BS EN ISO 13972:2022

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

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The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

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European foreword

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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of an identical text or by endorsement, at the latest by September 2022, and conflicting national standards shall be withdrawn at the latest by September 2022.

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Foreword

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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).

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®.

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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.

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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

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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.

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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/

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3.1.1
concept
unit of thought

3.1.2
concept analysis
formal linguistic strategy that enables the defining attributes or characteristics of a concept to be examined

[SOURCE: Reference [19]]

3.1.3
concept definition
description of the attributes of a concept to delineate its meaning

3.1.4
clinical concept
concept expressed by means of characteristics or attributes pertinent to its use in health or health care

3.1.5
model
abstract description of reality in any form (including concepts, data elements, terms, and their relationships, statistical, theoretical, mathematical, physical, symbolic, graphical or descriptive form of a domain) that presents a certain aspect of that reality

Note 1 to entry: It is often further specified to distinguish between conceptual, logical and computational models.

[SOURCE: ISO/TR 23087:2018, 3.5, modified —"concepts, data elements, terms and their relationships, added statistical, theoretical" and Note 1 to entry have added.]

3.1.6
modelling
construction of abstract representations in the course of design, for example to represent the logical structure of software applications before coding

[SOURCE: Reference [21]]

3.1.7
conceptual model
model that describes common concepts and their relationships, particularly in order to facilitate exchange of information between parties within a specific domain of healthcare

Note 1 to entry: This pertains in particular to concepts representing clinical information in conceptual models.

[SOURCE: ISO/TS 18864:2017, 3.6, modified —"description" changed to "model that describes", Note 1 to entry added.]

3.1.8
logical information model
logical model
information model that specifies the structures and relationships between data elements but is independent of any particular technology or implementation environment

[SOURCE: ISO/TR 20514:2005, 2.29, modified — "information" replaced with "data elements", note removed.]

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3.1.9
physical level
level of consideration at which all aspects deal with the physical representation of data structures and with mapping them on corresponding storage organizations and their access operations in a data processing system

Note 1 to entry: This document focuses on the flow from business concepts in any domain via clinical (logical) information models to their technical implementation in a specific application or system.

[SOURCE: ISO/IEC 20944-1:2013, 3.14.3.6, modified — Note 1 to entry added.]

3.1.10
information
knowledge concerning objects, such as facts, events, things, processes, or ideas, including concepts, that within a certain context has a particular meaning

Note 1 to entry: Information is something that is meaningful. Data might be regarded as information once its meaning is revealed.

[SOURCE: ISO/IEC 2382:2015, 2121271, modified — Notes to entry removed, new Note 1 to entry added.]

3.1.11
healthcare information
clinical information
information about a person, relevant to his or her health or health care

Note 1 to entry: This does include activities in which a patient and care professional interact directly or indirectly.

Note 2 to entry: Healthcare information about a patient can include information about the patient's environment and/or about related people where this is relevant.

[SOURCE: ISO 13940:2015, 3.9.4, modified — "clinical information" added as a term, "health" added, Notes to entry added.]

3.1.12
context
related conditions and situations that provide a useful understanding and meaning of a subject

[SOURCE: ISO/TR 17119:2005, 2.4]

3.1.13
clinical information model
CIM
health and care information model
HCIM
information model that expresses in a standardized and reusable manner one or more healthcare or clinical concepts and their context in a conceptual and logical model, specifying healthcare information as a discrete set of data elements, their characteristics and relationships, and appropriate terminology bindings

3.1.14
medical knowledge
field of knowledge pertaining to the structure, function, or dysfunction of the human body and how these can be influenced by external or internal factors and interventions

Note 1 to entry: Medical does not imply “physician”, all health professionals have medical knowledge according to this definition.

Note 2 to entry: This would pertain to observations, findings, diagnoses, outcomes, therapy, etc., to alleviate disease/dysfunction.

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[SOURCE: ISO 13119:2012, 2.1, modified — Note 1 to entry modified, Note 2 to entry added.]

3.1.15
semantic interoperability
ability for data shared by systems to be understood at the level of fully defined domain concepts

Note 1 to entry: EC Recommendation, COM (2008) 3282 final, stresses that this implies to work for any other system or application the defined domain concepts were not initially developed for.

[SOURCE: ISO 18308:2011, 3.45, modified — Note 1 to entry added.]

3.1.16
data
reinterpretable representation of information in a formalized manner suitable for communication, interpretation or processing

[SOURCE: ISO/IEC 2382:2015, 2121272, modified — Notes to entry removed.]

3.1.17
data element
variable, clinical elements are considered synonyms in a clinical information model unit of data that is considered, in context, to be indivisible

[SOURCE: ISO/IEC 14957:2010, 3.1, modified — "variable, clinical elements are considered synonyms in a clinical information model" added.]

3.1.18
attribute
characteristic of an object or set of objects

Note 1 to entry: In the context of this document it can be a specific characteristic of a data element.

[SOURCE: ISO/IEC 11179-1:2015, 3.1.1, modified — Note 1 to entry added.]

3.1.19
data model
description of the organization of data in a manner that reflects an information structure

[SOURCE: ISO 5127:2017, 3.1.13.33]

3.1.20
datatype
set of distinct values, characterized by properties of those values and by operations on those values

[SOURCE: ISO/IEC 11404:2007, 3.12]

3.1.21
metadata
data that defines and describes other data

Note 1 to entry: In the context of this document, the metadata that describe clinical information models are meant to govern the clinical information model (CIM) as objects, for instance to retrieve specific CIMs and to maintain CIM versions.

Note 2 to entry: It is possible to relate to persistent instance data using metadata that are based on the clinical information models in any storage or exchange format, for example to identify on which CIM specific data are based.

[SOURCE: ISO/IEC 11179-1:2015, 3.2.16, modified — Notes to entry added.]

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3.1.22
term
designation that represents a general concept by linguistic means

EXAMPLE "Patient", "Doctor", "Body temperature", "Pacemaker", "Covid-19 virus".

[SOURCE: ISO 1087:2019, 3.4.2, modified — EXAMPLE, modified, Note to entry, removed.]

3.1.23
terminological system
set of concepts structured according to the relations among them, each concept being represented by a sign which denotes it

Note 1 to entry: In terminology work, and in this document, three types of such signs (designations) are distinguished: symbols, appellations and terms.

[SOURCE: ISO 18308:2011, 3.50, modified — Note 1 to entry removed, Note 2 to entry has become new Note 1 to entry.]

3.1.24
coding system
combination of a set of code meanings and a set of code values, based on a coding scheme

Note 1 to entry: Code meanings are typically represented by terms or rubrics, but they can have other representations. Code values are typically numeric or alphanumeric.

Note 2 to entry: For clinical information models, the coding schemes are typically derived from terminological systems, for example because they have coding schemes included.

[SOURCE: ISO/TR 12300:2014, 2.2.5, modified — Notes to entry added.]

3.1.25
code value
result of applying a coding scheme to a code meaning

EXAMPLE "CDG" as the representation of "Paris Charles-De-Gaulle" in the coding scheme for three-letter representations of airport names.

[SOURCE: EN 1068:2005, 3.6, modified — Example added.]

3.1.26
value set
uniquely identifiable set of valid concept representations, where any concept representation can be tested to determine whether it is a member

Note 1 to entry: A value set is intended to be a set in the formal sense, and so should contain only one code for each uniquely identifiable concept that it contains.

[SOURCE: ISO/TS 18864:2017, 3.32, modified — "of the value set" removed.]

3.1.27
reference model for open distributed processing
RM-ODP
standardized approach to design and governance of information systems, in particular systems involving data communications between organizations that have different computing platforms.

[SOURCE: ITU-T Rec. X.901-X.904, Reference [36]]

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3.1.28
use case
set of scenarios that address a particular business/clinical domain or topic

Note 1 to entry: It specifies interactions between external actors and the system to attain particular goals or a particular methodology.

Note 2 to entry: Use cases can be used in system analysis to identify, clarify, and organize system requirements or process steps.

[SOURCE: ISO/TR 19669:2017, 3.17, modified — Note to entry removed, new Notes to entry added.]

3.1.29
archetype
instance of an archetype model, specifying the clinical concept and the value constraints that apply to one class of record component instances in an electronic health record extract

[SOURCE: ISO 13606-1:2019, 3.3.2]

3.1.30
archetype model
information model of the metadata to represent the domain-specific characteristics of electronic health record entries, by specifying values or value constraints for classes and attributes in the electronic health record reference model

[SOURCE: ISO 13606-1:2019, 3.3.3]

3.1.31
clinical template
clinical information model that structures information around discrete clinical concepts in a way that supports reuse of components across different clinical communication and record keeping activities and promotes common approaches to clinical information system development and interoperability

3.1.32
electronic health record
EHR
information relevant to the wellness, health and healthcare of an individual, in computer-processable form and represented according to a standardized information model

Note 1 to entry: It is the logical representation of information regarding or relevant to the health of a subject of care.

[SOURCE: ISO 18308:2011, 3.20, modified — Note to entry added.]

3.1.33
electronic health record architecture
formal description of a system of components and services for recording, retrieving and handling information in electronic health records

Note 1 to entry: It is about the logical components defined in terms of information models, and the computational services.

Note 2 to entry: The two-level modelling principle can be applied in electronic health record architectures using one generic information model for the whole system and specifying the details in clinical information models.

[SOURCE: ISO 18308:2011, 3.21, modified — Notes to entry added.]

3.1.34
association
relationship in which classes in a model relate to each other via a connector or link

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3.1.35
aggregation
special type of association in which child classes are configured together to create a more complex parent class

3.1.36
composition
special type of association in which a child class cannot exist independent of the parent class

3.1.37
generalization
mechanism to combine similar classes into one single, more generic class

3.1.38
specialization
mechanism to create new sub-classes from one existing class

3.1.39
information governance
processes by which an organization obtains assurance that the risks to its information and thereby the operational capabilities and integrity of the organization are effectively identified and managed

[SOURCE: ISO/TS 14441:2013, 3.25]

3.1.40
lifecycle
sequence of events that mark the development and use of an information resource

Note 1 to entry: Clinical information models are seen as information resources that undergo governance, for which a lifecycle is a key part.

EXAMPLE Conception of an invention, creation of a draft, revision of an article, publication of a book, acquisition by a library, transcription to magnetic disk, migration to optical storage, translation into English and derivation of a new work (e.g. a movie).

[SOURCE: ISO 15836-1:2017, 3.1.2, modified — "of a resource" removed from term and "information" added to definition, Note 1 to entry added.]

3.1.41
quality
degree to which a set of inherent characteristics of an object fulfils requirements

Note 1 to entry: This defines the degree to which all the properties and characteristics of a product, process, or service satisfy the requirements that ensue from the purpose for which that product, process, or service is to be used.

Note 2 to entry: In the context of clinical information models this is about the quality of the models, the quality of the developmental process and the services as to the governance of clinical information models.

[SOURCE: ISO 9000:2015, 3.6.2, modified — Notes to entry deleted, new notes to entry added.]

3.1.42
quality management system
QMS
part of a management system with regard to qualityNote 1 to entry: It is presented here as a framework described by ISO 9000 and ISO 9001 and it comprises of the three core elements: quality control, quality assurance and quality improvement.

[SOURCE: ISO 9000:2015, 3.5.4, modified — Note to entry added.]

3.2 Abbreviated terms

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ADL	Archetype Definition Language
CDA	Clinical Document Architecture
CEN	Comité Européen de Normalisation [Committee of European Norms]
CBB	Clinical Building Block
CIMI	Clinical Information Modeling Initiative
CMET	Common Message Element Type
DAM	Domain Analysis Model
DCM	Detailed Clinical Model
D-MIM	Domain Message Information Model
EHR-S FM	Electronic Health Record System Functional Model
EVM	Eye Verbal Motor
FHIR	Fast Healthcare Interoperability Resources
FM	Functional Model
GCM	Generic Component Model
GCS	Glasgow Coma Scale
HIT	Healthcare Information Technologies
HL7®	Health Level Seven
ICT	Information and Communication Technology
ID	Identifier
ITS	Information Technology Specification
IT	Information Technology
MDA	Model Driven Architecture
ReEIF	Refined eHealth European Interoperability Framework
RIM	Reference Information Model
RM	Reference Model
OCL	Object Constraint Language
PIM	Platform Independent Model
PSM	Platform Specific Model
QMS	Quality Management System
SFM	Specialized Functional Model
STU	Standard for Trial Use
UML	Unified Modelling Language
URI	Uniform Resource Identifier
URL	Uniform Resource Locator
VP	Viewpoint
zib	Zorg Informatie Bouwsteen [Care Information Building Block]

4 Health care information models - Concept, purpose, contexts and position

4.1 The Concept of Clinical Information Models

CIMs are used to capture functional, semantic (non-technical) agreements for the standardization of information used in the care process.

They are models constructed to bridge/link the intersection between the business, enterprise, and information perspectives. Traceability from a health, clinical or care process (regarding the context)

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and/or a health, clinical or care concept (regarding the content) is recommended for the use of CIMs. That means that for example, a clinical guideline can express the required data elements for quality care in the form of a set of required CIMs. CIMs for implementation in health care information technology should be further expressed against one or more implementable standards to make them useful, however that process is not part of this document.

Structurally, CIMs provide the data elements and attributes of a concept, including the possible values and types of attributes and the relationships between data elements needed to convey the health, clinical or care requirements to domain experts, data users, modellers and implementers.

Contextually, CIMs can be positioned in various (reference) information models. In such context, CIMs shall be positioned in the Information Layer. See the European Interoperability Framework that has such an information layer in Reference [44]. An alternative representation of CIMs is in the information layer according to the ISO 12967 series (HISA), and specifically, the CIM placement in the Information Viewpoint of ISO 12967-2.

Ideally, all CIMs make use of a pragmatic and where possible, a purposeful defined maximal data set for universal use cases. For safety, "for purpose" CIMs should only use the required or optimal data elements from a potential maximal data set, as needed to suit their purpose in common use cases. "For purpose CIMs" means in this context that they are dedicated to specific and not broad clinical concepts. This constraint is also in accordance with ISO 23903, reducing the complexity of the modelled system to the necessary level. CIMs, which represent the clinical concepts at the logical model level, shall be implemented in applications or systems. Examples of use are described below:

— A widely accepted conceptual model of health care, such as ISO 13940 (Contsys) and/or similar authoritative clinical reference models can refer to CIMs.

— An agreed standard Electronic Health Record (EHR) reference (information) model, such as ISO 13606-1 and/or OpenEHR[48], or HL7® EHR-S FM can refer to CIMs to specify clinical content. The reference (information) model guarantees that the common attributes for information in health records (such as who, when and where) have already been identified and do not need to be addressed again in each CIM.

— An agreed standard information exchange reference information model such as the HL7® v3 RIM or ISO 13606-1, ISO 13606-3, or alternatively, the HL7® FHIR® resources, profiles and extensions can refer to CIMs for the clinical materials.

— Requirements for EHR architectures, such as ISO 18308 or HL7® EHR-S-FM, or health architectures such as ISO 12967-2 (HISA) can refer to CIMs.

CIMs can be developed at different levels of complexity, ranging from one single data element to the more common situation where most CIMs have multiple data elements. CIMs should best be of a size appropriate for the content and scope of the health, clinical or care concept they represent. The question about how big or how small a CIM is depends on different factors: if a data element has a role by itself, it is logical to have a single data element CIM. Specific health, clinical or care purposes determine the logic to keep data elements together in the context for which they are specified. This is done to prevent wrong interpretations and misleading conclusions.

This is further clarified in the following examples:

a) Atomic CIMs. The CIMs consist of one single data element with a specific purpose. One example is the CIM Body Mass Index. The BMI has one data element, which is the result of a formula. To use this CIM "BMI", both the CIM for length and for weight are required. Another small CIM can be the skull circumference for youth care. Another reason to create an atomic CIM might be the reuse of the data element in various other CIMs, such as body position in the blood pressure CIM and in the body length CIM.

b) Molecular CIMs. Most CIMs consist of multiple data elements. There is no exact nature determined, due to the diversity of clinical practice documentation. For instance, the CIM body length has five data elements. Besides the value of the body length itself and the body position, the device used, potential confounding variables and the origin of the value are also specified. However

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most implementations will only use the actual measurement. Nevertheless, there are circumstances where all these other data elements would be useful. In the case of the general practitioner providing preventive care to diabetes patients, blood pressure must be measured in a consistent manner only, which the guideline defines as in a sitting position, to ensure reliable comparison over time. In this situation, the body position "sitting" can be used a default value or can be left out. Other examples of CIM can have many data elements. For example, a Dutch risk assessment scale for child abuse (DMO protocol) includes 80 data elements but can still be considered a (larger) molecule.

The reasons for reuse and separation of data elements into separate CIMs include:

— A single standing data element using other existing CIMs that can be used as separate entities themselves (e.g. Body Mass Index, using length and weight).

— A data element that is often reused in other CIMs with (almost) the same purpose; a generic level CIM can refer to a more specific (partial) CIM containing this data element (e.g. body position).

— A data element which, outside the scope of intended use, has a risk for misinterpretation and errors in judgment. Then the CIM serves to appropriately define the content. In contrast, it might be that a specified data element has been validated for secondary and tertiary uses, such as the HbA1c values for patient outcomes for diabetes care.

c) Partial CIMs. These are small, usually atomic sized, CIMs that are not used by themselves, but only as component in molecular CIMs to provide a specific context. Examples of such contexts include body position, anatomic location, laterality and more. These partial CIMs are almost never used as such, but only as part of another concept or CIM. These partial CIMs improve the use of CIMs through consistent modelling of frequently used contextual parts.

d) Compositions of CIMs. Typically, several CIMs can be grouped together in various compositions such as grouping CIM blood pressure, CIM heart rate, CIM body temperature and CIM breathing into a composition of vital signs. Similarly, in the HL7® organization, a DAM typically defines a whole clinical area (diabetes care, pressure ulcer risk prevention and care) in which it is logical to de-compose all data into a series of CIMs, each of which can be maintained separately and reused. Models for clinical context such as specific types of clinical situations and/or specific types of steps in the clinical process are other examples of CIM in compositions. References [8] and [9] describe how the de-composition of clinical artefacts as forms can lead to a collection of clinical information models that are reusable parts that can be composed into various healthcare ICT solutions. There are some differences in approach between various clinical modelling initiatives, but this decomposition and composition approach is common to all. The construction of clinical templates is an important approach to make CIMs useful in relationship to each other. The generic term for such combination of CIMs is composition. The major benefit is the overall standardization of data and its consistency.

4.2 Purpose for Clinical Information Models

The purpose of Health and Care Information models is to provide the basis for precise, semantically consistent data and terminology specifications plus the processing rules which are comparable and sharable between multiple care providers, health enterprises and standards-based HIT. Typically, a set of CIMs serves as building blocks for one or more use cases.

The conceptual context and knowledge expression of CIMs and their logical model of data elements provide a common starting point and resource for Reference Architectures or can be directly converted into machine processable representations. CIMs can also be mapped to different RIM/RM, see 4.4. CIMs can be used by software applications to provide for or contribute to a variety of functional needs. Each function requiring the processing and use of clinical (EHR) data determines the degree of semantic interoperability needed. This is largely determined by the required use of the terminology applied to define various CIMs data elements, attributes and relationships to support each function; what is important is a shared use of terminology by trading partners exchanging information expressed so that specifications on the same concept are consistent for all functions that it tries to achieve.

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The logical specification of a CIM is not restricted for use within one (or a limited number of) software application(s). It can be used for multiple purposes and/or applications including:

— Context and knowledge of health, clinical and care concepts that precisely express the conceptual and logical model of the CIMs to support data collection and management in EHRs, including Storage, Data Processing and User Interfaces.

— Clinical content and knowledge with unambiguous detail which can be used across domains and disciplines, for instance the use of health, clinical or care data communication and exchanges in messages and services, including Medical Devices and Applications.

— Standardization and reusability of data and knowledge to suit multiple functions and purposes, such as Clinical Decision Support Systems, Continuity of Care, reporting of Quality Measures to National Registries, submitting data for Epidemiology and/or Research, Management, Public Health management.

— Lifetime storage and retrieval of health, clinical or care data and metadata, linked to the knowledge applied and the context in which data collection took place.

4.3 Context of Health and Care Information Models

To be relevant and to contribute to healthcare quality, CIMs need to be specifically related to identified health problems and healthcare requirements. Health problems/conditions and clinical processes including healthcare activities are examples of important clinical concepts that need to be defined and explained conceptually as well as contextually. And the clinical concepts are at the heart of the business requirements for many (clinical) information management activities in healthcare.

CIMs can be developed bottom-up: specifying specific clinical concepts and their context, or top down, using a more abstract concept model of healthcare as a business, or a process description. A concept model or process model can be used as a basis for specifying the content and context of CIMs for common and shared understanding and interoperability. This is often specified in use cases using health concepts. ISO 13940 (Contsys) is a system of concepts in health informatics that can fulfil such needs when working top-down. The most relevant clinical concepts included in Contsys as bases for CIMs are clinical process, health condition (problem) and healthcare activity (intervention). CIMs specify and concretize such relevant general clinical concepts.

In many policies, including the European eHealth Framework, the business ecosystem or domain ontology is depicted on several layers. The ICT and infrastructure layers represent how they "integrate into" the health care business. Figure 1 presents an example of how CIMs can be positioned into a Business Framework. A Business Framework functions as a systematic organization of business requirements for the application of healthcare information and communication technology. Figure 1 shows the six aspects, as layers, of the development of an information enabled organizational unit that provides and/or consumes health and care services. Such an organizational unit can be as small as a single patient or health professional, or as large as the health system of a country. For clarity of the concept, the main actors are depicted on each of the layers. The CIMs are exclusively situated in the Information layer. The six layers are further explained below.

— The top layer (1) is the legal framework, guiding clinical work, IT, privacy, and data security requirements among others.

— Layer 2 includes the requirements on the policy level. Stakeholders come to agreements about use cases, architectures, clinical processes, models, IT solutions, infrastructures and many more aspects of implementing IT in healthcare.

— Layer 3 is the clinical process requirements level. Here the use case is described, who are involved, what is the patient journey, how is care arranged. In the ICT world, Contsys represents (parts of) this layer.

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— Layer 4 is then the information requirements layer. This is where the clinical ontologies reside, the terminologies, the CIMs, and more, to ensure the semantics of information in healthcare are useful and properly addressed.

— Layer 5 describes how various requirements for ICT solutions can assist the clinical processes and facilitate the semantics of information.

— The bottom layer (6) describes requirements for infrastructural choices.

For example, the Netherlands based its half a billion Euro policy in health care IT investments on choices made on these 6 layers of the eHealth Framework.

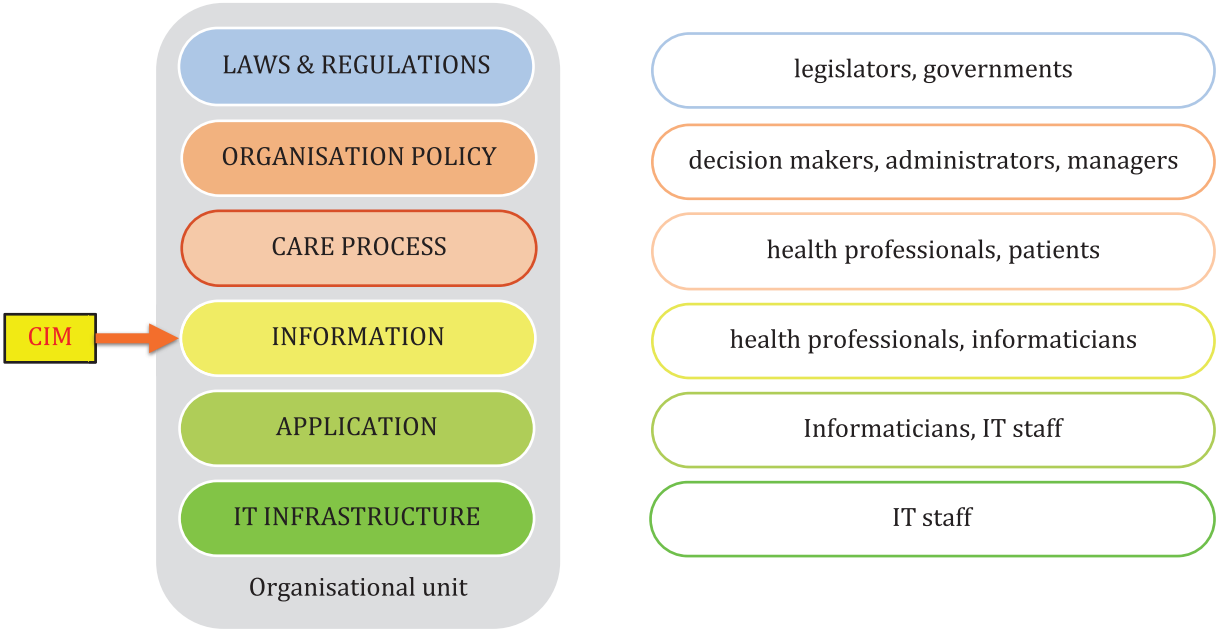

Figure 1 — Compact description of the business requirements essentials of the Refined eHealth European Interoperability Framework (ReEIF)[44]

The design of different logical models containing the same conceptual clinical content is acceptable. This occurs for example when some create CIMs, others create archetypes and a third creates specific HL7® FHIR® resources and profiles for the same clinical concepts. Such situations could introduce risks for errors and patient safety if their content differs due to the specific modelling approaches. Some will argue that this will bring unacceptable risks by potentially reducing the degree of quality of clinical documentation, semantic interoperability and impeding version control and traceability. Others will argue that it can be perfectly acceptable, depending on the clinical contexts and the intent of the CIMs and how they will be used in health, clinical or care settings. Such transformations and design from the conceptual and logical model into other richer logical models need to be carefully handled. The real test would be that the variations are isosemantic, that is, the meaning undergoes no changes. One should not assume a plug and play semantic interoperability at this stage. CIMs cover the data requirements for the continuum of care and multiple purposes for data use. Health, clinical and/or care knowledge is an essential component of any health ICT platform. As such, CIMs represent a key foundational building block for the introduction and use of interoperable person-centric health records and health information infrastructures. Transformations into archetypes based on ISO 13606-2 or ISO 13606-3 and/or FHIR® resources and profiles for implementations should be done with care.

Health IT platforms facilitate information sharing and integration within and between organizations and between subjects of care and their care providers. Both health information users and health software developers rely on the interoperability services provided by the health IT platform and, as such, depend on the reference information model upon which the platform is based.

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However, there is a mixed order of many different systems in the current health ICT environment which do not adhere to all standards relevant in a national platform and do not meet the business requirements. On many occasions a migration strategy is required to achieve seamless semantic interoperability and it is here that CIMs can fill a gap.

4.4 Architectural Considerations for Clinical Information Models

4.4.1 General

To guarantee that the quality of data of the healthcare systems', interoperability, and facilitation of data reuse are maintained, it is necessary to define the stakeholders' business objectives for that system along with its interrelation with (effects on) the environment. In this context, the real-world system must be properly designed, and the underlying concepts properly represented. Therefore, the components of the system, their functions and interrelationships (i.e. the architecture of that system) must be formally modelled through focusing on stakeholders' goals and their perspectives of the system, including naming and structuring the relevant concepts in the domains of interest, thereby ensuring the conceptual integrity of the resulting models.

When designing a new system, its level of need for interoperability can be determined by the functions to be supported and this is useful in positioning CIMs in the health care ICT environment. This forms the basis for choosing the many components that collectively make up the system architecture. It is necessary to understand that the choices made regarding each component must result in the best possible or optimum collective performance.

When working with existing (current) systems, the functions that can be supported are determined by the system's best possible interoperability capacity as determined by decisions made around the systems architecture. The CIMs framework provides a way to leverage the value of much of the health, clinical or care modelling work that has already been conducted. This document provides a level of abstraction that releases the expression of information requirements from the implementation framework in which they were developed. This can simplify the review process and allow wider and safer reuse of the logical model artefacts. The approach using CIMs aims to make sure that a mapping is always possible from the generic CIMs to an implementable specification, whichever technology is going to be deployed[15]. Annex D provides an example of mapping a CIM to ADL. Annex G presents a mapping from CIM to HL7 FHIR. Such mappings between types of models are sometimes called transformations.

To review CIMs initiatives appropriately, it is important to place them in this architecture for health care information.

4.4.2 CIMs in an architectural view

A good CIM shall be based on a real clinical business case or use case and business requirements. Therefore, it should describe the clinical business system architecture as the composition of that business system's components, their function, and their relations, in other words the system's structure and behaviour. The architectural components, operations and (logical) relations are represented by the underlying clinical concepts based on the clinical ontologies addressed. The ISO 12967 series (HISA) describes an open and modular architecture integrating the common data and business logic into a specific architectural layer and does not relate to specific applications. For instance, in the ISO 12967 series (HISA), CIMs would be placed in the information layer. ISO 12967-2 specifies the fundamental characteristics of information models implemented by the information ecosystem. ISO 12967-2 further provides comprehensive and integrated management of the health data and supports the fundamental business processes of the healthcare organization.

CIMs are models in which the relationship between concepts is represented using formal logic. For more information regarding the architectural model of a business case and its representation by a conceptual model based on business domain ontologies, see References [49][50][51][52] For implementing CIMs, the conceptual models of the business domain shall be transferred into ICT domain model representations using ICT ontologies, thereby starting with the business view and then covering the entire suite from the enterprise view through the information view, computational view and the engineering view up to

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the technology view as defined in the RM-ODP of the ISO/IEC 10746 series. Such an approach is defined by ISO 23903. The business view has been added to RM-ODP, preceding the enterprise level.

4.4.3 CIMs placed in the Generic Component Model

Clinical Information Models are not directly implementable. For implementation in running applications, CIMs shall be transformed into ICT models, thereby running the entire development process. The Generic Component Model (GCM) architecture for structurally and behaviourally modelling interoperable healthcare systems characterizes any system by three axes. The GCM is a cube and is represented in Figure 2. It consists of:

— Domains;

— System components;

— System development.

Each axis is discussed and the manner in which each axis fits in an interoperability and systems integration reference architecture according to ISO 23903 is explained. Based on the GCM[49][52], the relative position of CIMs in each of the three axes is further illustrated in Figure 2. The GCM cube's three axes are illustrated:

a) Domain

In the Business view a specific clinical domain is analyzed and modelled, leading to identification of actors, workflow, data, and data structures. The business view is represented on the vertical or y-axis of the GCM. On the bottom level, the required data elements and data structures link to a (collection of) CIMs. In addition, the Electronic Health Record architecture of ISO 18308 links the health care business requirements to logical models for records, addressing the cross-domain aspects of the GCM. Although there is potential to link EHR requirements to specific CIMs, a generic link from business to the detailed specifications would suffice. However, it is different for an EHR system as there is ample opportunity to link the required content to CIMs specifications in the functional model for EHR systems, such as HL7®/ ISO EHR-S FM.

b) System components

CIMs are placeholders for expressed clinical conceptual and logical content in the Business View as in ISO 23903, and in the Reference Model of Open Distributed Processing (RM-ODP) framework ISO/IEC 10746-1; ITU-T X.901. The RM-ODP is a coordinating framework for the standardization of open distributed processing (ODP). RM-ODP uses a five-component analytical model including enterprise, information, computational, engineering and technical viewpoints. The business view extends the RM-ODP. This x-axis is the horizontal base of the GCM in an enterprise architecture framework for the specification of ODP systems. CIMs fits into the business view and to the first parts of RM-ODP, enterprise view and information view. Some CIMs components by exception would fit in some of the computation view. The latter is specifically only for operations on data that are intrinsic to CIMs such as calculation specifications for total scores or the use of formulae or constraints on data, amongst others.

c) System development

Model Driven Architecture (MDA) provides an open, vendor-neutral approach to business and technology change. MDA separates business and application logic from underlying platform technology[53]. MDA is part of the solution that creates an integrated healthcare IT landscape which allows data use and reuse, bridges gaps between systems and facilitates aggregation from clinical data. MDA is dependent upon standards, traceability and on the relationships between components[49][52]. In MDA, CIMs are important as they provide this consistency, traceability, and reusability across domains. That is not only between clinical domains, e.g. between general practice and surgery, but also between the clinical care domain and the aggregate domains of, e.g. epidemiology and/or quality assurance. This is depicted in the z-axis of Figure 2, illustrating the various System Domains.

Full traceability of CIMs and data allows the identification of which processes and systems are affected when information definitions change. In MDA, a relation from the whole to the CIMs suffices. There

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is no need for duplication and thus no inconsistencies should occur. CIMs address the conceptual and the internal logical level and express links to the larger logical model such as Reference (Information) Models (RIM), illustrating relationships between data elements and constraints. CIMs do not address the physical implementation level. However, in an EHR system or in a HL7® message, there can be a reference to a particular CIM stored in a repository for full description.

4.4.4 The Interoperability and Integration Reference Architecture in ISO 23903

The GCM as explained above has been further developed into ISO 23903. ISO 23903 defines a system-oriented, ontology-based, policy-driven, sustainable model and framework for managing systems integration and advanced interoperability across multiple domains. It enables the analysis and design of multi-domain systems, but also systems integration. It does this by use case specific deployment of existing standards and/or artefacts from different domains, i.e. selection, placement, constraining of the ICT components and their relationships. Contrary to traditional enterprise architectures, ISO 23903 provides a way to easily reconcile different knowledge domains without requiring the alteration of their inherent structures and semantics to fit each other, as well as the ICT domain. This implies the reconciliation of perspectives and requirements of the domains' stakeholders without bothering them with technology. ISO 23903 plays the same role for domain knowledge-based interoperability as the HL7® Communication Standard[34] does it for data and information level interoperability. The ISO/IEC 21838 series supports knowledge representation and management across networks of information systems.

Figure 2 shows the placement of CIMs in the Reference Architecture in ISO 23903 in relation to other architectural approaches and information models. The CIMs are part of the business view, part of the enterprise view and part the information view. This model enables integration of the different standards, specifications and artifacts into a coherent and implementable Reference Architecture.

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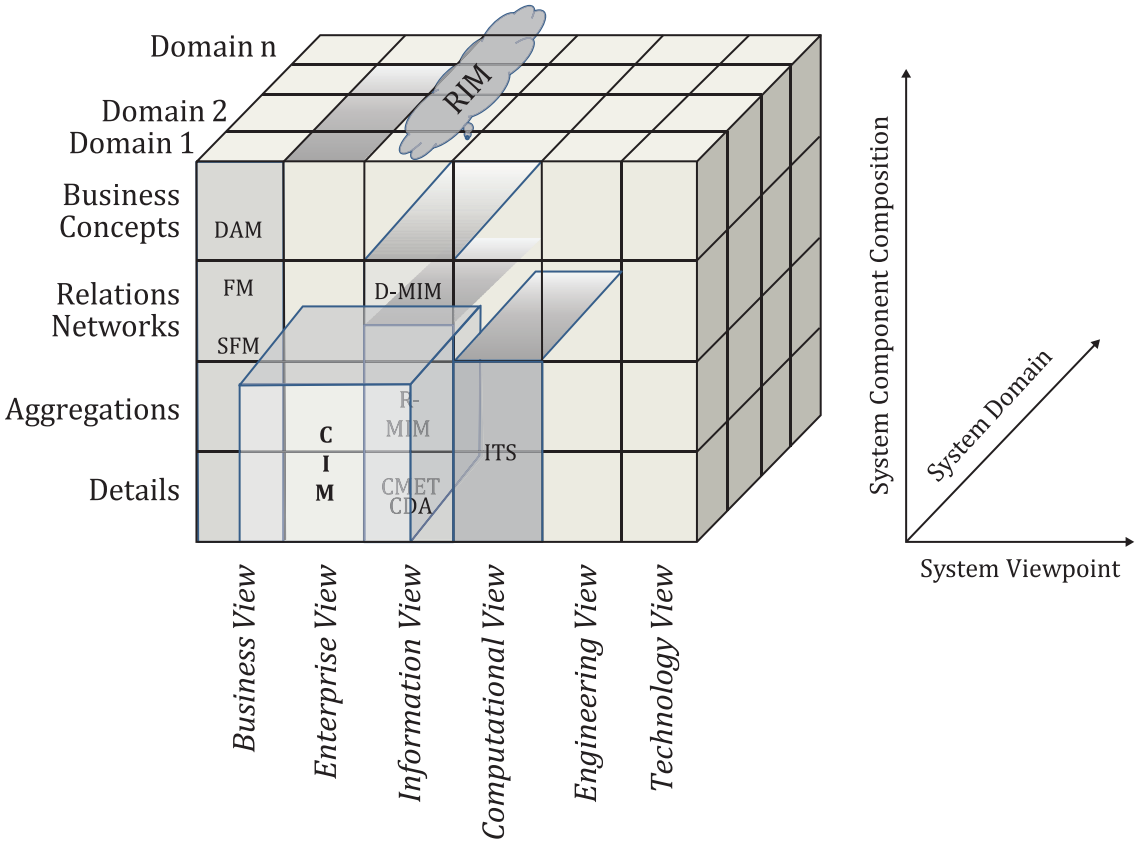

Key

DAM: Domain Analysis Model
FM: Functional Model
SFM: Specialized Functional Model
RIM: Reference Information Model
D-MIM: Domain Message Information Model
CEMT: Common Message Element Type
CDA: Clinical Document Architecture
ITS: Information Technology Specification

Figure 2 — Placement of CIMs in the Interoperability and integration reference architecture in ISO 23903 in relation to other architectural approaches and information models

Figure 3 illustrates the placement of ISO 13940, ISO 13606-2 archetypes and HL7® FHIR® in the Interoperability and Integration Reference Architecture in ISO 23903 in relation to other architectural approaches and information models. This schema enables integration of the different standards, specifications, and artifacts. This also illustrates the distinctions between for instance CIMs, archetypes and FHIR® specifications. In addition, design models at the physical level will ensure that the instantiation of logical information models respect the CIM defined constraints. This normally is the final step for CIM use in specific systems or products, in Figure 2, it is identified as the engineering view and technology view.

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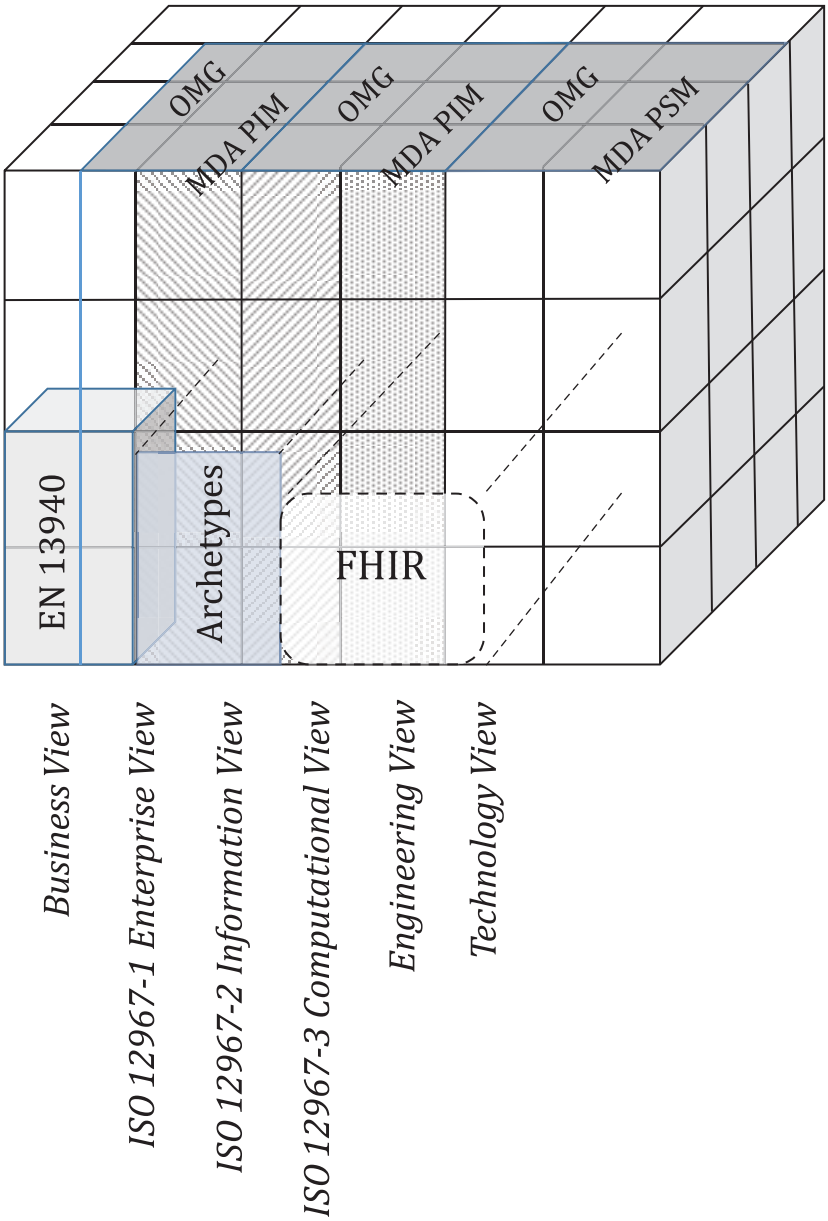

Key

OMG: Object Management Group

FHIR: Fast Healthcare Interoperability Resources

MDA: Model Driven Architecture

PIM: Platform Independent Model

PSM: Platform Specific Model

Figure 3 — Placement of other modeling approaches as ISO 13940, the ISO 12967 series, the ISO 13606 series and HL7® FHIR® in the Interoperability and integration reference architecture in ISO 23903

4.4.5 Representation of ReEIF through the ISO Interoperability and Integration Reference Architecture Framework

This subclause explores how ISO 23903 can assist the eHealth Framework to meet business requirements. To prevent confusion between the business requirements essentials of the Refined eHealth European Interoperability Framework (ReEIF)[44] and Interoperability and Systems Interoperability Reference Architecture in ISO 23903, an illustration is presented in Figure 4.

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