



**Technical
Specification**

ISO/TS 21405

**Health informatics — Identification
of medicinal products —
Methodology and framework for the
development and representation of
IDMP ontology**

*Informatique de santé — Identification des médicaments
— Méthodologie et cadre pour le développement et la
représentation de l'ontologie IDMP*

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

ISO 11615, ISO/TS 20443, ISO/TS 20451, ISO 11238, ISO/TS 19844, ISO 11239, ISO/TS 20440, and ISO 11240 are the ISO Standards and Technical Specifications which together provide the basis for the unique identification of medicinal products (IDMP). These documents present an opportunity to create global data interoperability for the unambiguous identification of medicinal products. However, implementations of IDMP by various IDMP stakeholders across jurisdictional domains are not fully standardized or harmonized and risk inconsistency of interpretation. A uniform approach is needed so that the envisioned benefits from IDMP in drug safety, innovation, regulatory, and other areas can be fully realized.

This document proposes an ontological framework for IDMP to provide the overarching structure and principles for organizing knowledge within the domain of unambiguous identification of medicinal products. Such a framework can provide the necessary foundation for global data interoperability through a set of concepts, formal definitions and other metadata, their properties, the relations between them, and the logical expressions that disambiguate them. This IDMP ontological framework complements the existing conceptual models defined in the ISO documents on IDMP.

An IDMP ontology instantiates the principles represented in the IDMP ontological framework through a particular representation of this domain knowledge. Furthermore, an IDMP ontology provides formal semantic definitions for IDMP concepts that allow auto-classification and linkage of IDMP data and detection of data issues and decrease the potential for misinterpretations and incorrect reporting.

The modelling of IDMP standards in the form of an open ontology requires the application of a set of rigorous processes combined with various technology components, which together form a collaborative ontology development structure. This framework includes feedback loops to IDMP stakeholders and interested parties, including regulators and standards development organizations (SDOs), to ensure the relevant level of governance for the accurate representation of IDMP standards representation.

Furthermore, considering the current global initiatives towards data interoperability, this ontological framework aims to leverage and support those initiatives towards the common goal of cross-jurisdictional unambiguous identification of medicinal products.

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Health informatics — Identification of medicinal products — Methodology and framework for the development and representation of IDMP ontology

1 Scope

This document describes a standardized methodology and framework for the development and representation of an ontology that supports a global, open-source approach to implementing the ISO standards on the identification of medicinal products (IDMP) (ISO 11615, ISO/TS 20443, ISO/TS 20451, ISO 11238; ISO/TS 19844, ISO 11239, ISO/TS 20440, and ISO 11240). Realization of the full potential of IDMP requires fully self-describing data. For this purpose, this document describes a methodology and framework that complements the existing conceptual and logical models in the ISO documents on IDMP with an IDMP ontology that enables deep, semantic interoperability based on findable, accessible, interoperable and reusable (FAIR) data principles. This methodology and framework enhance the usage of the IDMP data model as the foundation of medicinal product identification and will ultimately enable collaboration towards drug safety and overall operational efficiency.

This document also describes a methodology for the agile adaptation of the ISO documents on IDMP in connection with cross-jurisdictional IDMP-related legislation and initiatives. This document is intended to be complementary to and independent from formal regulatory guidance. Thus, it enables cross-jurisdictional consistency and supports stakeholders in their regional implementations of IDMP standards. This document does not mandate any specific ontology as an implementation tool, nor is it an instructional guideline on how to build ontologies, which is out of scope of this document.

This document includes key use cases described in the ISO documents on IDMP ISO 11615, ISO 11238 and ISO/TS 19844, as well as further use cases arising from the comprehensive deployment of the ISO documents on IDMP via an ontological framework. Thus, an ontology that represents the IDMP standards aims to cover the complete collection of ISO standards on IDMP regarding key interoperability issues that implementing stakeholders are facing.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1 axiom

statement that is taken to be true, to serve as a premise for further reasoning

Note 1 to entry: Axioms may be formulated as natural language sentences or as formulae in a formal language. In the Web Ontology Language (OWL) community, 'Axiom' is used to refer to statements that say what is true in the domain that are 'basic' in the sense that they are not inferred from other statements.

[SOURCE: ISO/IEC 21838-1:2021, 3.9]

3.2

chemical class

grouping that relates chemicals by similar features

Note 1 to entry: Chemicals can be classified by their structure (e.g. hydrocarbons), uses (e.g. pesticides), physical properties [e.g. volatile organic compounds (VOCs)], radiological properties (e.g. radioactive materials), or other factors.

Note 2 to entry: Adapted from Reference [18].

3.3

competency question

query that represents requirements in the form of questions

Note 1 to entry: An *ontology* (3.12) is required to answer competency questions.

Note 2 to entry: Adapted from Reference [19].

3.4

concept

unit of knowledge created by a unique combination of characteristics

[SOURCE: ISO 1087:2019, 3.2.7, modified — Notes to entry removed.]

3.5

conceptual model

description of common *concepts* (3.4) and their relationships, particularly in order to facilitate exchange of information between parties within a specific domain of healthcare

[SOURCE: ISO/TS 18864:2017, 3.6]

3.6

functional group

in organic chemistry, any substituent or moiety in a molecule that causes the molecule's characteristic chemical reactions

Note 1 to entry: Adapted from Reference [20].

3.7

international nonproprietary name

INN

generic name

globally recognised unique name of pharmaceutical substance and active pharmaceutical ingredient

Note 1 to entry: International nonproprietary name (INN) facilitates the identification of pharmaceutical substances or active pharmaceutical ingredients.

Note 2 to entry: In principle, INNs are selected only for the active moiety of the molecule, which is usually the base, acid, or alcohol.

Note 3 to entry: Each INN is public property.

Note 4 to entry: Adapted from Reference [21].

3.8

international nonproprietary name modified

INN_M

extension of *international nonproprietary name (INN)* (3.7) including inactive moiety of the molecule

EXAMPLE While oxacillin and ibufenac are INNs, oxacillin sodium and ibufenac sodium are INN_Ms designating their salts in the name.

Note 1 to entry: Adapted from Reference [21].

3.9

knowledge graph

graph representation of structured knowledge on *concepts* (3.4) and relationships between them

Note 1 to entry: A knowledge graph can comprise an *ontology* (3.12) and data related to the ontology.

Note 2 to entry: A knowledge graph can be represented as a collection of triples, with each triple (head, tail, relation) denoting the fact that relation exists between head entity and tail entity.

[SOURCE: ISO/IEC 5392:2024, 3.14]

3.10

logical model

information model that specifies the structures and relationships between data elements but is independent of any particular technology or implementation environment

[SOURCE: ISO 13972:2022, 3.1.8, modified — The preferred term “logical information model” was removed.]

3.11

metadata

record containing a description of a resource

[SOURCE: ISO 24622-1:2015, 2.10, modified — The preferred terms “metadata record” and “metadata description” were removed.]

3.12

ontology

formal, explicit specification of a shared conceptualization

Note 1 to entry: An ontology typically includes definitions of *concepts* (3.4) and specified relationships between them, set out in a formal way so that a machine can use them for reasoning.

Note 2 to entry: An ontology provides a comprehensive description of terminology, concepts, and nomenclature; outlines the relationships among and between concepts and individuals; and includes statements that clarify concepts, refine definitions, and specify relationships (such as constraints, restrictions, and regular expressions) relevant to a particular domain or area of interest.^[22]

Note 3 to entry: Conceptualization is meant to denote the objects, concepts, and other entities that are presumed to exist in some area of interest and the relationships that hold them.^[23]

[SOURCE: ISO 25964-2:2013, 3.57 modified — Note 1 to entry was changed, Notes 2 and 3 were added.]

3.13

provenance

information on the place and time of origin, derivation or generation of a dataset, proof of authenticity of the dataset, or a record of past and present ownership of the dataset

[SOURCE: ISO/IEC 11179-33:2023, 3.11]

3.14

regression test

test type used following modifications to a test item or to its operational environment, to identify whether regression failures occur

Note 1 to entry: Adapted from ISO/IEC/IEEE 29119-1:2022, 3.64.

3.15

use case

description of behavioural requirements of a system and its interaction with a user

Note 1 to entry: A use case describes the users' goal and the requirements including the sequence of interactions between users and the system.

[SOURCE: ISO/IEC/IEEE 26515:2018, 3.15]

3.16

user story

simple narrative illustrating a user requirement from the perspective of a persona

[SOURCE: ISO/IEC/IEEE 26515:2018, 3.16]

3.17

vocabulary

terminological dictionary that contains designations and definitions from one or more domains or subjects

[SOURCE: ISO 1087:2019, 3.7.5, modified — Note 1 to entry was removed.]

4 Benefits of an ontological approach for IDMP

4.1 General

The provision of a shared vocabulary and a common understanding of concepts and relationships (conceptual model) enables information to be shared and reused across different applications and domains. In a logical model, relationships and data structures are further specified. Ontologies can facilitate interoperability even further by providing a formal framework for querying, reasoning and inference, which enables automated processing of information based on logical rules and constraints. [Figure 1](#) shows the differences between vocabulary, conceptual model, logical model and ontology, demonstrating an increased semantic enrichment at each upper level.

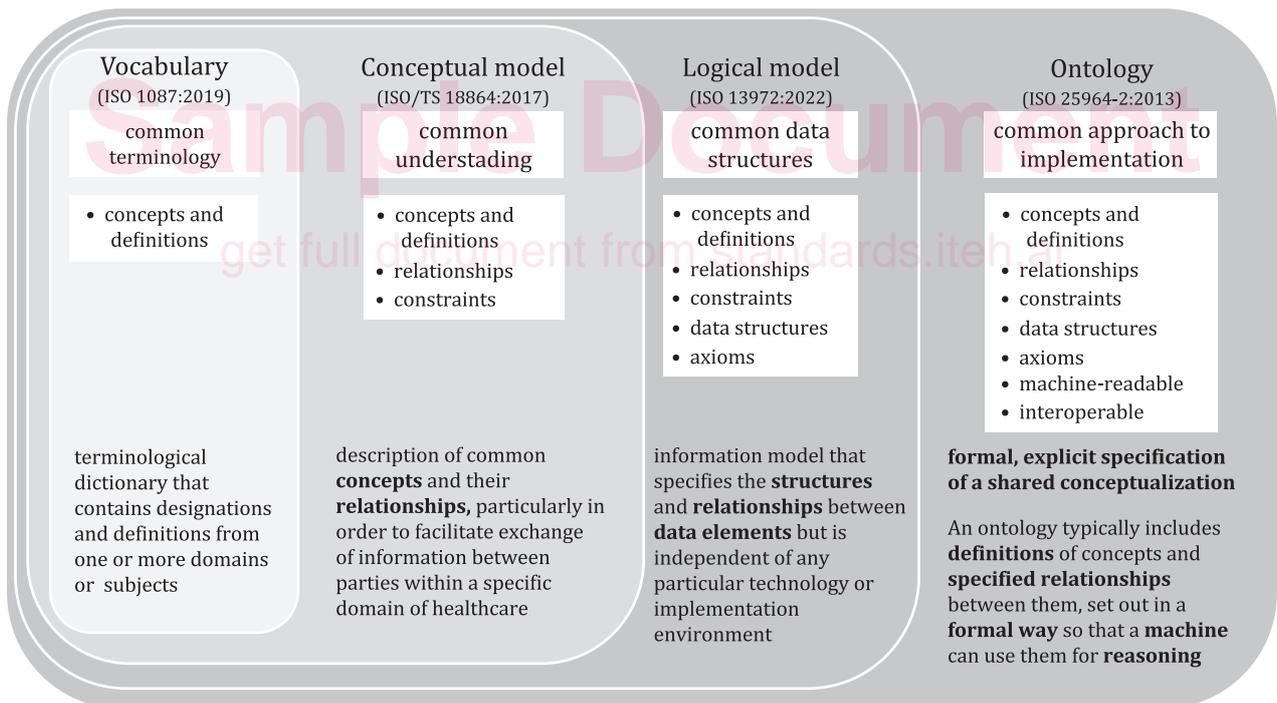


Figure 1 — Differences in semantic richness between vocabulary, conceptual model, logical model, and ontology

4.2 Recommended methodology for collaborative IDMP ontology development – Ontology governance in a collaborative ontology development framework

Governance in the context of ontology-related work provides a set of rules, policies, and procedures for managing the ontology development process, and is thus critical to the success of collaborative ontology development. It ensures that all involved stakeholders work effectively towards common goals, and that the resulting ontology is consistent, accurate, and useful. The framework for overall development of an IDMP

ontology is the set of ISO standards on IDMP and related standards on their implementation. Extensions to that framework supporting the development of the IDMP ontology described herein include:

- development guidelines and policies^[24];
- common, standardized modelling patterns^[25];
- methods for mapping the ontology to reference as well as internal pharma company data to prove the efficacy and interoperability of the ontology^[26];
- sample data and queries for regression testing^[27];
- a continuous integration (CI) and continuous delivery (CD) environment supporting global development collaboration^{[28][29]}.

The methodology supported herein adheres to the policies and guidelines, follows best practices in ontology engineering, including development of key use cases and scoping competency questions as described in [Clause 5](#), and extends best practices using this framework for collaborative development, evolution, and maintenance.

Important governance requirements in collaborative ontology development, which can also be beneficial in ensuring the wide adoption of ISO standards on IDMP, include the following.

- **Standardization:** Ontology governance ensures that all ontology developers follow the same standards, naming conventions, and modelling methodologies, making it easier to integrate and share ontologies across different systems and other ontologies.
- **Quality Assurance:** Ontology governance provides guidelines for verifying the accuracy and completeness of the ontology, ensuring that it meets the needs of its intended users, and that it is free of errors and inconsistencies. It also provides a feedback mechanism that is required for continuous improvement and for any incident requiring immediate attention.
- **Collaboration:** Ontology governance encourages collaboration and communication among ontology developers, helping them to identify and resolve issues, share knowledge, and ensure that the ontology is aligned with the needs of its stakeholders and business area.
- **Management:** Ontology governance provides a framework for managing the development and maintenance of the ontology, including versioning, change management, and release management.
- **Sustainability:** Ontology governance helps to ensure the sustainability of the ontology by providing guidelines for ongoing maintenance and updates and ensuring that the ontology remains relevant and useful over time.

4.3 Governance structures in ontology development and maintenance in alignment with the ISO standards on IDMP

Decisions regarding ontology modelling and adaptations can be made by an executive board consisting of standards development organizations, e.g. ISO, HL7 FHIR, regulatory agencies, pharma representatives and further stakeholders, to ensure their alignment. These changes can be related to e.g. emerging requirements, IDMP model clarification, controlled vocabularies, cardinalities and other constraints, and implementation lessons learned, and include updates due to results of the systematic reviews of each of the ISO standards on IDMP. These are implemented and documented in the IDMP ontology in an agile manner. In addition, end-to-end testing for quality assurance and regression tests are performed throughout the ontology development process, to identify any errors in syntax, logic, potential performance issues, missing content required by development policies and guidelines, and other quality-related issues.

5 Use cases for an IDMP ontology

5.1 Practical applications of IDMP ontology in regulatory frameworks

The overarching goals of integrating and managing product data within an organizational framework encompass a variety of critical business questions that need answers to ensure operational efficiency and compliance. The unambiguous identification of medicinal products is vital for gaining and maintaining oversight of the various identifiers involved in the manufacturing and regulatory processes. This clear identification and linkage of product information entities to their medicinal products and manufactured items are crucial for streamlining manufacturing operations, increasing quality and responsiveness, and ensuring a smooth supply chain, and promoting patient safety at the end of the supply chain.

Furthermore, establishing a robust association between the internal and external identifiers required for product data submission is essential for regulatory compliance and efficiency. By simplifying product data management processes, the goal is to increase overall performance and reduce the occurrence of errors, which can have far-reaching implications for both safety and compliance. Improving data best practices is another key objective, ensuring that the organization's data management strategies are aligned with industry standards and across the industry domain. This includes enabling an automation strategy to reduce manual interventions and increase reliability across all aspects of product data management.

An IDMP ontology also aims to unlock advanced analytics potential, particularly in the realm of pharmacovigilance, where the ability to analyse data effectively can lead to significant improvements in signal detection, and consequently patient safety and product quality. The use of an IDMP ontology as a data fabric will enhance multi use case support, increasing the high precision required in the representation of scientific knowledge. Using its natural property of modularity, this ontology will support different pharmaceutical industry use cases and processes ensuring a constant alignment with IDMP specifications.

The use of an IDMP ontology should be thoroughly tested end-to-end with publicly available data as well as internal pharma company data to prove its efficacy. The ISO standards on IDMP being revised on a regular basis, there is a need to ensure a continuous testing with any further revisions for regular checks on backwards compatibility.

With regards to some key quality assurance criteria, the creation of an IDMP ontology requires the establishment of internal, organization-specific set of testing to ensure each new version of the ISO standards on IDMP results in a smooth integration and careful assessment of the potential impacts. This can be achieved by setting-up a regression testing, a testing regarding syntactic pitfalls, to maintain backwards compatibility by analysing the impact of the changes. The setting of acceptance criteria for assessing the quality and completeness of the ontology and ensuring it meets regulatory requirements and interoperability standards will depend on the level of criticality of the IDMP ontology and the systems using it (e.g. GxP, non-GxP). This way the quality of the ontology is ensured and sustainable for the organization, ensuring a continuous support of the evolving use cases.

Exemplary use cases specific to the application of an IDMP ontology are described in [5.2](#), [5.3](#), [5.4](#), [5.5](#), and [5.6](#).

5.2 Identifying substances, pharmaceutical and medicinal products unambiguously

5.2.1 Use case 1 (UC1): Ensuring unambiguous identification of substances

For the representation of the ISO standards on IDMP in an ontological format, an important use case to consider is that of the unambiguous identification of substances. It emphasizes the importance of establishing a robust, interoperable framework that enables the consistent and accurate classification of substances in medicinal products. An IDMP ontology facilitates a unified structure for medicinal product information, thus supporting regulatory compliance and enhancing the efficiency and reliability of data-sharing across borders and contributing to improved patient safety.