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Health informatics - Identification of medicinal products - Methodology and framework for the development and representation of IDMP ontology (ISO/TS 21405:2026)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 07/26

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English Version

Health informatics - Identification of medicinal products - Methodology and framework for the development and representation of IDMP ontology (ISO/TS 21405:2026)

Informatique de santé - Identification des médicaments - Méthodologie et cadre pour le développement et la représentation de l'ontologie IDMP (ISO/TS 21405:2026)

Medizinische Informatik - Identifikation von Arzneimitteln - Methodik und Rahmenbedingungen für die Entwicklung und Darstellung der IDMP-Ontologie (ISO/TS 21405:2026)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Ref. No. CEN ISO/TS 21405:2026 E

Contents

Page

European foreword

This document (CEN ISO/TS 21405:2026) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

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The text of ISO/TS 21405:2026 has been approved by CEN as CEN ISO/TS 21405:2026 without any modification.

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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Contents

Page

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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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.

Technical Specification **ISO/TS 21405:2026(en)**

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.