SLOVENSKI STANDARD
SIST-TS CEN ISO/TS 5499:2024

01-junij-2024

Zdravstvena informatika - Klinični podatki - Temeljna načela za uskladitev izrazov in identifikatorjev terapevtskih indikacij (ISO/TS 5499:2024)

Health informatics - Clinical particulars - Core principles for the harmonization of therapeutic indications terms and identifiers (ISO/TS 5499:2024)

Medizinische Informatik - Klinische Besonderheiten - Grundprinzipien für die Harmonisierung von Indikationsbegriffen und -bezeichnungen (ISO/TS 5499:2024)

Informatique de santé - Spécificités cliniques - Principes fondamentaux pour l'harmonisation des termes et identifiants des indications thérapeutiques (ISO/TS 5499:2024)

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ICS:

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

SIST-TS CEN ISO/TS 5499:2024 **en,fr,de**

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TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

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English Version

Health informatics - Clinical particulars - Core principles for the harmonization of therapeutic indications terms and identifiers (ISO/TS 5499:2024)

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European foreword

This document (CEN ISO/TS 5499:2024) 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 5499

Health informatics — Clinical particulars — Core principles for the harmonization of therapeutic indications terms and identifiers

Informatique de santé — Spécificités cliniques — Principes fondamentaux pour l'harmonisation des termes et identifiants des indications thérapeutiques

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Foreword

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Introduction

The need for improved communication between health agencies, hospitals, pharmacies, pharmaceutical companies and the general public about drug safety and efficacy information requires migration from manual text entry and unstructured data that cannot be coded, to a structured data model that is interoperable across the health care ecosystem[1]. The clinical particulars conceptual class of the ISO 11615 Identification of Medicinal Products (IDMP) data model captures information about a medicinal product's indication(s), contraindication(s), undesirable effect(s) and interactions. Within this conceptual class, the Therapeutic Indication subclass captures information about the therapeutic indication for the target disease or condition for which a medicinal product is authorized, under investigation, or utilized in clinical practice. Therapeutic indications can be described using free text as presented in approved product labelling documents, and as terms and codes from standard terminologies. Consistent and accurate coding of therapeutic indication terms is needed to support a variety of processes and is found in various terminological resources and official documents, which include epidemiological and real-world databases, electronic health records and health authority reporting processes. Therefore, a key principle for terminology mapping is that maps are based on specific use cases, and stakeholders who can provide feedback on the form, content and scope of the mapping should be engaged from the beginning of and throughout the mapping exercise.

A universally accepted terminology for coding therapeutic indications does not yet exist and is not feasible due to differing international medicinal product and healthcare regulations and reporting requirements. There is a difference between the therapeutic indication of a specific medicinal product and the diseases, conditions or problems listed in an electronic health record (EHR). While most EHRs will manage a problem list and/or a list of findings and diagnoses and a medication list, it is less frequent that the indication (or indications) for each specific medication is specified for a particular patient.

In medicinal product labels, a range of authorized indications is listed, often with qualifiers (diagnostic, preventive, curative, disease-modifying) or specified patient target groups. Sometimes, diseases or conditions are explicitly listed as not being indications for a specific drug. For example, "drug x" is not indicated in von Willebrand disease, or "drug y" is contraindicated with Haemophilia A. Use of medicinal products outside the authorized indications is considered off-label.

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The indication wording, and thus the related coding, is based on a highly complex process over the years-long development of a pharmaceutical product. The relationship between a medicinal product and an indication is based on evidence from clinical trials, which are often comparative in nature (e.g. placebo versus active substance, or active substance A versus active substance B). Evidence synthesis in systematic reviews is often constrained by a Patient/intervention/comparator/outcome (PICO) statement, which results in a clinical recommendation to prefer or not to prefer the use of a particular medicinal product over another intervention for a particular patient (with a specific disease or condition), aiming at a specific outcome. In a regulatory document, this information is often reduced to a statement that "this medicinal product is indicated for ....".

In regulatory documents, the relationship is specified between a particular medicinal product (with specific substance(s), dose form(s), strength(s) and pack sizes), on the one hand and the indication(s), which are often specified in a detailed form. The formulation of this detailed indication often results from strong and intricate debate between the medical department of a pharmaceutical company, medical experts and regulators. The finesse of such formulation is often difficult to catch by any of the existing terminologies. For example, the therapeutic indications for a preparation that is licensed for over-the-counter (OTC) use can be more restrictive than the indications for the same preparation when prescribed by a clinician. For example, treatment of candidiasis in pregnancy using a clotrimazole must be under the direction of a physician; an OTC preparation is not authorized for this indication.

In handbooks of pharmacology and in drug classifications, indications might be formulated at a higher level of aggregation, and substances can be aggregated to drug classes. Hence, relationships between high level indications and drug classes (rather than individual substances) can be described.

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