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)

© ISO 2019



COPYRIGHT PROTECTED DOCUMENT

© ISO 2019

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
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
Website: www.iso.org

Published in Switzerland

 © ISO 2019 – All rights reserved

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

© ISO 2019 – All rights reserved

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

 © ISO 2019 – All rights reserved

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 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.

© ISO 2019 – All rights reserved

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.

 © ISO 2019 – All rights reserved

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.

© ISO 2019 – All rights reserved

Health informatics — Electronic health record communication —

Part 3: Reference archetypes and term lists

1 Scope

This document specifies a means for communicating part or all of the electronic health record (EHR) of one or more identified subjects of care between EHR systems, or between EHR systems and a centralised EHR data repository.

It can also be used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components), or personal health applications and devices, that need to access or provide EHR data, or as the representation of EHR data within a distributed (federated) record system.

This document defines term lists that each specify the set of values for the particular attributes of the Reference Model defined in ISO 13606-1. It also defines normative and informative Reference Archetypes that enable frequently-occurring instances of EHR data to be represented within a consistent structure when communicated using this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13606-1, *Health informatics — Electronic health record communication — Part 1: Reference model*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 13606-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
healthcare activity
activity intended directly or indirectly to improve or maintain a health state

Note 1 to entry: Each specialization of this concept represents *healthcare activities* performed by a specialization of *healthcare actor*.

Note 2 to entry: Different types of *healthcare activity elements* (e.g. *healthcare investigation* or *healthcare treatment)* may be performed during a *healthcare activity*.

Note 3 to entry: See the *concepts healthcare provider activity*, *self-care activity*, *healthcare third party activity* and *automated healthcare* when it comes to the recording of *information* that are the result of *healthcare activities* (e.g. ratified observations).

© ISO 2019 – All rights reserved

EXAMPLE A blood pressure measurement completed by a qualified nurse including the *healthcare activity elements* of taking, documenting and evaluation.

[SOURCE: ISO 13940:2015]

3.2
reference archetype
archetype serving as a base pattern for archetype specialisations

4 Abbreviations

For the purposes of this document, the following abbreviations apply.

EHR	Electronic Health Record
EU	European Union
GP	General Practitioner
HL7	Health Level Seven
ISO	International Organization for Standardization
OID	Object Identifier
UML	Unified Modelling Language

5 Conformance

When electronic health record information is to be communicated using ISO 13606 (all parts) and where an attribute of the Reference Model defined in ISO 13606-1 requires a value to be taken from a bounded set of codes from a named term list, the code shall be one of those defined in Clause 6 for the correspondingly-named term list.

An archetype that is used to organize the structure and semantics of part of an electronic health record that is communicated using this standard series shall be a logical transformation or specialization of a normative reference archetype defined in Clauses 7 or 8, if the archetype is intended to communicate information corresponding to the scope of one of those reference archetypes. This document does not prescribe the structure or semantics of any other archetypes used to communicate electronic health record information.

6 Term lists

6.1 Introduction

The Reference Model defined in ISO 13606-1 defines several attributes whose values are to be selected from a fixed list of values. This clause defines those value lists (term lists) for each of those attributes. Attributes not included in this clause (or defined in ISO 13606-4) may take any value that conform to the data type and invariant specifications defined in ISO 13606-1.

There are no attributes in the Reference Model to specify the clinical content being communicated, except for the identifier of the archetypes that specify its overall structure and semantics and the term list defining semantic linkage between RECORD_COMPONENTs. Clinical concepts as they are defined in ISO 13940:2015, and a reference information structure as the informative basis for developing clinical reference archetypes, are presented in Clause 12.

© ISO 2019 – All rights reserved