

# SLOVENSKI STANDARD SIST EN 13606-3:2008

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Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists

Medizinische Informatik Kommunikation von Patientendaten in elektronischer Form - Teil 3: Referenzarchetypen und Begriffslisten (Standards.iteh.ai)

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# EUROPEAN STANDARD

# EN 13606-3

# NORME EUROPÉENNE EUROPÄISCHE NORM

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# **English Version**

# Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists

Informatique de la santé - Communication des dossiers de santé informatisés - Partie 3: Archétypes de référence et listes de termes

Medizinische Informatik - Kommunikation von Patientendaten in elektronischer Form - Teil 3: Referenzarchetypen und Begriffslisten

This European Standard was approved by CEN on 28 February 2008.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

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

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# **Foreword**

This document (EN 13606-3:2008) has been prepared by Technical Committee CEN/TC 251 "Health informatics", the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2008, and conflicting national standards shall be withdrawn at the latest by September 2008.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

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# Introduction

# 0.1 Summary

Part 3 of the 13606 standards series contains two kinds of specifications:

- 1 normative set of (coded) term lists that each defines a controlled vocabulary for a Reference Model attribute that is defined in Part 1 of this standard series;
- informative set of Reference Archetypes: expressed as mappings that each specifies how the Part 1 Reference Model should be used to represent information originating from:
  - set of HL7 version 3 Acts that form part of the Clinical Statement Domain Message Information Model;
  - o specialisations of ENTRY that are defined in the *open*EHR Reference Model.

### 0.2 Term Lists

Each term list is referenced by its corresponding attribute as an invariant constraint in Part 1 of this standard series, 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 to be 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 standard.

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Should any future revision prove necessary for these term lists, a technical revision of this standard will be required. Such a revised standard shall specify an updated Reference Model identifier that shall then be used as the value of the rm\_id of an EHR\_EXTRACT, to inform the recipient of the version of this standard that was used in its creation.

A cross-mapping of the term list for LINK.role to HL7 actRelationship codes is also provided for the convenience of those wishing to adopt or interface this standard with HL7 version 3. This is part of a longer-term vocabulary harmonisation project between the health informatics standards development organizations (SDO's), and might therefore be extended in the future via other publications, such as the planned HL7-13606 Implementation Guide (see below). It is therefore informative in this standard.

### 0.3 Reference Archetypes

Each Reference Archetype is represented in this standard as a mapping correspondence table to indicate the way in which the ITEM structure within a 13606 Part 1 ENTRY is to be used to represent the classes and attributes of relevant HL7 v3 and *open*EHR classes. These two external models have been chosen for inclusion as these are the most likely internationally-used source models from which fine-grained clinical data may need to be transformed into this standard for communication.

These Reference Archetypes are included as an aid to those adopting this standard and wishing to transform Electronic Health Record (her) data from existing HL7 v3 or openEHR instances or messages. It is recognised that full two-way interoperability between these various representations requires more detail, including rich vocabulary and data type harmonisation, and a corresponding set of technical artefacts such as eXtensible Markup Language (XML) Schemata and Extensible Stylesheet Language Transformation (XSLT) scripts. Such interoperability is very much the goal of current SDO harmonisation efforts, and will be published as an HL7-13606 Implementation Guide, possibly as an open-access and regularly updated resource. However, the outstanding work required to achieve this level of interoperability might take up to another year from when this standard is expected to be published. It has therefore been decided to offer what does exist towards harmonisation in an informative form within this standard, as an aid to those already needing to make such data transformations. A worked example of the HL7 v3 to ISO 13606 mapping is given in Annex B.

# 1 Scope

This Standard addresses the communication of part or all of electronic health records (EHR) of a single identified subject of care between EHR systems, or between EHR systems and a centralised EHR data repository. It may also be used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components) that need to access or provide EHR data, or as the representation of EHR data within a distributed (federated) record system.

This Standard, Part 3 of the 13606 EHR Communications Standard Series, defines term lists that each specify the set of values that particular attributes of the Reference Model defined in Part 1 of this Series may take. It also defines informative Reference Archetypes that correspond to ENTRY-level compound data structures within the Reference Models of *open*EHR and HL7 Version 3, to enable those instances to be represented within a consistent structure when communicated using this standard.

# 2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

#### 3.1

# archetype instance

individual metadata class 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

#### 3.2

# clinical information iTeh STANDARD PREVIEW

information about a person, relevant to his or her health or health care (standards.iteh.ai)

#### 3.3

#### committed

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information that has been persisted within an electronic health record system and which constitutes part of the electronic health record for a subject of care 4cb/sist-en-13606-3-2008

#### 3.4

#### committer

agent (party, device or software) whose direct actions have resulted in data being committed to an electronic health record

#### 3.5

# composer

agent (party, device or software) responsible for creating, synthesising or organising information that is committed to an electronic health record

# 3.6

## electronic health record extract

part or all of the electronic health record for a subject of care, communicated in compliance with EN 13606

## 3.7

# electronic health record system

system for recording, retrieving and manipulating information in electronic health records

## 3.8

# entries

health record data in general (clinical observations, statements, reasoning, intentions, plans or actions) without particular specification of their formal representation, hierarchical organisation or of the particular Record Component class(es) that might be used to represent them

#### 3.9

# patient

synonym for a subject of care

# EN 13606-3:2008 (E)

#### 3.10

#### **Record Component**

part of the electronic health record extract of a single subject of care, represented as a node within a hierarchical data structure conforming to EN 13606

#### 3.11

### state (of a process)

condition or situation during the lifecycle of an object during which it satisfies some condition, performs some activity or waits for some event

[ISO/TS 18308:2004]

#### 3.12

### subject of care

person scheduled to receive, receiving, or having received health care

# 3 Abbreviations

#### CEN

Comité Européen de Normalisation (European Committee for Standardization)

### **CEN/TC 251**

**CEN Technical Committee 251** 

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# **EHR**

Electronic Health Record

SIST EN 13606-3:2008

European Union https://standards.iteh.ai/catalog/standards/sist/330ac994-31c3-4ea9-bcce-351eca4484cb/sist-en-13606-3-2008

## HISA

Health Information Systems Architecture

# HL7

Health Level Seven

# ISO

International Organization for Standardization

#### UML

**Unified Modelling Language** 

#### **XML**

Extensible Mark-up Language

# 4 Conformance

When electronic health record information is to be communicated using the 13606 Standard Series and where an attribute of the Reference Model defined in Part 1 of this series 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 5 of this standard for the correspondingly-named term list.

# 5 Term lists

# 5.1 Introduction

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

# 5.2 Termlist SUBJECT\_CATEGORY, Class ENTRY, attribute subject\_of\_information\_category

This attribute provides a coarse-grained definition of the person who is the subject of an ENTRY. The default value is DS00 (the patient or subject of care). A more fine-grained definition of the information subject (such as the precise relative with a family history) can be specified through the ENTRY.subject of information.relationship attribute.

Code	Meaning	Description	
DS00	subject of care	subject of care	
DS01	relative of subject of care	any human relative, without limitation to biological or adoptive relatives	
DS02	foetus or neonate or infant	baby or babies being described by an ENTRY in the EHR of the mother	
DS03	mother iTeh STAND	mother of a foetus or neonate if being described in the EHR of a baby (e.g. during pregnancy)	
DS04	donor (standa	donor of an organ or body specimen being described by an ENTRY in the EHR of the recipient	
DS05	unrelated person SIST EN https://standards.iteh.ai/catalog/sta	any other person not related to the subject of care, such as an employer friend garer 3-4ea9-bcce-	
NOTE If ENTRY.subject_of_information_category is null, the value DS00 is assumed.			

# 5.3 Termlist ITEM\_CATEGORY, Class ITEM, attribute item\_category

Some kinds of ENTRY might have a complex internal data structure, comprised of the main values of interest and other kinds of context. This optional attribute in the Reference Model permits the communication of the category of information for each ELEMENT or CLUSTER. This may be of value to a receiving EHR system, to enable easier processing of the data.

Code	Meaning	Description
IC01	Principal or 'core' value	The CLUSTERS or ELEMENTS that contain the main values that are the subject of the ENTRY
IC02	Supplementary/complementary details about the value	Contextual information that most users would regard as necessary to interpret the core values
IC03	Patient state/circumstances	Contextual information about the subject of care's circumstances when an observation is made e.g. fasting, standing
IC04	Method details	Contextual information about the method of an observation, such as the technique or device used
IC05	Clinical reasoning  iTeh STANDARD  (standards.i	Any explanatory information provided by the author to explain a clinical decision or interpretation, other than a specific reference to a protocol of guideline or knowledge source
IC06	Protocol/guideline  SIST EN 13606-3  https://standards.iteh.ai/catalog/standards/sis	A description, reference or explanation of any protocol or guideline that informed the ENTRY (e.g. to perform an observation, or initiate a plan of care)
IC07	Knowledge source	A reference to any external knowledge source, such as a web site or medical text, that explains or amplifies a clinical decision
IC08	Presentation	Any information about how the values in the ENTRY should be presented; image rendering information is one example
IC09	Assertion status	To indicate that the ELEMENT contains a value that indicates the presence/absence, normality/abnormality of the core values (e.g. if the core value is a questionnaire question and the ELEMENT contains the yes/no answer)

# 5.4 Termlist VERSION\_STATUS, Class AUDIT\_INFO, attribute version\_status

This attribute is used to indicate the status of a particular version of a RECORD\_COMPONENT. This attribute is optional, and if no value is provided it is to be assumed that the RECORD\_COMPONENT is the first definitive version corresponding to code value VER01. In all cases, the new version of a RECORD\_COMPONENT shall replace the former version, as specified in Part 1 of this series.

Code	Meaning	Description		
VER00	Draft	The version is known at the time of committal to be incomplete (because additional information is expected later) or if the necessary authorisations have not been made, VER00 implies that the EHR_recipient might in future expect to receive a more definitive updated version of this RECORD_COMPONENT		
VER01	Finished	The version is committed with the intention of being a final version, with no anticipated reason for revision		
VER02	Update	The version is an update of the previous version, usually by adding supplementary information that was not available at the time of committal		
i	Teh STANDAI	NOTE 1 Revision is intended for additions usually to be made by the original author within a short time frame, and not for recoding an evolving clinical story		
VER03	Correctiontandard	The version corrects errors made in the recording of the previous version		
VER04 https://s	Deletion SIST EN 13: standards.iteh.ai/catalog/standa 351eca4484cb/sist-	The Version logically deletes the previous version (e.g. if the RECORD_COMPONENT-blad been placed in the wrong patient's EHR)		
NOTE 2 If AUDIT_INFO.version_status is null, the value VER01 is assumed.				

# 5.5 Termlist MODE, Class FUNCTIONAL\_ROLE, attribute mode

This attribute is used to describe the physical or electronic means by which an entity has participated in the provision or documentation of health care. This term list is taken from the corresponding code set in EN 14822-2, for the attribute mode, except that codes have been added for use within an EHR Extract.

Code	Meaning	Description	EN14822-2 term
MOD01	electronic data	Participation by non-human-language based electronic signal	ELECTRONIC
MOD02	verbal	Participation by voice communication	VERBAL
MOD03	dictated	Participation by pre-recorded voice. Communication is limited to one direction (from the recorder to recipient)	DICTATED
MOD04	face-to-face	Participation by voice communication where parties speak to each other directly	FACE
MOD05	telephone	Participation by voice communication where the voices of the communicating parties are transported over an electronic medium	PHONE
MOD06	videoconferencing	Participation by voice and visual communication where the voices and images of the communicating parties are transported over an electronic medium	VIDEOCONF
MOD07	written	Participation by human language recorded on a physical material	WRITTEN
MOD08	email	Participation by text or diagrams transmitted over an electronic mail system	EMAIL
MOD09	telefax	Participation by text or diagrams printed on paper that have been transmitted over a fax device	FAX
MOD10	handwritten	Participation by text, or diagrams printed on paper or other recording medium  351eca4484cb/sist-en-13606-3-2008	HANDWRITTEN
MOD11	typewritten	Participation by text or diagrams printed on paper or other recording medium where the recording was performed using a typewriter, typesetter, computer or similar mechanism	TYPEWRITTEN
MOD12	physical presence	Participation by direct action where subject and actor are in the same location. (The participation involves more than communication)	PHYSICAL
MOD13	remote presence	Participation by direct action where subject and actor are in separate locations, and the actions of the actor are transmitted by electronic or mechanical means. (The participation involves more than communication)	REMOTE
NOTE	If FUNCTIONAL_ROLE.mode is null, the value MOD04 is assumed.		

# 5.6 Termlist ACT\_STATUS, Class ENTRY, attribute act\_status

This term list is identical to the act status values in the HISA standard EN 12967, except that codes have been added for use within an EHR Extract. Formal definitions of these terms are given in the HISA standard, and their mapping to HL7 appropriate act. Status and mood. Code values.

Code	Meaning	
ACT01	Foreseen	
ACT02	Requested	
ACT03	Accepted	
ACT04	Booked	
ACT05	Planned	
ACT06	Ready	
ACT07	In progress	
ACT08	Completed	
ACT09	Reported	
ACT10	Terminated	
ACT11	Forwarded	RD PREVIEW
ACT12	Suspended	
ACT13	Annulled-Cancelled ard	s.iteh.ai)
ACT14	Annulled-Rejected	506-3:2008
ACT15 https://s	Substituted standards tandards and a standards and a standards and a standard standards and a standard	rds/sist/330ac994-31c3-4ea9-bcce-

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