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

01-julij-2026

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**

ICS:

35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

SIST-TS CEN/TS ISO 21405:2026 **en,fr,de**

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)

This Technical Specification (CEN/TS) was approved by CEN on 23 March 2026 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Specification: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

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

First edition
2026-03

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

Reference number
ISO/TS 21405:2026(en)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.