Health informatics - Clinical information models - Characteristics, structures and requirements (ISO 13972:2022)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 13972:2022 sisaldab Euroopa standardi EN ISO 13972:2022 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 13972:2022 consists of the English text of the European standard EN ISO 13972:2022.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 09.03.2022.	Date of Availability of the European standard is 09.03.2022.
Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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Health informatics - Clinical information models - Characteristics, structures and requirements (ISO 13972:2022)

Informatique de santé - Modèles d'informations cliniques - Caractéristiques, structures et exigences (ISO 13972:2022)

Medizinische Informatik - Detaillierte klinische Modelle - Charakteristika und Prozesse (ISO 13972:2022)

This European Standard was approved by CEN on 20 October 2021.

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

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European foreword

This document (EN ISO 13972:2022) 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.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2022, and conflicting national standards shall be withdrawn at the latest by September 2022.

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.

This document supersedes CEN ISO/TS 13972:2015.

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 implement this European Standard: 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, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 13972:2022 has been approved by CEN as EN ISO 13972:2022 without any modification.

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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).

This first edition of ISO 13972 cancels and replaces ISO/TS 13972:2015, which has been technically revised.

The main changes are as follows:

— reduction of content that is not directly aiming at the clinical information models, such as clinician involvement, governance, and patient safety matters;

— updates on modelling practices, e.g. the strict relationship to a RIM or RM has been loosened to reflect ongoing practices, such as with HL7® FHIR®.

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

In current health care, the exchange of information from one healthcare professional to another and hence, the exchange of data from one application to the other, has become a necessity. As sender and receiver want to understand the exchanged information or data properly, it is of utmost importance to achieve mutual understanding through 'semantic interoperability'. Semantic interoperability represents the core need for electronic health records (EHR) and other health ICT systems, and for communication between these systems. This document provides an approach to achieve semantic interoperability through Clinical Information Models (CIMs).

There are five reasons for this document:

a) CIMs describe the **clinical world** of patients and health professionals, representing the clinical knowledge in ICT.

b) CIMs function as **building blocks** from which many different useful solutions can be created, keeping the underlying data standardized.

c) CIMs are **specific instances of representations** of clinical concepts, contexts, and relations. CIMs function as specific instances of health ICT architectures. CIMs bridge between real world clinical processes and IT solutions supporting them. For example, when using ISO 23903, CIMs can be represented in IT models using IT ontologies.

d) CIMs are **independent from technology choices** and can be used in any health information technology.

e) CIMs define **representations** of clinical concepts independent of implementation, enabling safe translation from one technological implementation of a CIM into another technology based on the same CIM.

Each reason for CIMs is described further below.

Firstly, CIMs are models that describe the clinical world, the world of patients and health professionals, in all kinds of fashions. CIMs provide views on the healthcare business at the most detailed level. CIMs allow providers to represent and capture the meaning of specific types of clinical information consistently and precisely to exchange that information without concerns about misinterpretation and to re-use, re-purpose and re-position that information in multiple contexts. Consistent clinical documentation in electronic health record systems (EHRs) and personal health record systems (PHRs) is at the core of CIM's benefit to assure and ascertain continuity of care across time, provider, and location. This is a prerequisite for data use, data reuse and data exchange. In addition, semantic interoperability addresses issues of how to enable health professionals and ICT professionals to establish and maintain this meaning, coding and transmission of data across time and health services, and to perform meaningful and cooperative care, based on shared knowledge. CIMs support exchanging meaning between health care professionals, providers, patients, and citizens, with a focus on the end user independent of the actual ICT system(s) used.

In addition, they facilitate mutual understanding between authorities, researchers, managers, policy makers, educators and more[2]. A key requirement to achieve meaningful data use and exchange is the standardization of clinical concept representation within health data, including its content, structure, context, and transmission processes. The ability to use and exchange information between clinical information systems without loss of clinical meaning is also essential to enable safe and effective implementation of automated decision support. Interoperability and system integration are challenges that CIMs can help overcome to meet business objectives.

Standardization of clinical concept representation is a desirable and cost-effective way to aggregate data from EHR systems for multiple data use and reuse, for example for decision support, clinical quality, epidemiology, management, policy making, and research. These are the main information processing activities in healthcare. With respect to the processes relevant to CIMs governance, a Quality Management System (QMS) based on a framework such as ISO 9001 can be used. Defined processes for development, application, and governance ensure the quality of CIM artefacts and its use.

A second important aspect of CIMs is that in any given implementation context, they will need to be combined into larger interlinked structures or compositions. CIMs facilitate use as building blocks from which meaningful and useful integrated information solutions can be composed. An individual CIM does usually not actually facilitate anything. CIMs can best be grouped together to create a working solution. CIMs are not specific for a particular use case but can be created and combined for specific use cases to meet the clinical needs. CIMs facilitate a bottom up approach. A consequence of such requirements is that mechanisms such as composition and decomposition are needed to enable CIMs to be safely represented at different levels of detail. For example, a hospital discharge summary will consist of many data elements, many of which might be CIMs. However, the data specification of a discharge summary is a separate artefact making use of several CIMs and is not a CIM in itself. How these combinations of CIMs can be achieved using ISO 23903 is not part of this document. For example, a quality indicator or quality report will usually consist of several CIMs (as a composition): one CIM to identify the patient (even if anonymous, but with a respondent number), the health organization CIM, the clinical problem CIM, the clinical activities CIM, and so on. Similarly, for quality care, the same and other CIMs will be used along a patient journey or clinical pathway.

The third reason for this document is the transformation of health care towards personalized ubiquitous care. This requires the advancement of data exchange between computer systems to knowledge sharing among the stakeholders involved, including patients, or even citizens. For that reason, CIMs facilitate the representation of any clinical business processes' clinical concepts, contexts, and relations into finally implementable IT models, using IT ontologies. To perform this challenge correctly and consistently, ISO 23903 can be deployed to formally represent the clinical business system based on the knowledge space of the experts of the domains involved represented by those domains' terminologies and ontologies. In some policies, this level is referred to as the information layer, representing the detailed semantic level of the healthcare business. As part of a standardized software development process, this formalized system is then transformed into specific instances for specific enterprise and information models to specify platform-specific models and implement them.

Another International Standard conceptualizing health care processes is ISO 13940. The need to evidence the quality of the CIMs is inevitable. This document refers to standardized terminologies, relationships, standardized datatypes, and the need to reference term or value sets, and units of measure. CIMs model clinical concepts that are defined precisely at the logical level. CIMs are logical constructs, specifying modular data for clinical information. This document reflects a pragmatic consensus based on experience, regarding the level of detail in the breakdown and representation of a CIM representing medical knowledge. Similarly, pragmatic views present examples of CIM, and support how instance data based on CIMs can be used within Healthcare Information Architectures. The development and management of CIMs requires common and more generic definitions/descriptions of clinical concepts, such as health care processes and the constructs health professionals use within these processes, as generally depicted in ISO 13940. Contsys is suitable as a common base for development of CIMs.

A fourth reason is that CIMs do not force into taking one direction with respect to technologies. CIMs are independent from technology choices, and are therefore core assets describing the healthcare domains, which are crucial in the negotiations with health IT professionals. There is widespread acceptance that CIMs need to be developed and standardized by stakeholders including health professionals, patients, managers, and (clinical) researchers on one hand while being technology 'neutral' yet usable in real systems. CIMs address the conceptual content for the logical levels of modelling, but do not intervene in the physical implementation of IT systems in healthcare. Hence, each CIM can be used in various use cases, IT architectures, and IT technologies.

An implementation technology standard should be chosen and the CIMs should be translated to this document within the limits and the constraints of that standard before technical artefacts for that specific implementation technology can be derived. These resources, artefacts, or archetypes themselves can be transformed into various computational representations and programming languages such as ISO/IEC 21778 JSON, or XML, OWL, Java, C# among many others. In such developments, CIMs are the core source material and their main function is to offer all technologies the same core clinical information model, so that the consistency and logic of data can remain in various systems, offering a key benefit to stakeholders to retain knowledge when replacing old technologies with new. In the world

of ubiquitous personalized health, this applies for the new technologies used by patients themselves, which offer highly dynamic interoperability services provided in real time.

NOTE For specific implementations, the use of a reference (information) model can be required or recommended, but that is only in the stage where technology decisions are or have been made. Constraints that technology choices impose on the clinical world do not apply at the CIMs level, hence the CIMs remain the "pure" unconstrained descriptions of the healthcare business.

Fifth, CIMs define representations of clinical concepts independent of implementation, enabling safe translation from one technological implementation of a CIM into another technology based on the same CIM. CIMs facilitate various products from standards and technology developers to seamlessly work together, hence, CIMs build bridges between different technologies, e.g. exchange data from an archetype based EHR via HL7®[1] FHIR®[2] to a SQL based EHR. Data specifications similar to the CIMs described in this document have been found to be useful in a wide range of health care information and communication technologies, including but not limited to EHR systems, telehealth applications, messaging integration, medical devices, computer algorithms, and deductive reasoning for decision support (see References [6][7][8][9][10][11][12][13][14][15][16]).

CIMs also offer a migration path in perspective of ISO 23903, facilitating an approach in which old systems or applications can be replaced by new ones, without affecting other layers or views in the architecture, if of course the standards in the various layers are applied.

Standardized CIMs further underpin the coherence of Electronic Health Records (EHR), for instance ISO 18308, where data needs to be accepted from multiple sources and stored in a consistent and predetermined format. In addition, for a functional EHR system (ISO/HL7 10781), queries need to be constructed based on clinical knowledge and tied to clinical context, content, semantics and workflow; services need to be automated based on known values of patient data linked to agreed protocols and terminologies; data display and data entry needs to reference clinical guidelines; and safety and quality issues for clinicians moving from system to system can be minimized through consistent information representation. In this way, standardized CIMs form the lingua franca of use, reuse and reusability within and across various health, clinical and care related systems.

In summary, CIMs can be used as a set of accurate clinical building blocks representing clinical concepts that together meet the requirements for specific healthcare related use cases for which a mixed set of information and communication technological solutions are developed and/or deployed.

The target audience for this document includes health informaticians in general but it does have a particular relevance for Chief Medical Information Officers, Chief Nursing Information Officers, Chief Patient Information Officers, Healthcare Information Analysts, Healthcare Information Modelers, and Healthcare Information Architects.

In this document, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "can" indicates a possibility or a capability;

— "may" indicates a permission.

1) HL7 is the registered trademark of Health Level Seven International. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

2) FHIR is a trademark of HL7®. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

Health informatics — Clinical information models — Characteristics, structures and requirements

1 Scope

This document:

— Specifies **clinical information models** (CIMs) as health and care concepts that can be used to define and to structure information for various purposes in health care, also enabling information reuse;

— Describes **requirements** for CIMs content, **structure** and context and specification of their data elements, data element relationships, meta-data and versioning, and provides guidance and examples;

— Specifies key **characteristics** of CIMs used in conceptual and logical analysis for use cases such as (reference) architectures, information layers, EHR and PHR systems, interoperability, systems integration in the health domain, and secondary use of data including for public health reporting;

— Defines a **Quality Management System** (QMS) for a systematic and effective governance, quality management, and measurement of CIMs through their lifecycle of development, testing, distribution, application and maintenance;

— Provides **principles** for the transformation and application of clinical information models through the wide variation of health information technology.

This document excludes:

— Requirements on the content or application of any particular clinical information model or clinical information modelling methodology;

— Specific applications of clinical information models such as for dynamic modelling of workflow;

— Specifications for modelling entire domains or aggregates of many CIMs such as complete assessment documents or discharge summaries. It does not specify CIMs compositions;

— Specification of how to involve specific clinicians, how to carry out governance including information governance, or how to ensure patient safety.

2 Normative references

There are no normative references in this document.

3 Terms, definitions and abbreviated terms

3.1 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/