governance: Consider how the IDMP-O implementation affects data governance and data quality processes.

Resource Implications: Evaluate time, personnel, and budget needs.



IDMP Ontology Implementation Factors

What Implementation Strategy is right for you?

Existing Data Ecosystem Maturity: A company's data ecosystem maturity impacts IDMP implementation.

Advanced Semantic Data Fabric:

- *Prioritize seamless IDMP integration and alignment with existing semantic data models.*

Less Mature Data Ecosystem

- *Start fresh without legacy constraints.*
- *Deploy the IDMP ontology as a foundational element.*

Business Use Cases:

- *Understand critical business outcomes and desired capabilities.*
- *Tailor implementation strategy to specific use cases.*
- *Consider existing data ecosystem maturity.*

Alignment with External Standards:

- *Influences effective IDMP implementation.*
- *The approach varies based on ecosystem complexity.*
- *Prioritize semantic interoperability considerations.*



IDMP Ontology Implementation Scenarios

What Implementation Strategy is right for you?

Option 1: Do not leverage IDMP-O but revise the existing ontology models

Approach:

- Embark on a thorough exploration of the existing ontology models across data domains.
- Understand the business concepts and their inter-relationships and
 - refactor/refine the human-readable business concept definitions.
 - align without directly leveraging the IDMP-O

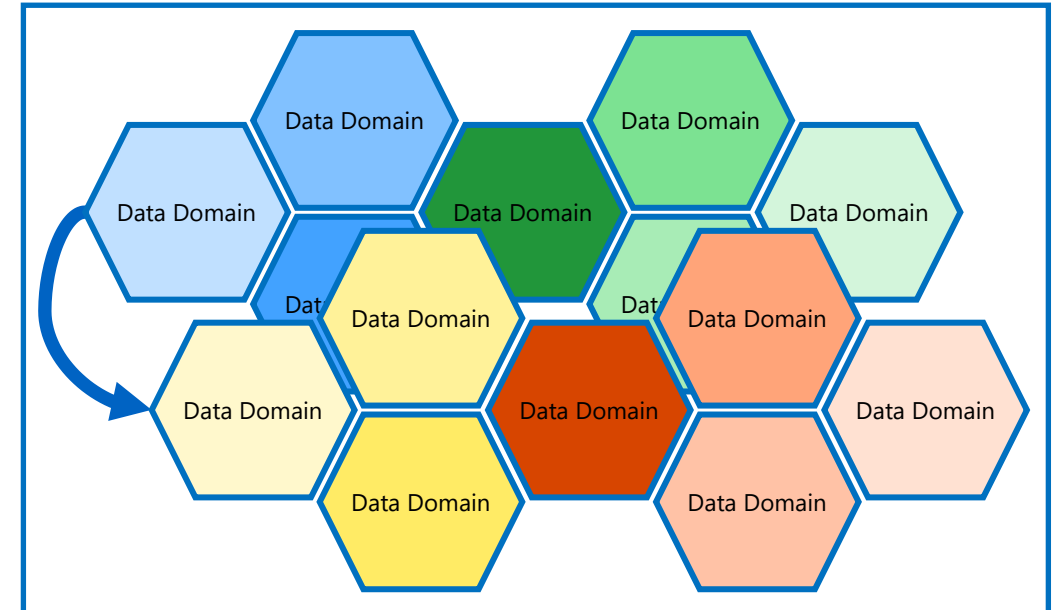
Pros:

- Quicker Time-to-Value — building upon existing data models, implementation may be faster.
- Avoiding IDMP-O complexities — steering clear of an evolving IDMP-O may simplify the implementation.

Cons:

- Pistoia Alliance Membership Justification — no return on investment (ROI).
- Lack of IDMP-O semantics — waving the opportunity to benefit from IDMP-O's rich semantics.
- Limited Semantic Interoperability — models may lack the full semantic richness needed for seamless integration.

Data Domain Models



IDMP Ontology Implementation Scenarios

What Implementation Strategy is right for you?

Option 2: Directly implement the IDMP-O into an existing semantic data ecosystem

Approach:

- Analyze IDMP-O terminological semantics.
- Map and align to IDMP-O constructs.

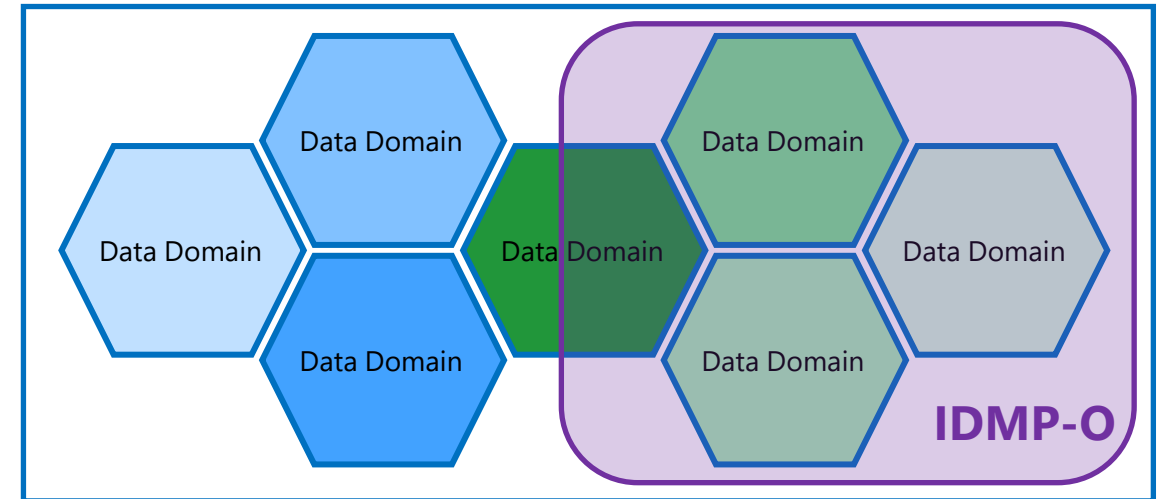
Pros:

- IDMP-O adoption supports precision model semantics.
- Facilitates IDMP alignment.
- Promotes semantic interoperability.

Cons:

- Mapping and aligning with IDMP-O may lead to a slower time-to-value.
- Integration challenges with the existing data architecture.
- IDMP-O updates require repeated refactoring.

Data Domain Models



IDMP Ontology Implementation Scenarios

What Implementation Strategy is right for you?

Option 3: Use IDMP-O semantics to inform the existing ontology models and a Normalized Model in an App Repo

Approach:

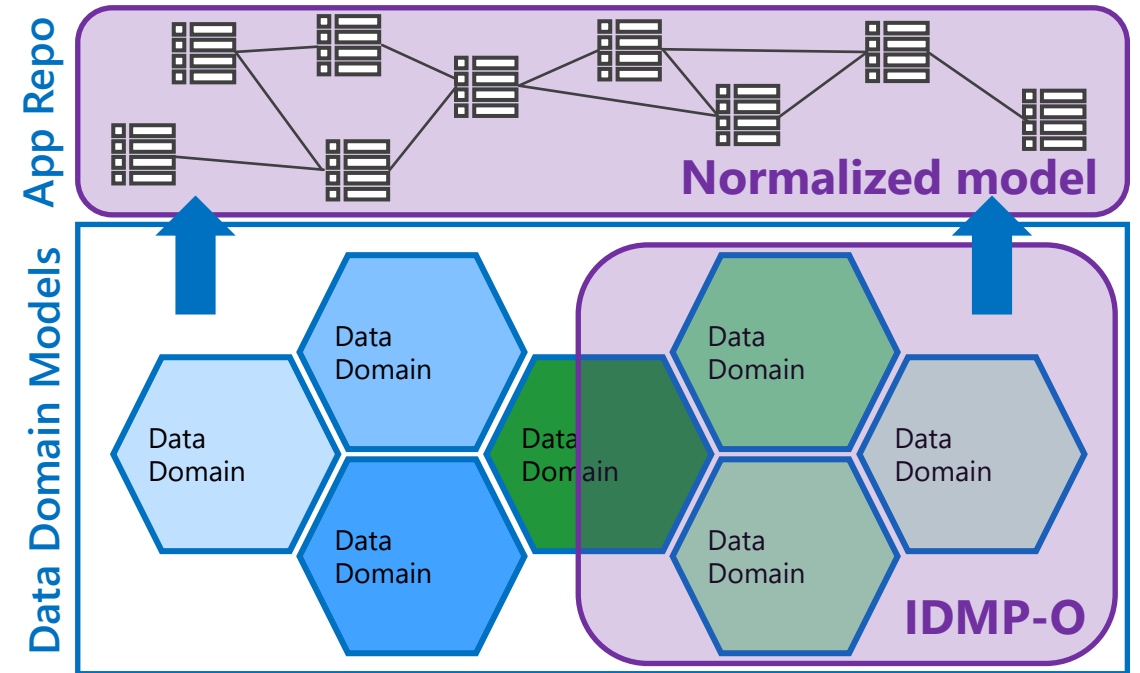
- Identify relevant IDMP-O terminology.
 - Where alignment exists, incorporate IDMP-O semantics into existing business concept definitions.
 - Refactor data domain ontology models accordingly.

Pros:

- Best of Both Worlds — combining IDMP-O semantics with existing data models.
- Enhanced Alignment — where appropriate it facilitates alignment with IDMP-O.
- Promoting Semantic Interoperability — data models become more interoperable.

Cons:

- Slower Implementation Effort — refactoring across data domains demands significant effort & resources.
- Staying Agile with the IDMP-O — IDMP-O updates require repeated refactoring.



IDMP Ontology Implementation Scenarios

Why Option 3 may be the best option for Amgen?

Modularity & Flexibility

- A normalized model within an App Repo achieves modularity.
- Changes to IDMP-O & external standards won't impact existing data models.
- A normalized model can be updated independently, ensuring flexibility and adaptability.

Isolation from Volatility

- External standards evolve.
- A normalized model acts as a buffer, shielding core data models from changes.
- Updates to a normalized model can be more deliberate, minimizing disruptions.

Focused Use Cases

- A normalized model can be tailored specifically for IDMP-related use cases.
- A normalized model captures the essential semantics needed for compliance with IDMP standards.
- Existing data models remain stable/durable for broader business needs.

Semantic Clarity

- A normalized model can express IDMP concepts precisely using OWL 2 DL or other formalisms.
- This clarity aids in understanding and ensures semantic consistency.
- It avoids a growing complexity of existing data models.

Interoperability and Integration

- A normalized model serves as a bridge between IDMP-specific semantics and a broader data ecosystem.
- A normalized model facilitates integration with other systems, both internal and external.
- IDMP concepts can be mapped to existing data models where relevant.

Future-Proofing

- As external standards evolve, a normalized model can be gradually aligned.
- If IDMP-O undergoes significant changes, one can adapt without disrupting existing systems.
- An existing data ecosystem remains robust and future-proof.

A normalized model balances IDMP compliance with safeguarding existing data models against volatility, without creating semantic silos for specific use cases.

Summary

1. The IDMP Ontology is the first semantic framework representing the ISO IDMP standards.
2. IDMP-O provides a common language for describing medicinal products globally.
3. Implementing IDMP-O requires consideration of diverse internal data models, regional variations, and alignment with external standards.
4. A successful IDMP implementation strategy involves defining specific objectives, ensuring compatibility with existing data principles, prioritizing relevant data domains, and assessing how existing ontology models align with IDMP-O semantics.
5. IDMP implementation scenarios include revising existing ontology models, directly implementing IDMP-O, or using IDMP-O semantics to inform existing ontology models and a normalized model in an App Repo.
6. A normalized model within an App Repo balances IDMP compliance with safeguarding existing data models against volatility and facilitates semantic interoperability.