



**SLOVENSKI STANDARD**  
**SIST-TS CEN/TS ISO 21405:2026**

**01-julij-2026**

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**Zdravstvena informatika - Identifikacija medicinskih izdelkov - Metodologija in okvir za razvoj in predstavitev ontologije IDMP (ISO/TS 21405:2026)**

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

Medizinische Informatik - Identifikation von Arzneimitteln - Methodik und Rahmenbedingungen für die Entwicklung und Darstellung der IDMP-Ontologie (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)

**Ta slovenski standard je istoveten z: CEN ISO/TS 21405:2026**

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**ICS:**

35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology
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TECHNICAL SPECIFICATION  
SPÉCIFICATION TECHNIQUE  
TECHNISCHE SPEZIFIKATION

**CEN ISO/TS 21405**

April 2026

ICS 35.240.80

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 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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# 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*

**First edition  
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**ISO/TS 21405:2026(en)**

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### Foreword

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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).

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## ISO/TS 21405:2026(en)

### 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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