სსტ ისო 13606-3:2019/2020

საქართველოს სტანდარტი

საინფორმაციო ნაწილი. სრული ტექსტის სანახავად შეიძინეთ სტანდარტი.

ჯანმრთელობის ინფორმატიკა - ელექტრონული სამედიცინო ჩანაწერის კავშირი- ნაწილი 3: ეტალონური არქეტიპი და ტერმინების სიები

საქართველოს სტანდარტებისა და მეტროლოგიის
ეროვნული სააგენტო
თბილისი

სსტ ისო 13606-3:2019/2020

საინფორმაციო მონაცემები

1 შემუშავებულია საქართველოს სტანდარტების და მეტროლოგიის ეროვნული სააგენტოს სტანდარტების დეპარტამენტის მიერ

2 დამტკიცებულია და შემოღებულია სამოქმედოდ საქართველოს სტანდარტების და მეტროლოგიის ეროვნული სააგენტოს 2020 წლის 01 ივნისის № 59 განკარგულებით

3 მიღებულია გარეკანის თარგმნის მეთოდით სტანდარტიზაციის საერთაშორისო ორგანიზაციის სტანდარტი ისო 13606-3:2019 ,, ჯანმრთელობის ინფორმატიკა - ელექტრონული სამედიცინო ჩანაწერის კავშირი- ნაწილი 3: ეტალონური არქეტიპი და ტერმინების სიები”

4 პირველად

5 რეგისტრირებულია საქართველოს სტანდარტების და მეტროლოგიის ეროვნული სააგენტოს რეესტრში: 2020 წლის 01 ივნისი №268-1.3-017272

საინფორმაციო ნაწილი. სრული ტექსტის სანახავად შეიძინეთ სტანდარტი.

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საინფორმაციო ნაწილი. სრული ტექსტის სანახავად შეიძინეთ სტანდარტი.

INTERNATIONAL STANDARD

ISO 13606-3

Second edition
2019-06

Health informatics — Electronic health record communication —

Part 3: Reference archetypes and term lists

Informatique de santé — Communication du dossier de santé informatisé —

Partie 3: Archétypes de référence et listes de termes

Reference number
ISO 13606-3:2019(E)

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CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
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Published in Switzerland

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Contents

Page

Foreword ... **v**
Introduction ... **vi**
1 Scope ... **1**
2 Normative references ... **1**
3 Terms and definitions ... **1**
4 Abbreviations ... **2**
5 Conformance ... **2**
6 Term lists ... **2**
6.1 Introduction ... 2
6.2 Termlist SUBJECT_CATEGORY, Class ENTRY, attribute subject_of_information_category ... 3
6.3 Termlist VERSION_STATUS, Class BASE_COMPONENT, attribute version_status ... 3
6.4 Termlist MODE, Reference Archetype Healthcare activity participation ... 4
6.5 Class LINK, attribute link_description ... 4
6.5.1 Termlist RELATED_TO, Class LINK, attribute link_description ... 5
6.5.2 Termlist AUTHORISED_BY, Class LINK, attribute link_description ... 5
6.5.3 Termlist SAME_HEALTH_ISSUE, Class LINK, attribute link_description ... 6
6.5.4 Termlist SAME_PLAN, Class LINK, attribute link_description ... 8
6.5.5 Termlist RELATED_DOCUMENTATION, Class LINK, attribute link_description ... 8
6.6 Termlist, Class EXTERNAL_LINK, attribute target_information_type ... 9
6.7 Termlist, Classes ELEMENT and DEMOGRAPHIC_ELEMENT, attribute null_flavour ... 10
6.8 Termlist, Class ATTACHMENT, attribute IntegrityCheckAlgorithm ... 10
7 Reference archetype for null_flavor ... **10**
7.1 Archetype name: Null_flavor ... 10
8 Reference archetype for the access policy COMPOSITION ... **11**
8.1 Archetype name: Access_policy_rule ... 11
9 Reference archetypes for demographic entities ... **12**
9.1 Archetype name: EntityIdentifier ... 12
9.2 Archetype name: useablePeriod ... 13
9.3 Archetype name: LocationAddress ... 13
9.4 Archetype name: TelecommunicationAddress ... 14
9.5 Archetype name: Address ... 16
9.6 Archetype name: Namepart ... 17
9.7 Archetype name: PersonName ... 18
9.8 Archetype name: Person ... 19
9.9 Archetype name: HealthcareOrganization ... 20
9.10 Archetype name: ServiceDepartment ... 21
9.11 Archetype name: HealthcarePersonnel ... 22
9.12 Archetype name: MedicalDevice ... 23
9.13 Archetype name: SubjectOfInformation ... 25
9.14 Archetype name: Contact ... 25
9.15 Archetype name: HealthcareActivityParticipation ... 26
9.16 Archetype name: HealthcareActivityFacility ... 26
9.17 Archetype name: HealthcareActivityFramework ... 27
9.18 Summary of demographic-related data types in ISO 21090 ... 27
9.18.1 Identification and Location Datatypes ... 27
9.18.2 Name and Address Datatypes ... 29
10 Reference archetypes for medicinal product ... **31**
10.1 Archetype name: MedicinalProduct ... 31
11 Reference archetypes for clinical information specifications ... **37**
11.1 General ... 37

საინფორმაციო ნაწილი. სრული ტექსტის სანახავად შეიძინეთ სტანდარტი.

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11.2 Archetype name: Health condition 38
11.3 Archetype name: Healthcare activity element 42
11.4 Archetype name: ClinicalContext 47
11.5 Archetype name: Activity management 49
11.6 Archetype name: Association 50
11.7 Archetype name: Consideration 51
11.8 Archetype name: Dosage 52
11.9 Archetype name: Method 52

12 Contsys-based clinical reference information structures as the basis for development of clinical archetypes 54
12.1 Introduction 54
12.1.1 Criteria/characteristics 56
12.1.2 Basic concepts as bases for the Contsys-based information structure 56
12.1.3 Method for development of Contsys-based clinical reference information structures 56
12.1.4 Steps in defining the information structures 57
12.2 Content of information structures 58
12.2.1 Structures for single concepts 58
12.2.2 Structures for reuse in clinical situations — Clusters complementing structures for basic clinical concepts 58
12.2.3 Structures for compound documents in an EHR 59
12.2.4 Other comments 59
12.2.5 Format 60
12.3 Specializations of types of Health condition 60
12.4 Information structures for single concepts 61
12.4.1 Health condition 61
12.5 Healthcare activity element 67
12.5.1 Performer 72
12.6 Pharmacological treatment 73
12.6.1 Pharmacological treatment 73
12.6.2 Dosage 74
12.7 Indirect healthcare activity elements 74
12.7.1 Healthcare assessment 75
12.7.2 Assessments to conclude or exclude health conditions 75
12.7.3 Healthcare needs Assessment 76
12.7.4 Clinical risk assessment 78
12.7.5 Healthcare evaluation 78
12.8 Care plan 80
12.9 Clusters complementing the information structures for single clinical concepts 83
12.9.1 Activity Management including healthcare planning 83
12.9.2 Assessment scale representation 84
12.9.3 Association 84
12.9.4 Clinical Context 85
12.9.5 Clinical process concern 87
12.9.6 Clinical risk 87
12.9.7 Consideration 88
12.9.8 Knowledge base 89
12.9.9 Method specification 90
12.9.10 Priority Level 91
12.9.11 Version information 92
12.10 Compound structures as combinations of the Contsys based clinical reference information structures for clinical content and clinical context 93
12.10.1 Personal health record overview 93
12.10.2 Professional health record overview 93
12.10.3 Knowledge based healthcare activity planning of healthcare investigations 93
12.10.4 Knowledge based healthcare activity planning of healthcare treatments 94

Bibliography 95

საინფორმაციო ნაწილი. სრული ტექსტის სანახავად შეიძინეთ სტანდარტი.

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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).

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For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health Informatics*.

This second edition cancels and replaces the first edition (ISO 13606-3:2009), which has been technically revised. The main changes compared to the previous edition are summarised in the Introduction.

A list of all parts in the ISO 13606 series can be found on the ISO website.

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.

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Introduction

0.1 General

This document is part of a five-part series of standards, published jointly by CEN and ISO through the Vienna Agreement. In this document, dependency upon any of the other parts of this series of standards is explicitly stated where it applies.

0.2 Preface

ISO 13606-3 defines two kinds of specifications.

1) A normative set of (coded) term lists that each defines a controlled vocabulary for a Reference Model attribute that is defined in ISO 13606-1;

2) A set of Reference Archetypes that specify how the ISO 13606-1 Reference Model should be applied for communicating information for:

   — null_flavor;

   — access policies;

   — demographic entities;

   — example clinical reference archetypes, conforming to ISO 13940 (Contsys).

0.3 Term Lists

Each term list is referenced by its corresponding attribute as an invariant constraint in ISO 13606-1, by referring to its term list name. For each term list, every code value is accompanied by a phrase and description; however, in each case it is the code that is used as the Reference Model attribute value. Language translations of the phrase and description will therefore not affect the instances of RECORD_COMPONENT that are communicated using this document.

Should any revision prove necessary in the future to these term lists, a technical revision to this document will be required. Such a revised document should specify an updated Reference Model identifier that should then be used as the value of the rm_id of an EHR_EXTRACT, to inform the recipient of the version of this document that was used in its creation.

0.4 Reference archetypes

An archetype, sometimes known as a clinical model, specifies a pattern for representing an aspect of clinical documentation within an electronic health record. An archetype defines the structural and semantic relationships between fine-grained data items, including the domains of content each data item may contain in order to be a valid component of that archetype. The concept of archetypes is outlined in the introduction of ISO 13606-1, and the formal representation of archetypes is specified in ISO 13606-2. Archetypes are used in this document to shape parts of an EHR extract, in order to provide predictability of the way in which clinical information is represented within it.

Given the vast domain of health and healthcare, there might eventually be hundreds of archetypes covering its many different documentation and communication needs. Because archetypes might be created by different communities in different countries and settings, there is a risk that archetypes for similar areas of documentation will be made differently by different groups, and therefore hamper interoperability. *Reference archetypes* are archetypes that represent very fundamental areas of clinical documentation, which might be used as they are or may serve as a kind of *base pattern* for more specialised archetypes. By acting as the base pattern for a set of specialised archetypes, the members of the set are likely to be better structurally and semantically aligned with each other. Their use will facilitate semantic interoperability by making it easier for EHR extracts that have used different members of that set to be interpreted collectively.

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A reference archetype is a starting point for archetype specialisation (using a sub-set of properties and/or constraints on the ELEMENT value domains), or localised by adding natural language or local terminology mappings, or may be extended with additional properties. In all such cases the reference archetype should be specified as the underlying "specialisation parent", in accordance with ISO 13606-2. Some reference archetypes may be implemented directly. A reference archetype is therefore a conventional archetype that has been designated as a recommended (informative) or mandated (normative) basis for developing commonly required archetypes.

This document defines several categories of reference archetypes, some of which have been designated as normative and others informative. The decision of which to make normative is based on the information source used to create each reference archetype: if the underlying source is itself part of this document or is required to implement it then it has been designated as normative. If it is an external source such as another standard, which might be revised at a different time point to this document, then the reference archetype has been made informative.

In this document, a normative null_flavor reference archetype is defined to be used for the corresponding property in ISO 13606-1. A normative access policy rule reference archetype is specified in accordance with the corresponding information model for an access policy rule specified in ISO 13606-4. Informative reference archetypes are defined for the most frequently needed demographic entities. An informative archetype is specified for medicinal product, which has been defined in accordance with the ISO IDMP standard series.

The examples of clinical reference archetypes presented in Clause 11 are based on the clinical reference information structures in Clause 12. The clinical reference information structures in Clause 12 are developed out from the clinical concepts as they are defined in ISO 13940:2015 (Contsys).

Each selected clinical concept in Contsys has been elaborated based on the definition, relations and explanations in notes given in ISO 13940. The attributes of the clinical reference information structures are thus mainly based on ISO 13940. Some further attributes are added to harmonize the structures with e.g. FHIR resources or openEHR.

The result is information structures representing basic clinical concepts including a gross list of attributes for each concept. The gross list is intended to be comprehensive and cover all needs for clinical information in different specializations and applications. This approach reflects the general idea to include all needed types of characteristics/attributes and constrain the number applied when specializing clinical archetypes for instantiation.

The level of granularity/abstraction of the classes/selected concepts in the clinical reference information structures in Clause 12 and in the examples of clinical reference archetypes in Clause 11 is explained by the purpose of being general at the conceptual level for all clinical situations where information about this type of concept is relevant (content as well as context) but still specific for that clinical concept.

One example of the chosen level of abstraction is healthcare activity element as the concretized specialization of healthcare activity with a specific purpose (e.g. investigation or treatment). Another example could be that the method of performing activity elements are specified at a general level common for surgical treatments, pharmacological treatments (including administration routes) and laboratory tests as investigations.

Clause 12 includes clinical reference information models, conformant to ISO 13940(Contsys), to be used as bases for specifying clinical reference archetypes. These are aimed for further specializations as clinical archetypes in an EHR. The clinical reference information models are also aimed for further use as a basis for harmonizing between coexisting standards for specifying clinical content. A future possibility could be to develop FHIR resources based on these reference models. Another possibility for future development is that CIMI archetypes could accept the same bases as a "middle layer" between their reference model and specific archetypes. Altogether such approaches could result in harmonization of the different information specification standards/approaches to the common conceptual basis of Contsys. These resources are offered in an informative Clause to indicate the direction of ongoing work to develop a portfolio of Reference Archetypes that align with Contsys and with corresponding FHIR resources, but which are not yet mature enough to include here as normative specifications.

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