

DIN EN ISO 13606-3

ICS 35.240.80

Entwurf

Einsprüche bis 2017-07-05
Vorgesehen als Ersatz für
DIN EN 13606-3:2008-06

**Medizinische Informatik –
Kommunikation von Patientendaten in elektronischer Form –
Teil 3: Referenzarchetypen und Begriffslisten (ISO/DIS 13606-3:2017);
Englische Fassung prEN ISO 13606-3:2017**

Health informatics –
Electronic health record communication –
Part 3: Reference archetypes and term lists (ISO/DIS 13606-3:2017);
English version prEN ISO 13606-3:2017

Informatique de santé –
Communication du dossier de santé informatisé –
Partie 3: Archétypes de référence et listes de termes (ISO/DIS 13606-3:2017);
Version anglaise prEN ISO 13606-3:2017

Anwendungswarnvermerk

Dieser Norm-Entwurf mit Erscheinungsdatum 2017-05-05 wird der Öffentlichkeit zur Prüfung und Stellungnahme vorgelegt.

Weil die beabsichtigte Norm von der vorliegenden Fassung abweichen kann, ist die Anwendung dieses Entwurfs besonders zu vereinbaren.

Stellungnahmen werden erbeten

- vorzugsweise online im Norm-Entwurfs-Portal von DIN unter www.din.de/go/entwuerfe bzw. für Norm-Entwürfe der DKE auch im Norm-Entwurfs-Portal der DKE unter www.entwuerfe.normenbibliothek.de, sofern dort wiedergegeben;
- oder als Datei per E-Mail an named@din.de möglichst in Form einer Tabelle. Die Vorlage dieser Tabelle kann im Internet unter www.din.de/go/stellungnahmen-norm-entwuerfe oder für Stellungnahmen zu Norm-Entwürfen der DKE unter www.dke.de/stellungnahme abgerufen werden;
- oder in Papierform an den DIN-Normenausschuss Medizin (NAMED), 10772 Berlin, Burggrafenstr. 6, 10787 Berlin.

Die Empfänger dieses Norm-Entwurfs werden gebeten, mit ihren Kommentaren jegliche relevanten Patentrechte, die sie kennen, mitzuteilen und unterstützende Dokumentationen zur Verfügung zu stellen.

Gesamtumfang 135 Seiten

DIN-Normenausschuss Medizin (NAMED)

Nationales Vorwort

Dieses Dokument (prEN ISO 13606-3:2017) wurde in der WG 1 „Architecture, Frameworks and Models“ des Technischen Komitees ISO/TC 215 „Health Informatics“ und mit dem Technischen Komitee CEN/TC 251 „Medizinische Informatik“, dessen Sekretariat von NEN (Niederlande) gehalten wird, erarbeitet. Der Arbeitsausschuss NA 063-07-02 AA „Interoperabilität“ des Fachbereichs 7 „Medizinische Informatik“ des DIN-Normenausschusses Medizin (NAMed) hat an der Erarbeitung ebenfalls mitgewirkt.

Dieses Dokument enthält unter Berücksichtigung des Präsidialbeschlusses 1/2004 nur die englische Originalfassung von prEN ISO 13606-3:2017.

Änderungen

Gegenüber DIN EN 13606-3:2008-06 wurden folgende Änderungen vorgenommen:

- a) Übernahme der Internationalen Norm;
- b) der Norminhalte wurde mit ISO 13940 *Medizinische Informatik — Begriffssystem zur Unterstützung der Kontinuität der Versorgung* und der Normenreihe ISO 12967 *Medizinische Informatik — Servicearchitektur* und harmonisierte;
- c) die Teile dieser Normenreihe wurden untereinander harmonisiert.

Zusammenfassung

Diese Norm legt fest, wie die elektronische Gesundheitsakte (eGA) von einem identifizierten Behandelten oder mehreren identifizierten Behandelten zwischen eGA-Systemen oder zwischen eGA-Systemen und einem zentralen eGA-Repository vollständig oder teilweise übermittelt werden kann.

Sie kann auch verwendet werden für die eGA-Übermittlung zwischen einem eGA-System oder -Repository und klinischen Anwendungen bzw. Middleware-Komponenten (wie z. B. Entscheidungsunterstützungskomponenten), wenn diese Zugriff auf eGA-Daten benötigen oder diese bereitstellen, oder als Darstellung von eGA-Daten innerhalb eines verteilten (föderierten) Datensatzsystems.

Diese Norm, Teil 3 der Normserie 13606 zur eGA-Übermittlung, definiert Begriffslisten, die jeweils den Satz von Werten spezifizieren, den bestimmte Attribute des Referenzmodells, das in Teil 1 dieser Serie definiert ist, annehmen können. Sie definiert auch normative und informative Referenz-Archetypen, die es ermöglichen, häufig auftretende Instanzen von eGA-Daten in einer konsistenten Struktur darzustellen, wenn sie mithilfe dieser Norm übermittelt werden.

Nationaler Anhang NA (informativ)

Begriffe

Für die Anwendung dieses Dokuments gelten die Begriffe nach EN ISO 13606-1.

Contents

Foreword	7
0 Introduction (Informative)	8
0.1 General.....	8
0.2 Preface.....	8
0.3 Term Lists.....	9
0.4 Reference archetypes.....	9
1 Scope	11
2 Normative references	11
3 Terms and definitions	11
4 Abbreviations	12
5 Conformance	13
6 Term lists	14
6.1 Introduction.....	14
6.2 Termlist SUBJECT_CATEGORY, Class ENTRY, attribute subject_of_information_category.....	14
6.3 Termlist VERSION_STATUS, Class BASE_COMPONENT, attribute version_status	15
6.4 Termlist MODE, Reference Archetype Healthcare activity participation.....	15
6.5 Class LINK, attribute role.....	16
6.5.1 Termlist RELATED_TO, Class LINK, attribute role	16
6.5.2 Termlist AUTHORISED_BY, Class LINK, attribute role.....	17
6.5.3 Termlist SAME_HEALTH_ISSUE, Class LINK, attribute role	18
6.5.4 Termlist SAME_PLAN, Class LINK, attribute role.....	19
6.5.5 Termlist RELATED_DOCUMENTATION, Class LINK, attribute role.....	19
6.6 Termlist, Class EXTERNAL_LINK, attribute target_information_type	20
6.7 Termlist, Classes ELEMENT and DEMOGRAPHIC_ELEMENT, attribute null_flavour	21
6.8 Termlist, Class ATTACHMENT, attribute IntegrityCheckAlgorithm	21
7 Reference archetype for null_flavor (normative)	23
7.1 Archetype name: Null_flavor	23
8 Reference archetype for the access policy COMPOSITION (normative)	24
8.1 Archetype name: Access_policy_rule.....	24

9	Reference archetypes for demographic entities (informative)	25
9.1	Archetype name: EntityIdentifier	25
9.2	Archetype name: useablePeriod	25
9.3	Archetype name: LocationAddress	26
9.4	Archetype name: TelecommunicationAddress	28
9.5	Archetype name: Address	29
9.6	Archetype name: Namepart	31
9.7	Archetype name: PersonName	32
9.8	Archetype name: Person	33
9.9	Archetype name: HealthcareOrganization	35
9.10	Archetype name: ServiceDepartment	36
9.11	Archetype name: HealthcarePersonnel	38
9.12	Archetype name: MedicalDevice	40
9.13	Archetype name: SubjectOfInformation	42
9.14	Archetype name: Contact	42
9.15	Archetype name: HealthcareActivityParticipation	43
9.16	Archetype name: HealthcareActivityFacility	44
9.17	Archetype name: HealthcareActivityFramework	45
9.18	Summary of demographic-related data types in ISO 21090	46
9.18.1	Identification and Location Datatypes	46
9.18.2	Name and Address Datatypes	48
10	Reference archetypes for medicinal product (informative)	51
10.1	Archetype name: MedicinalProduct	51
11	Reference archetypes for clinical information specifications (informative)	61
11.1	Archetype name: Health condition	61
11.2	Archetype name: Healthcare activity element	68
11.3	Archetype name: ClinicalContext	75
11.4	Archetype name: Activity management	78
11.5	Archetype name: Association	80
11.6	Archetype name: Consideration	81
11.7	Archetype name: Dosage	82
11.8	Archetype name: Method	83
12	Annex A: Consys-based clinical reference information structures as the basis for development of clinical archetypes (informative)	86
12.1	Introduction	86

12.1.1	Criteria/characteristics.....	87
12.1.2	Basic concepts as bases for the Contsys-based information structure.....	87
12.1.3	Method for development of Contsys-based Information structures	88
12.1.4	Steps in defining the information structures	89
12.2	Content of information structures.....	90
12.2.1	Structures for single concepts.....	90
12.2.2	Structures for reuse in clinical situations – clusters complementing those for basic clinical concepts 90	
12.2.3	Structures for compound documents in an EHR.....	91
12.2.4	Other comments.....	91
12.2.5	Format.....	92
12.3	Specializations of types of Health condition.....	92
12.4	Information structures for single concepts.....	95
12.4.1	Health condition.....	95
ReferenceRange.....		101
12.5	Healthcare activity element	102
12.5.1	Performer	107
12.6	Pharmacological treatment.....	108
12.6.1	Pharmacological treatment.....	108
12.6.2	Dosage	109
12.7	Indirect healthcare activity elements	111
12.7.1	Healthcare assessment.....	111
12.7.2	Assessments to conclude or exclude health conditions.....	112
12.7.3	Healthcare needs Assessment.....	113
12.7.4	Clinical risk assessment.....	115
12.7.5	Healthcare evaluation.....	116
12.8	Care plan	119
12.9	Clusters complementing the information structures for single clinical concepts.....	122
12.9.1	Activity Management including healthcare planning.....	122
12.9.2	Assessment scale representation.....	123
12.9.3	Association.....	123
12.9.4	Clinical Context.....	124
12.9.5	Clinical process concern	126
12.9.6	Clinical risk.....	127
12.9.7	Consideration.....	128
12.9.8	Knowledge base.....	129

12.9.9	Method specification.....	130
12.9.10	Priority Level.....	132
12.9.11	Version information.....	132
12.10	Compound structures as combinations of the Contsys based information structures for clinical content and clinical context.....	133
12.10.1	Personal health record overview.....	133
12.10.2	Professional health record overview	133
12.10.3	Knowledge based healthcare activity planning of healthcare investigations	134
12.10.4	Knowledge based healthcare activity planning of healthcare treatments	134

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. 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. 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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 215.

0 Introduction (Informative)

0.1 General

This Standard, EN ISO 13606 Part 3, is part of a five-part standard series, published jointly by CEN and ISO through the Vienna Agreement. These five parts are as follows.

Part 1: Reference Model. An information model, represented in UML, that may be used to communicate the content and context of any possible electronic health record information, for part or all of a person's electronic health record, or potentially for a set of persons such as a family. This model supports communication between distinct electronic health record repositories or may act as the information model underpinning a federation, such as a regional, national or multi-national network of interconnected repositories of EHR data.

Part 2: Archetype Interchange Specification. An information model represented in UML, accompanied by requirements, for the representation of clinical models which specify how individual areas of clinical information should be represented using the reference model of part 1.

Part 3: Reference Archetypes and Term Lists. A set of high-level archetype patterns that may be used (specialised) to develop specific archetypes covering commonly needed areas of clinical and demographic information. This part standard also includes a set of vocabularies (term lists) to populate properties of the information models included in other parts of this overall standard.

Part 4: Security. A vocabulary framework, and a more detailed generic representation for policy information, to communicate the access permissions covering the EHR content that is being communicated according to this standard. This part standard additionally contains an interoperable specification for audit log information that could inform a subject of care about who has accessed their health record.

Part 5: Interchange Specification. The information properties that should be included within interfaces that implement communication according to the other parts of this standard.

In this part standard, dependency upon any of the other parts of this series is explicitly stated where it applies.

0.2 Preface

Part 3 of the 13606 standards series 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 Part 1 of this standard series;
2. An set of Reference Archetypes, that specify how the Part 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 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.

Should any revision prove necessary in the future to these term lists, a technical revision to this standard will be required. Such a revised standard must 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.

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 to part 1 of the standard, and the formal representation of archetypes is specified in part 2. Archetypes are used in this standard 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 thousands 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.

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 must be specified as the underlying “specialisation parent”, in accordance with Part 2 of this standard. 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 standard 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 standard 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 standard, then the reference archetype has been made informative.

In this standard, a normative null_flavor reference archetype is defined to be used for the corresponding property in part 1. A normative access policy rule reference archetype is specified in accordance with the corresponding information model for an access policy rule specified in part 4 of this standard series. 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. Example clinical reference archetypes are defined that conform to EN ISO 13940 Consys, as guidance for how future clinical reference archetypes can be defined (outside the scope of this standard).

Annex A includes clinical reference information models, conformant to ISO 13940(Consys), 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 Consys. These resources are offered in an informative annex to indicate the direction of ongoing work to develop a portfolio of Reference Archetypes that align with Consys and with corresponding FHIR resources, but which are not yet mature enough to include here as normative specifications.

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

1 Scope

This Standard 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 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 normative and informative Reference Archetypes that enable frequently-occurring instances of EHR data to be represented within a consistent structure when communicated using this standard.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Drafting note: *References to the other Parts of EN ISO 13606 will be added before publication.*

3 Terms and definitions

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

4 Abbreviations

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

CEN	Comité Européen de Normalisation (European Committee for Standardization, a federation of 28 national standards bodies that are also ISO member bodies)
CEN/TC 251	CEN Technical Committee 251 (develops standards within health informatics)
EHR	Electronic Health Record
EU	European Union
GP	General Practitioner
HISA	Health Information Systems Architecture
HL7	Health Level Seven
IANA	Internet Assigned Numbers Authority
IETF	Internet Engineering Task Force
ISO	International Organization for Standardization
ODP	Open Distributed Processing (ISO/IEC 10746, used for describing distributed systems)
OID	Object Identifier
R&D	Research and Development
RFC	Request For Comments
UML	Unified Modelling Language
W3C	World Wide Web Consortium
XML	Extensible Mark-up Language

5 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 the 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 6 of this standard for the correspondingly-named term list.

An archetype used to organize the structure and semantics of part of an electronic health record that is communicated using this standard shall be a logical transformation or specialization of a normative reference archetype defined in Clauses 7 or 8 of this standard, if the archetype is intended to communicate information corresponding to the scope of one of those reference archetypes. This standard 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 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 conform to the data type and invariant specifications defined in Part 1 of this series.

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 Annex A.

6.2 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	<i>healthcare actor</i> with a <i>person role</i> ; who seeks to receive, is receiving, or has received healthcare
DS01	relative of subject of care	<i>person role</i> being any human relative, without limitation to biological or adoptive relatives
DS02	next of kin	<i>person role</i> being either the closest living relative of <i>the subject of care</i> or identified as the one he has a close relationship with
DS03	foetus or neonate or infant	the baby or babies being described by an ENTRY in the EHR of the mother
DS04	mother	the mother of a fetus or neonate, if being described in the EHR of a baby (e.g. during pregnancy)
DS05	donor	<i>person role</i> being the donor of an organ or body specimen being described by an ENTRY in the EHR of the recipient
DS06	unrelated person	<i>person role</i> being any other person not related to the subject of care, such as an employer, friend, carer
DS07	healthcare third party	<i>healthcare actor</i> (organization or person) other than a <i>healthcare provider</i> or the <i>subject of care</i>

NOTE If ENTRY.subject_of_information_category is null, the value DS00 is assumed.

NOTE: the original list has been extended and revised to align with terms and concepts used in ISO 13940 (Contsys).

6.3 Termlist VERSION_STATUS, Class BASE_COMPONENT, 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	Updated	The version is an update of the previous version, usually by adding supplementary information that was not available at the time of committal. NOTE: 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	Correction	The version corrects errors made in the recording of the previous version
VER04	Deletion (in error)	The version logically deletes the previous version to correct an error of documentation (e.g. if the RECORD_COMPONENT had been placed in the wrong patient's EHR)
VER05	Legal deletion	The version logically deletes the previous version because the removal is the outcome of a legal or policy matter (e.g. if the subject of care has exercised rights to have the information removed)
VER06	Encoded	The version updates the previous version through the addition of coded terms to which content in the previous version has been mapped, without replacing any of the original content of the previous version

NOTE If BASE_COMPONENT.version_status is null, the value VER01 is assumed.

DRAFTING NOTE: the original list has been extended by adding two terms (VER04 and VER05) to facilitate alignment with FHIR.

6.4 Termlist MODE, Reference Archetype Healthcare activity participation

Code	Description
MODE01	Participation in person
MODE02	Participation using remote control to perform healthcare activity elements
MODE03	Participation via videoconference or similar electronics means (sound and video)
MODE04	Participation via telephone or similar electronics means (sound only)
MODE05	Participation using on-line communication of text and possibly also pictures
MODE05	Contributing by providing text and/or pictures ahead of the healthcare activity

NOTE If MODE is null, the value MODE01 is assumed.

6.5 Class LINK, attribute role

Six separate term lists are defined for this Reference Model property, reflecting the main purposes for which links may need to be communicated between EHR systems. The main advantage of sub-dividing the set of link terms into these six categories is to enable archetypes or other constraints and profiles of the Reference Model to specify if only a particular category of link terms is relevant to a given situation.

The six categories are:

Related to: a generic category for linking parts of the EHR.

Authorised by or confirmed by: links that connect the documentation of the legal or authoritative basis for an activity documented in another part of the EHR, including mandates for care and attestations of EHR content.

Related to the same health condition or health problem: links that connect two health or health care situations, events or activities that pertain to the same healthcare matter, such as defining a health problem for which the linked component is a manifestation (as an inclusion criteria), specifying the health condition being the motivation/indication for a healthcare activity, asserting a cause and effect relationship, relates to specified phases of a clinical process, linking stages in an evolving clinical history, or connecting different interpretations of an observation.

Related to the same clinical process, care plan, healthcare activity or episode of care: linking parts of the same health condition (as criteria for a health condition and/or as a motivation for healthcare activities), clinical process (as a clinical process concern), care plan, healthcare activity or episode of care.

Related documentation: linking alternative documentary forms, such as re-use of pre-existing EHR content in another part of the EHR, the re-expression of the same clinical information, additional supplementary explanatory information or a summary.

Plays a role: linking EHR content to a demographic entity that has played a (structural) role in the information that is documented.

NOTE: the list from the previous version of this standard has now been divided into subgroups for easier specification in archetypes and for easier maintenance. It has been extended by adding terms identified in previous implementer feedback, terms to align with changes to Part 1, terms to link a RECORD_COMPONENT to an attestation or to link two attestations, and terms corresponding to Consys associations that were not covered in the original term list.

6.5.1 Termlist RELATED_TO, Class LINK, attribute role

Code	Meaning	Description
LINK-A1	concerns, or unspecified link	The term is used when no semantic information is available for the Link in the EHR system from which the EXTRACT has been created.
LINK-A2	suggests/considered (tentatively related to)	The interpretation expressed in the target component is assessed to be a possible (considered) cause or outcome of the findings documented in the source component.

LINK-A2i	is considered/suggested by	The inverse relationship of LINK-A2.
LINK-A3	re-occurrence or repeat of	The source component documents a clinical situation which, in the opinion of the composer, is a repeat occurrence of the clinical situation documented in the target. This is intended for re-occurrences of real world situations, not repeated documentation of the same real-world event.

6.5.2 Termlist AUTHORISED_BY, Class LINK, attribute role

Code	Meaning	Description
LINK-B1	endorses/concluded (agrees with, confirms, verifies)	The interpretation expressed in the source component provides confirmatory evidence or a confirmatory opinion of the interpretation expressed in the target component. An example of this is where specified observed conditions documented in source component are considered being inclusion criteria for a health condition expressed in the target component.
LINK-B2	disagrees with (e.g. another opinion)	The interpretation expressed in the source component disproves or disagrees with or excludes the interpretation expressed in the target component. An example of this is where specified observed conditions in the source component are considered being exclusion criteria for a health condition in the target component.
LINK-B3	permits (sanctions, authorises)	The source component documents a permission or an authorization of an action documented in the target component. A permission can include an informed consent from a subject of care or an authorization by law.
LINK-B3i	permitted by	The inverse relationship of LINK-B3.
LINK-B4	assumes responsibility for	The participant (e.g. composer) identified in the source component is taking responsibility for the care acts documented in the target component (accepting a healthcare mandate). A mandate includes a commitment to perform an activity and a permission to perform it.
LINK-B5	declines (refuses, cancels)	The participant (e.g. composer) identified in the source component is declining or withdrawing consent to take responsibility for the care acts documented in the target component. Refusal to accept a healthcare mandate.
LINK-B6	consents to	The participant identified in the source component is proving consent to care actions documented in the target component. A subject of care gives an informed consent to a commitment for provision of healthcare given by a healthcare provider.
LINK-B6i	consented by	The inverse relationship of LINK-B6.
LINK-B7	countersigns	The source component is a countersignature of the information contained in the target component
LINK-B8	revokes attestation	The source component contains information or an attestation that effectively revokes the validity of the target attestation, or the source attestation that revokes the validity of the target attestation
LINK-B9	removes attestation	The source component contains information or an attestation that logically deletes the target attestation because the original attestation had been added in error, or the source attestation logically deletes the target attestation because the original attestation had been added in error.
LINK-B10	unspecified reference to an attestation	The target of the LINK is an attestation, but its relationship to the source component is not otherwise specified
LINK-B11	regulates	The source component specifies a regulation or policy or procedure or rule that governs activities or decisions documented within the target component
LINK-B11i	is regulated by	The activities or decisions documented within the source component

		are governed by a regulation or policy or procedure or rule specified in the target component
LINK-B12	commissions	The source component specifies the commissioning basis for care documented within the target component
Link-B12i	is commissioned by	The care documented in the target commitment has been commissioned as specified in the target component

6.5.3 Termlist SAME_HEALTH_ISSUE, Class LINK, attribute role

Code	Meaning	Description
LINK-C1	cause (interpretation)	The clinical situation documented in the source component is considered by the author to be the cause of the clinical situation documented in the target component. This is commonly an association between health conditions (e.g. an observed condition in the source component is assessed to be the cause of a professionally assessed condition in the target component), but could also be an association between an activity or an event and a health condition.
LINK-C1i	caused by	The inverse relationship of LINK-C1.
LINK-C2	revised interpretation	The interpretation documented in the source component is a revision of or difference in clinical thinking compared to that documented in the target component.
LINK-C3	evidence for	The observation or interpretation documented in the source component provides confirmatory evidence of the interpretation expressed in the target component. This is an association between health conditions where one observed condition by knowledge is an inclusion criterion for a more composite health condition.
LINK-C3i	justified by	The inverse relationship of LINK-C3.
LINK-C4	evidence against	The observation or interpretation documented in the source component provides evidence against the interpretation expressed in the target component. This is an association between health conditions where one observed condition by knowledge is an exclusion criteria for a more composite health condition.
LINK-C4i	countered by	The inverse relationship of LINK-C4.
LINK-C5	Indicated/motivated by	The target component documents a clinical indication for the care action documented in the source component. This is an association between a health condition being the motivation for a healthcare activity element.
LINK-C5i	Indication/motivation for	The inverse relationship of LINK-C5.
LINK-C6	contraindicated by	The target component documents an observation or interpretation that is a contraindication for a care action documented in the source component. This is commonly an association between a health condition and a healthcare activity but could also be an association between two healthcare activities.
LINK-C6i	contraindication for	The inverse relationship of LINK-C6.
LINK-C7	trigger for	The source component is the trigger event or situation for the clinical situation documented in the target component. This is e.g. a component of a clinical risk describing the trigger for an event that could have consequences for the health state of a subject of care (a risk condition).
LINK-C7i	triggered by	The inverse relationship of LINK-C7.
LINK-C8	manifestation of	The source component documents a clinical manifestation of the phenomenon documented in the target component.
LINK-C8i	manifested by	The inverse relationship of LINK-C8.
LINK-C9	sequel (consequence,	The source component documents a clinical situation that is a temporal successor to the target component (expected or unexpected time span)

	progression)	or unintended). Health condition evolution is an example of a sequel.
LINK-C10	intended (aim, goal, target, hoped for, desired)	The clinical situation documented in the target component is an intended consequence, sequel or outcome of the situation documented in the source component. A target condition is an example of "intended".
LINK-C11	anticipated (predicted)	The clinical situation documented in the target component is an anticipated consequence, sequel or outcome of the situation documented in the source component (desirable or undesirable). A prognostic condition is an example of "anticipated".
LINK-C12	to be avoided (at risk of, fear of, prophylaxis against)	The clinical situation documented in the target component is an undesirable but possible consequence, sequel or outcome of the situation documented in the source component. A risk condition is an example of "to be avoided".

6.5.4 Termlist SAME_PLAN, Class LINK, attribute role

Code	Meaning	Description
LINK-D1	outcome	The clinical situation documented in the target component is the direct outcome of the situation documented in the source component. A resultant condition is an example of "outcome".
LINK-D2	has pre-condition	The clinical situation (possibly an objective or criterion) documented in the target component is a pre-condition of the situation documented or intended action in the source component.
LINK-D3	healthcare evaluation (assessment, milestone)	The source component documents a clinical evaluation/assessment or milestone of the care activity, clinical process, objective or clinical condition documented in the target component.
LINK-D4	contributes to or fulfils goal, plan or act	The source component documents a care activity or clinical situation that makes some positive contribution towards the achievement of a plan of care or objective. This is e.g. an association between a healthcare activity and a health condition.
LINK-D5	revised state of the same act	The source component is a revised status of a care activity documented in the target component; e.g. the source might be a completed or cancelled state of a planned healthcare activity documented in the target. This is e.g. an association between a health condition and a healthcare activity.
LINK-D6	sub-task of	The healthcare activity documented in the source is a part of or sub-routine of an activity (e.g. a planned activity) documented in the target.

6.5.5 Termlist RELATED_DOCUMENTATION, Class LINK, attribute role

Code	Meaning	Description
LINK-E1	documented by (is documented within)	A clinical situation documented in the source component is more formally, documented in the target component.
LINK-E1i	documents (describes, reports)	The inverse relationship of LINK-E1.
LINK-E2	summarises	The source component documents in summary form the clinical situation documented by the target component.
LINK-E3	supplements	The source component provides supplementary information to the situation documented by the target.
LINK-E4	excerpts	The source component is an extract (copy) of part or all of information contained within the target component.
LINK-E5	derived from	The source component contains information that has been derived (e.g. calculated) from information documented in the target component.
LINK-E6	has reference ranges	The target component provides a reference basis for the interpretation

		of the values in the source component.
LINK-E7	identified within (study product)	The source component is an observation or interpretation taken directly from information contained within the target component.
LINK-E8	copied from	The source component is an exact copy of the target component, including its child components
LINK-E8i	copied to	The source component and its child components have been directly copied to the target component
LINK-E9	included by reference	The target components are not explicitly included as part of the source components but the source components should be interpreted as if the target components were included
LINK-E10	unspecified reference to a link	The target component is itself a LINK that is relevant to the interpretation of the source component LINK, but not otherwise specified

6.6 Termlist, Class EXTERNAL_LINK, attribute target_information_type

Code	Meaning	Description
ELINK-1	External data relating to this subject of care	The linked material is external to this EHR_EXTRACT, about the subject of care, and is relevant to the full interpretation and use of the source components referencing this external data. It may be externally-held clinical data, such as data in another EHR systems or large volume multimedia data, or relevant non-health data
ELINK-2	Part or all of the EHR of another subject of care	The linked material is EHR data or healthcare related data about another subject of care, which is relevant to the full interpretation and use of the source components referencing this external data
ELINK-3	Clinical guideline, protocol or clinical pathway	The linked material is a guideline, protocol or clinical pathway that is relevant to the clinical data contained in the source component, usually because the source components document a step in planning/pursuing the care pathway or the grounds for choosing or not choosing to adhere to it
ELINK-4	Study protocol	The linked material is a research study protocol that is relevant to the clinical data contained in the source component, because the source components document a step in pursuing the protocol or the eligibility criteria for adopting it, or the exclusion criteria for not adopting it
ELINK-5	Policy or operating procedure	The linked material is a policy, operating procedure or other rules that are relevant to the clinical documentation in the source components, usually because these were applicable to the activities documented. This can be e.g. a method specification of healthcare activity.
ELINK-6	Safety report	The linked material is a patient safety report to which the source components are an affirmation (i.e. the patient has experienced this safety issue) or the grounds for not pursuing a particular care activity (such as avoiding a particular drug)
ELINK-7	Educational resource	The linked material is educationally relevant to the health matter reflected in the source components and is potentially for use by the subject of care
ELINK-8	Research publication	The linked material is published research that has informed the care activities all decisions reflected in the source components
ELINK-9	Standard, profile or publicly available specification	The linked material is a published specification that may have a health or a health ICT relevance to the EHR information in the source components
ELINK-10	Clinical model	The linked material is a clinical model that may have relevance to the EHR information in the source components. NOTE: this external link should not be used to identify the archetype to which the source component conforms

ELINK-11	Terminological resource	The linked material is a terminological resource that may have relevance to the EHR information in the source components. NOTE: this external link should not be used to identify the terminology from which a data value contained within an ELEMENT has been used, but it may be used to reference a resource that facilitates further interpretation or cross mapping of an ELEMENT data value
ELINK-12	Algorithm or derivation rule	The linked material is the logical / mathematical basis on which values within the source components have been derived or calculated or inferred
ELINK-13	Product or service specification	The linked material is the specification of a product or service that is relevant to, may have been used as part of, or may have contributed as the cause of, the health or care activities documented in the source components
ELINK-14	Other external resource	The relevance of the linked material to the source components needs to be inferred from the content and context

6.7 Termlist, Classes ELEMENT and DEMOGRAPHIC_ELEMENT, attribute null_flavour

Code	Rubric	Description	ISO 21090
NI	No information	The value is exceptional (missing, omitted, incomplete, improper). No information as to the reason for being an exceptional value is provided. This is the most general exceptional value. It is also the default exceptional value	NI
INV	Invalid	The value as represented in the instance is not a member of the set of permitted data values in the constrained value domain of a variable	INV
UNK	Unknown	A proper value is applicable, but not known	UNK
MSK	Masked	There is information on this item available but it has not been provided by the sender due to security, privacy or other reasons. There may be an alternate mechanism for gaining access to this information. Warning: Using this null flavor does provide information that may be a breach of confidentiality, even though no detail data is provided. Its primary purpose is for those circumstances where it is necessary to inform the receiver that the information does exist without providing any detail	MSK
NA	Not applicable	No proper value is applicable in this context (e.g., last menstrual period for a male)	NA

6.8 Termlist, Class ATTACHMENT, attribute IntegrityCheckAlgorithm

The algorithm used to compute the IntegrityCheckAlgorithm value. If populated, the value of this attribute SHALL be taken from the HL7 IntegrityCheckAlgorithm code system. OID: 2.16.840.1.113883.5.1010

Code	Meaning	Description
------	---------	-------------

SHA1	secure hash algorithm - 1	This algorithm is defined in FIPS PUB 180-1: Secure Hash Standard. As of April 17, 1995
SHA256	secure hash algorithm - 256	This algorithm is defined in FIPS PUB 180-2: Secure Hash Standard

7 Reference archetype for null_flavor (normative)

7.1 Archetype name: Null_flavor

Identifier:

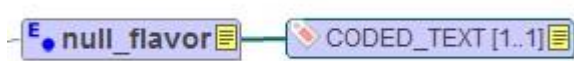
Scope: This ELEMENT archetype may be added by an archetype developer to any relevant archetype for which it is foreseen that information might be missing or unavailable to include in some instances of EHR data. This reference archetype provides a standardized way of communicating that this information is missing. This reference archetype effectively enables the archetype developer replicate the function of the null_flavour property of an ELEMENT or DEMOGRAPHIC_ELEMENT to other higher-level of the RECORD_COMPONENT hierarchy.

Standards incorporated: EN ISO 13606 Part 3 Clause 6.7

Method for applying the standard(s):

This ELEMENT reference archetype replicates the term list given in Clause 6.7 of this part standard.

Mind map:



URL: *Drafting note: to be added before publication*

Attribute description:

This is given in Clause 6.7 of this part standard.

8 Reference archetype for the access policy COMPOSITION (normative)

8.1 Archetype name: Access_policy_rule

Identifier: ISO-EN13606-PART4_COMPOSITION.Access_policy_rule.v1

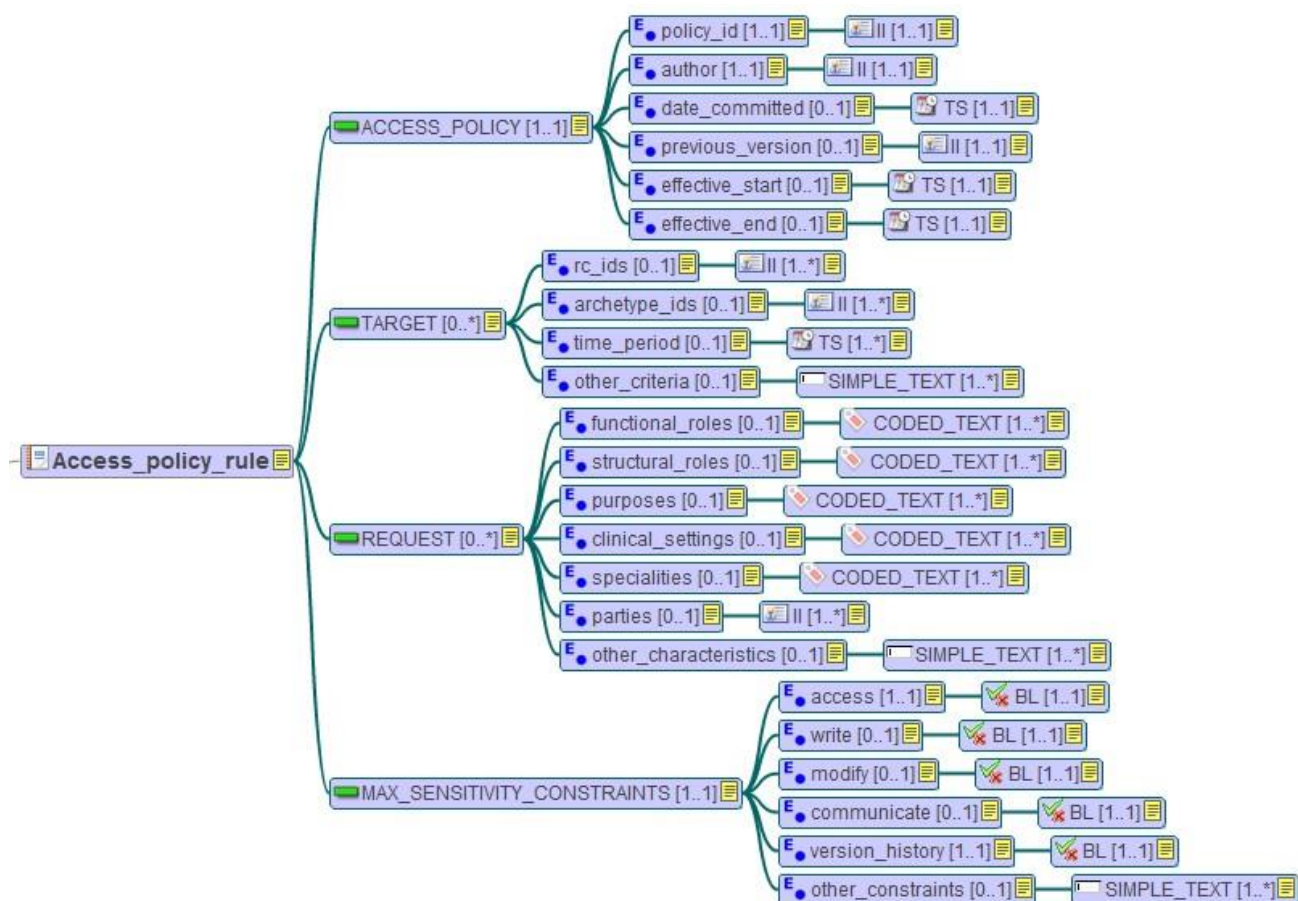
Scope: A COMPOSITION reference archetype for communicating access policy information as part of an EHR_EXTRACT.

Standards incorporated: EN ISO 13606 Part 4 Clause 7.2

Method for applying the standard(s):

This reference archetype, when used to structure the RECORD_COMPONENT hierarchy of a COMPOSITION according to Part 1 of this Standard, conforms to the UML access policy model defined in Clause 7.2 of Part 4 of this standard.

Mind map:



URL: *Drafting note: to be added before publication*

Attribute description:

This is given in Clause 7.2 of Part 4 of this standard.

9 Reference archetypes for demographic entities (informative)

The datatypes for each ELEMENT node of the reference archetypes included in this section are shown in the mind map diagrams. These datatypes correspond to those defined in Part 1 of this standard.

9.1 Archetype name: EntityIdentifier

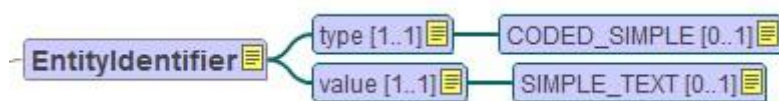
Identifier: ISO-EN13606-DEMOGRAPHIC_CLUSTER.EntityIdentifier.v1

Scope: A cluster for identifiers of an entity.

Standards incorporated: None

Method for applying the standard(s): n/a

Mind map:



URL: *Drafting note: to be added before publication*

Attribute description:

Attribute	Description
type	Signifying the identifier of an entity
value	Value of the identifier

9.2 Archetype name: useablePeriod

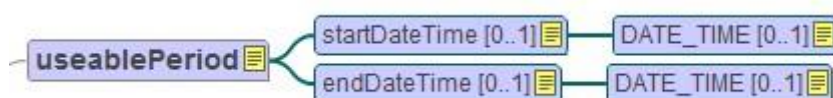
Identifier: ISO-EN13606-DEMOGRAPHIC_CLUSTER.useablePeriod.v2

Scope: A cluster for period of use of a property.

Standards: -

Method: -

Mind map:



URL: *Drafting note: to be added before publication*

Attribute description:

Attribute	Description
startDateTime	Start time and date of use of a property
endDateTime	End time and date of use of a property

9.3 Archetype name: LocationAddress

Identifier: ISO-EN13606-DEMOGRAPHIC_CLUSTER.LocationAddress.v3

Scope: Home or office address. It is primarily used to communicate data that will allow a person to physically visit that address.

Standards incorporated: ISO 21090

Method for applying the standard(s)

This reference archetype conforms to the following properties.

XP (Name or Address Part)

A part of a name or an address. Each part is a character string that may be coded, and that also may have a nullFlavor. The string content must always be provided whether a code is provided or not.

ADXP (Address Part)

A part that may have a type-tag signifying its role in the address. Typical parts that exist in about every address are street, house number, or post box, postal code, city, country but other roles may be defined regionally, nationally, or on an enterprise level (e.g. in military addresses).

Addresses are usually broken up into lines, which may be indicated by special line-breaking delimiter elements (e.g., DEL).

The possible values of the “type” attribute are (AL, ADL, UNID, UNIT, DAL, DINST, DINSTA, DINSTQ, DMOD, DMODID, SAL, BNR, BNN, BNS, STR, STB, STTYP, DIR, INT, CAR, CEN, CNT, CPA, CTY, DEL, POB, PRE, STA, ZIP)

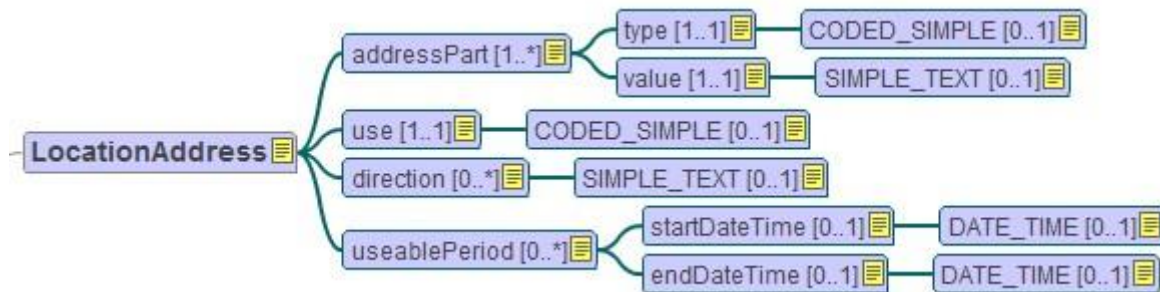
AD (Address)

Mailing and home or office addresses. AD is primarily used to communicate data that will allow printing mail labels, or that will allow a person to physically visit that address. The postal address datatype is not supposed to be a container for additional information that might be useful for finding geographic locations (e.g., GPS, coordinates) or for performing epidemiological studies. Such additional information should be captured by other, more appropriate data structures.

Addresses are essentially sequences of address parts, but add a “use” code and a valid time range for information about if and when the address can be used for a given purpose.

The possible values of the “use” attribute are (H, HP, HV, WP, DIR, PUB, BAD, TMP, ABC, IDE, SYL, PHYS, PST, SRCH, SNDX, PHON).

Mind map:



URL: *Drafting note: to be added before publication*

Attribute description:

Attribute	Description
use	Identifies the purpose of this address. Location address use (Home address, work place, direct, temporary address, physical visit address, postal address, postal and physical address)
useablePeriod	A valid time range for information about if and when the location address can be used for a given purpose
direction	A textual description how to get the specific location address
address part	A part that may have a type-tag signifying its role in the address. Typical parts that exist in about every address are street, house number, or post box, postal code, city, country but other roles may be defined regionally, nationally, or on an enterprise level
type	Address part type (Address line, additional locator, unit identifier, street address line, building number, country, municipality, post box, state or province, district, city, postal code, C/O (care off))
value	Textual representation of the address

9.4 Archetype name: TelecommunicationAddress

Identifier: ISO-EN13606-DEMOGRAPHIC_CLUSTER.TelecommunicationAddress.v3

Scope: A locatable resource that is identified by a URI, such as a web page, a telephone number (voice, fax or some other resource mediated by telecommunication equipment), an e-mail address, or any other locatable resource that can be specified by a URL. Details for all kinds of technology mediated contact points for a person or organization.

Standards incorporated: ISO 21090

Method for applying the standard(s)

This reference archetype conforms to the following properties.

TEL (Telecommunication Address)

A locatable resource that is identified by a URI, such as a web page, a telephone number (voice, fax or some other resource mediated by telecommunication equipment), an e-mail address, or any other locatable resource that can be specified by a URL.

The intent of this datatype is to be a locator, not an identifier; this datatype is used to refer to a locatable resource using a URL, and knowing the URL allows one to locate the object. However, some use cases have arisen where a URI is used to refer to a locatable resource. Though this datatype allows for URIs to be used, the resource identified SHOULD always be locatable. A common use of locatable URI's is to refer to SOAP attachments.

The possible values for the “use” attribute are (H, HP, HV, WP, DIR, PUB, BAD, TMP, AS, EC, MC, PG).

The possible values of the “capabilities” attribute are (voice, fax, data, tty, sms).

TEL.URL

TEL.URL constrains TEL so that it must point to a locatable resource that returns binary content. No use codes. The URL scheme must be file, nfs, ftp, cid (for SOAP attachments), http, or https.

TEL.PERSON

TEL.PERSON constrains TEL so that it must refer to a method of communication with a person. The URL scheme must be tel, x-text-fax, x-text-tel or mailto.

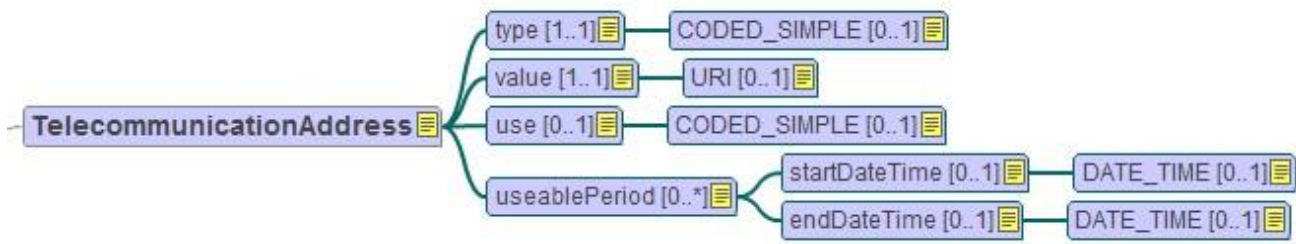
TEL.PHONE

TEL.PHONE constrains TEL.PERSON so it must refer to some telephone based communication system with a person. The URL scheme must be tel, x-text-fax, or x-text-tel.

TEL.EMAIL

TEL.EMAIL constrains the TEL.PERSON type to be an email address. The URL scheme must be mailto.

Mind map:



URL: *Drafting note: to be added before publication*

Attribute description:

Attribute	Description
value	A textual representation of the value
use	Telecommunication address use (Home address, work place, direct, temporary address, answering service, emergency contact)
type	The type of telecommunication device for which the information is being captured e.g. whether it is a fax, mobile, landline, pager etc.
useablePeriod	A valid time range for information about if and when the telecommunication address can be used for a given purpose

9.5 Archetype name: Address

Identifier: ISO-EN13606-DEMOGRAPHIC_CLUSTER.Address.v3

Scope: An email address, telephone number and home or office addresses.

Standards incorporated: ISO 21090

Method for applying the standard(s)

This reference archetype conforms to the following properties.

TEL (Telecommunication Address)

A locatable resource that is identified by a URI, such as a web page, a telephone number (voice, fax or some other resource mediated by telecommunication equipment), an e-mail address, or any other locatable resource that can be specified by a URL.

The intent of this datatype is to be a locator, not an identifier; this datatype is used to refer to a locatable resource using a URL, and knowing the URL allows one to locate the object. However, some use cases have arisen where a URI is used to refer to a locatable resource. Though this datatype allows for URIs to

be used, the resource identified SHOULD always be locatable. A common use of locatable URI's is to refer to SOAP attachments.

The possible values for the “use” attribute are (H, HP, HV, WP, DIR, PUB, BAD, TMP, AS, EC, MC, PG).

The possible values of the “capabilities” attribute are (voice, fax, data, tty, sms).

TEL.URL

TEL.URL constrains TEL so that it must point to a locatable resource that returns binary content. No use codes. The URL scheme must be file, nfs, ftp, cid (for SOAP attachments), http, or https.

TEL.PERSON

TEL.PERSON constrains TEL so that it must refer to a method of communication with a person. The URL scheme must be tel, x-text-fax, x-text-tel or mailto.

TEL.PHONE

TEL.PHONE constrains TEL.PERSON so it must refer to some telephone based communication system with a person. The URL scheme must be tel, x-text-fax, or x-text-tel.

TEL.EMAIL

TEL.EMAIL constrains the TEL.PERSON type to be an email address. The URL scheme must be mailto.

XP (Name or Address Part)

A part of a name or an address. Each part is a character string that may be coded, and that also may have a nullFlavor. The string content must always be provided whether a code is provided or not.

ADXP (Address Part)

A part that may have a type-tag signifying its role in the address. Typical parts that exist in about every address are street, house number, or post box, postal code, city, country but other roles may be defined regionally, nationally, or on an enterprise level (e.g. in military addresses).

Addresses are usually broken up into lines, which may be indicated by special line-breaking delimiter elements (e.g., DEL).

The possible values of the “type” attribute are (AL, ADL, UNID, UNIT, DAL, DINST, DINSTA, DINSTQ, DMOD, DMODID, SAL, BNR, BNN, BNS, STR, STB, STTYP, DIR, INT, CAR, CEN, CNT, CPA, CTY, DEL, POB, PRE, STA, ZIP)

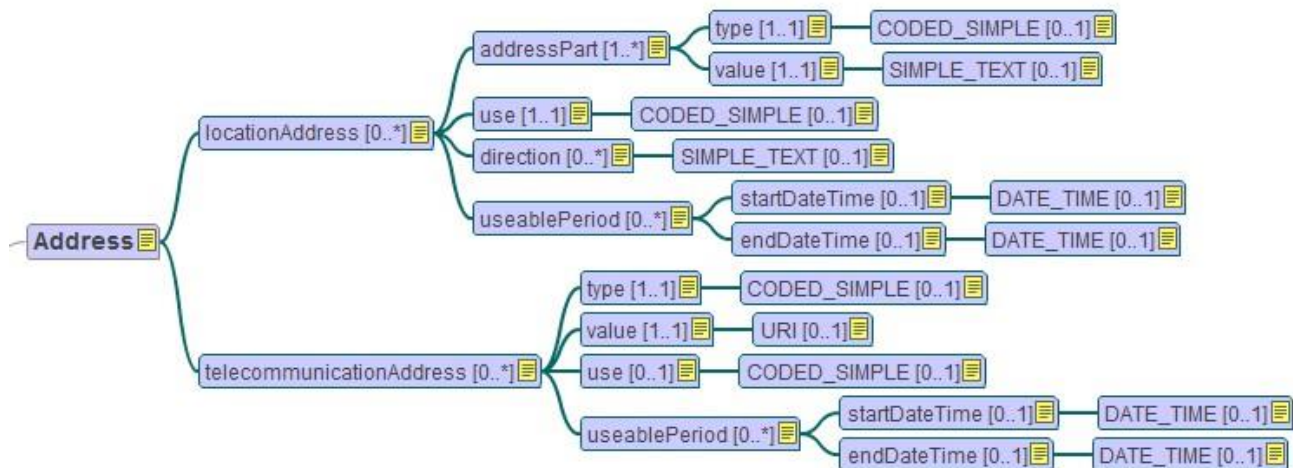
AD (Address)

Mailing and home or office addresses. AD is primarily used to communicate data that will allow printing mail labels, or that will allow a person to physically visit that address. The postal address datatype is not supposed to be a container for additional information that might be useful for finding geographic locations (e.g., GPS, coordinates) or for performing epidemiological studies. Such additional information should be captured by other, more appropriate data structures.

Addresses are essentially sequences of address parts, but add a "use" code and a valid time range for information about if and when the address can be used for a given purpose.

The possible values of the "use" attribute are (H, HP, HV, WP, DIR, PUB, BAD, TMP, ABC, IDE, SYL, PHYS, PST, SRCH, SNDX, PHON).

Mind map:



URL: Drafting note: to be added before publication

Attribute description:

Attribute	Description
location address	Home or office address. It is primarily used to communicate data that will allow a person to physically visit that address
telecommunication address	A locatable resource that is identified by a URI, such as a web page, a telephone number (voice, fax or some other resource mediated by telecommunication equipment), an e-mail address, or any other locatable resource that can be specified by a URL. Details for all kinds of technology mediated contact points for a person or organization

9.6 Archetype name: Namepart

Identifier: ISO-EN13606-DEMOGRAPHIC_CLUSTER.Namepart.v3

Scope: A part that is signifying the role of the part in the whole entity name.

Standards incorporated: ISO 21090

Method for applying the standard(s)

This reference archetype conforms to the following properties.

XP (Name or Address Part)

A part of a name or an address. Each part is a character string that may be coded, and that also may have a nullFlavor. The string content must always be provided whether a code is provided or not.

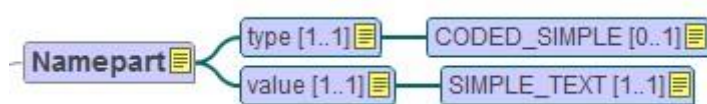
ENXP (Entity Name Part)

A part that may have a type code signifying the role of the part in the whole entity name, and qualifier codes for more detail about the name part type. (Typical name parts for person names are given names, and family names, titles, etc).

The possible values of the “use” attribute are (FAM, GIV, TITLE, DEL).

The possible values of the “qualifier” attribute are (LS, AC, NB, PR, HON, BR, AD, SP, MID, CL, IN, PFX, SFX).

Mind map:



URL: *Drafting note: to be added before publication*

Attribute description:

Attribute	Description
type	Signifying the role of the part in the whole entity name. Entity name part type (family name, given name, middle name)
value	A textual representation of the name part

9.7 Archetype name: PersonName

Identifier: ISO-EN13606-DEMOGRAPHIC_CLUSTER.PersonName.v2

Scope: A name of the person

Standards incorporated: ISO 21090

Method for applying the standard(s)

This reference archetype conforms to the following properties.

EN (Entity Name)

A name for a person

Entity names are essentially sequences of entity name parts, but add a "use" code and a valid time range for information about when the name was used and how to choose between multiple aliases that may be valid at the same point in time.

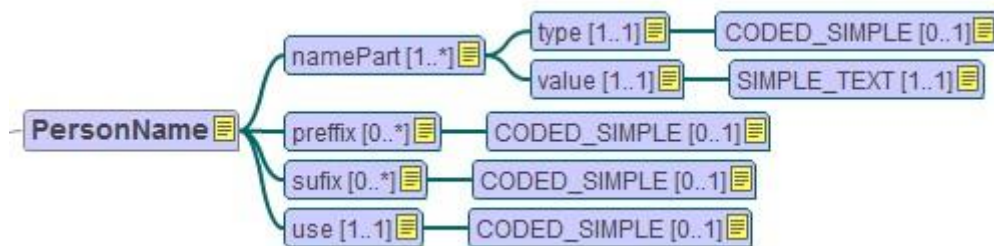
The possible values of the "use" attribute are (C, OR, T, I, P, A, R, OLD, DN, M, SRCH, PHON, ABC, SYL, IDE).

EN.PN (Person Name)

A restriction of EN used when the named Entity is a Person. A sequence of name parts, such as given name or family name, prefix, suffix, etc.

A name part is a restriction on entity name part that only allows those entity name parts qualifiers applicable to person names.

Mind map:



URL: *Drafting note: to be added before publication*

Attribute description:

Attribute	Description
namePart	A part that is signifying the role of the part in the whole entity name
use	Person name use (Customary, official registry name, temporary, anonymous, maiden name, academic, nobility, professional, birth, acquired, spouse)
prefix	Mr, Ms
sufix	PhD, Senior

9.8 Archetype name: Person

Identifier: ISO-EN13606-DEMOGRAPHIC_ENTITY.Person.v3

Scope: Human being regarded as an individual

Standards incorporated: EN ISO 13940, ISO 21090

Method for applying the standard(s)

© ISO 2017 – All rights reserved

This reference archetype conforms to the following properties.

EN (Entity Name)

A name for a person

Entity names are essentially sequences of entity name parts, but add a "use" code and a valid time range for information about when the name was used and how to choose between multiple aliases that may be valid at the same point in time.

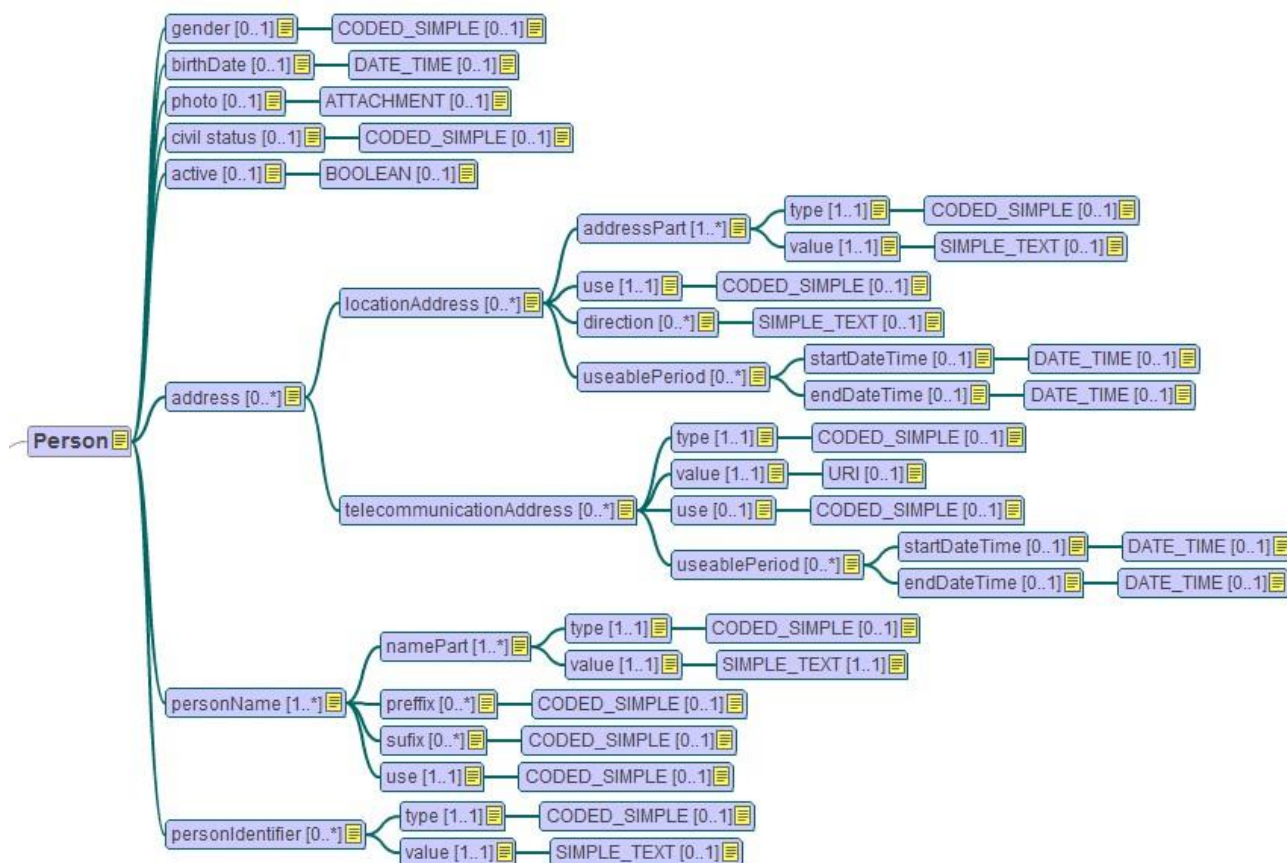
The possible values of the "use" attribute are (C, OR, T, I, P, A, R, OLD, DN, M, SRCH, PHON, ABC, SYL, IDE).

EN.PN (Person Name)

A restriction of EN used when the named Entity is a Person. A sequence of name parts, such as given name or family name, prefix, suffix, etc.

A name part is a restriction on entity name part that only allows those entity name parts qualifiers applicable to person names.

Mind map:



URL: **Drafting note:** to be added before publication

Attribute description:

Attribute	Description
personName	A name of the person
photo	A photo of this person
personIdentifier	A identifier of the person (hospital id, SSN, National id)
address	An email address, telephone number and home or office addresses
active	This person's record is in active use
birthDate	The date on which the person was born
civil status	Marital status
gender	The gender (male, female, unknown) of the person

9.9 Archetype name: HealthcareOrganization

Identifier: ISO-EN13606-DEMOGRAPHIC_ENTITY.HealthcareOrganization.v5

Scope: Healthcare provider having an organization role

Standards incorporated: EN ISO 13940, ISO 21090

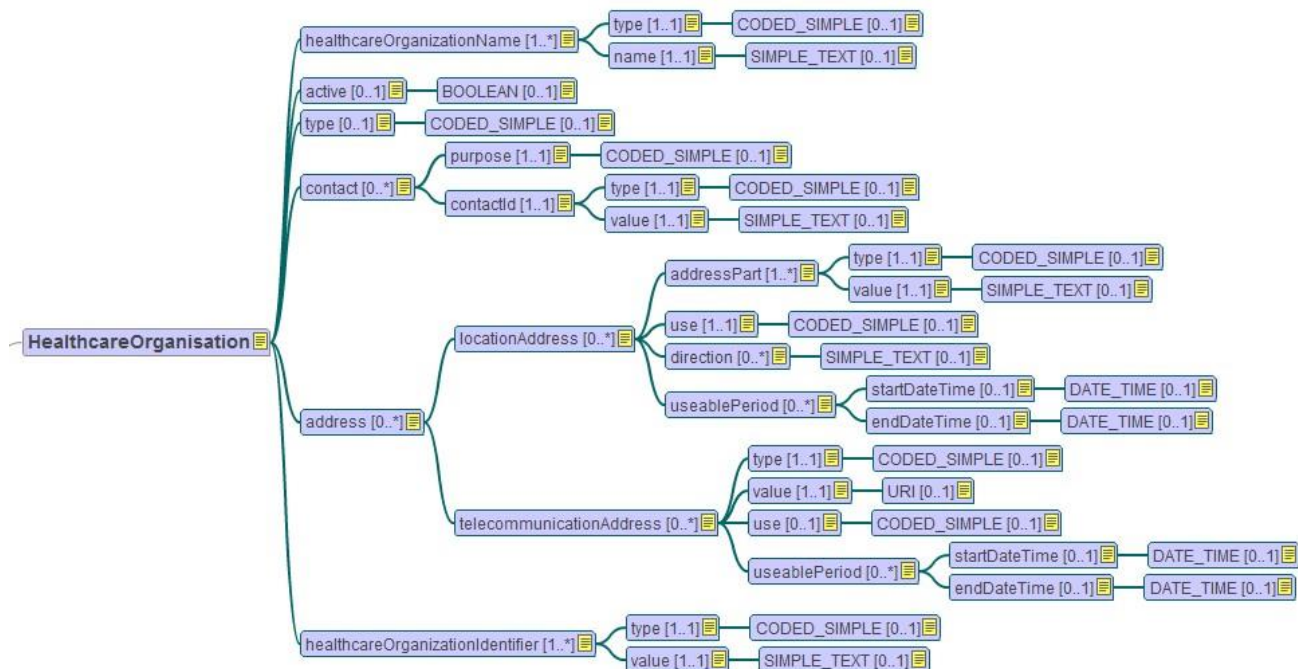
Method for applying the standard(s)

This reference archetype conforms to the following properties.

EN.ON (Organization Name)

None of the parts of an organization name can be FAM or GIV. The following qualifiers SHALL not be used in the name of an organization: I, P, ANON, A, R, DN, and M.

Mind map:



URL: *Drafting note: to be added before publication*

Attribute description:

Attribute	Description
healthcareOrganizationName	Name used for the organization
name	A name of the healthcare organization
type	A type of name
address	An email address, telephone number and/ or office addresses
active	Whether the organization's record is still in active use
type	Kind of organization
healthcareOrganizationIdentifier	An identifier of the healthcare organization
contact	Contact for the organization for a certain purpose
contactId	Identifier for the contact
purpose	The type of the contact

9.10 Archetype name: ServiceDepartment

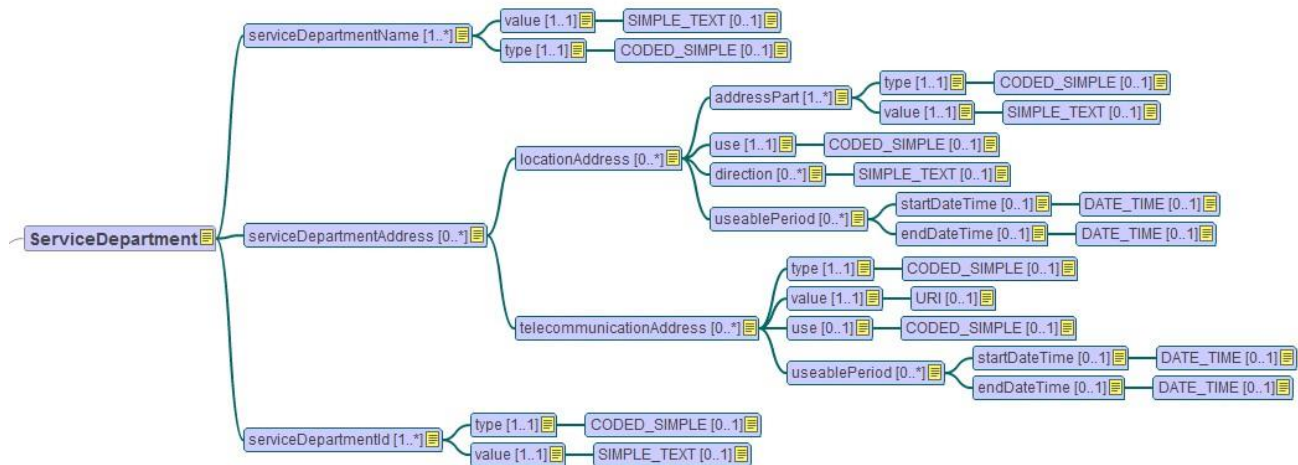
Identifier: ISO-EN13606-DEMOGRAPHIC_ENTITY.ServiceDepartment.v3

Scope: A department of the healthcare service

Standards incorporated: None

Method for applying the standard(s): n/a

Mind map:



URL: *Drafting note: to be added before publication*

Attribute description:

Attribute	Description
serviceDepartmentName	A name of the service department
value	A textual representation of a name of the service department
type	A type of the name
serviceDepartmentAddress	An email address, telephone number and home or office addresses
serviceDepartmentId	An identifier for service department
value	A textual representation of a identifier of the service department
type	A type of the identifier
isPartOf	This service department is a part of the healthcare organization or another service department

9.11 Archetype name: HealthcarePersonnel

Identifier: ISO-EN13606-DEMOGRAPHIC_ENTITY.Person-HealthcarePersonnel.v1

Specialize ISO-EN13606-DEMOGRAPHIC_ENTITY.Person.v3

Scope: An individual healthcare actor having a person role in a healthcare organization

Standards incorporated: EN ISO 13940, ISO 21090

Method for applying the standard(s)

This reference archetype conforms to the following properties.

EN (Entity Name)

A name for a person

Entity names are essentially sequences of entity name parts, but add a "use" code and a valid time range for information about when the name was used and how to choose between multiple aliases that may be valid at the same point in time.

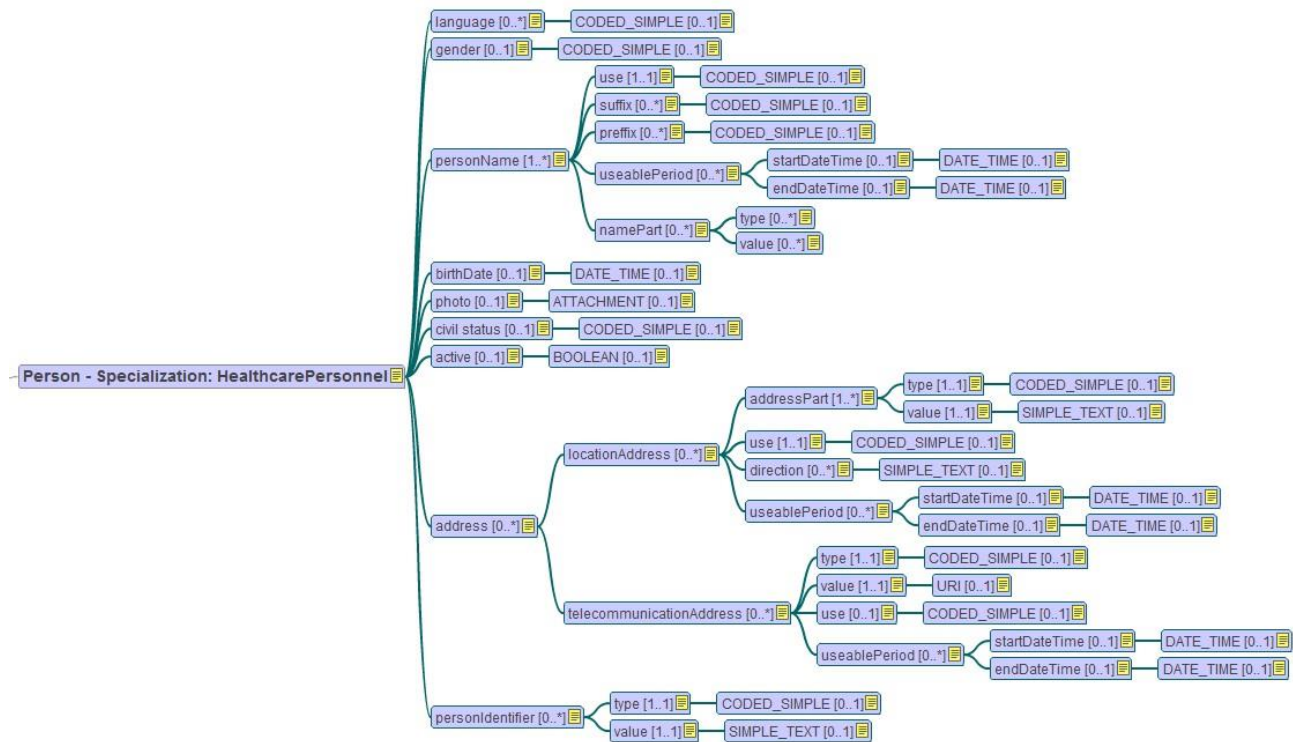
The possible values of the "use" attribute are (C, OR, T, I, P, A, R, OLD, DN, M, SRCH, PHON, ABC, SYL, IDE).

EN.PN (Person Name)

A restriction of EN used when the named Entity is a Person. A sequence of name parts, such as given name or family name, prefix, suffix, etc.

A name part is a restriction on entity name part that only allows those entity name parts qualifiers applicable to person names.

Mind map:



URL: Drafting note: to be added before publication

Attribute description:

Attribute	Description
personName	A name of the person
photo	A photo of this person
personIdentifier	A identifier of the person (hospital id, SSN, National id)
address	An email address, telephone number and home or office addresses
active	This person's record is in active use
birthDate	The date on which the person was born
civil status	Marital status
gender	The gender (male, female, unknown) of the person
language	The languages that healthcare personnel mastered

9.12 Archetype name: MedicalDevice

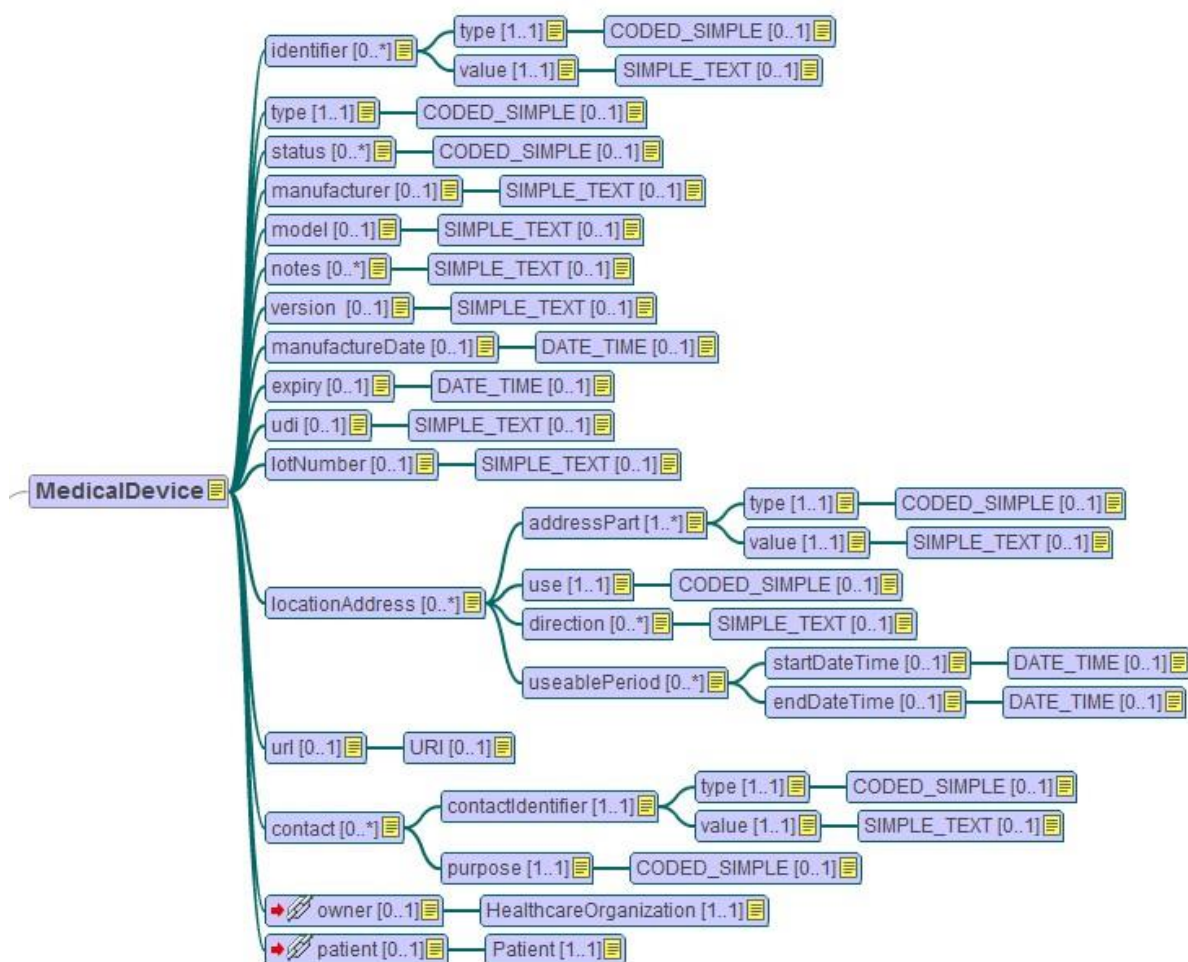
Identifier: ISO-EN13606-DEMOGRAPHIC_ENTITY.MedicalDevice.v1

Scope: Includes any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life, control of conception, disinfection of medical devices, providing information for medical purposes by means of in vitro examination of specimens, derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Standards incorporated: None

Method for applying the standard(s): n/a

Mind map:



URL: *Drafting note: to be added before publication*

Attribute description:

Attribute	Description
identifier	Identifier from manufacturer, owner, etc
type	Signifying the identifier of an entity
value	Value of the identifier
type	What kind of device this is. Preferred to use The Global Medical Device Nomenclature (GMDN) that is a system of internationally agreed generic descriptors used to identify all medical device products. Such products include those used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans.
status	Available, not-available, etc
manufacturer	Name of device manufacturer
model	Model id assigned by the manufacturer
notes	Medical device notes and comments
version	Version number
manufactureDate	Manufacture date
expiry	Date and time of expiry of this device
udi	Unique Device Identifier (it can be FDA or GS1)
lotNumber	Lot number of manufacture
contact	Contact details for an organization or a particular human that is responsible for the device
url	Network address to contact device
owner	Organization that is responsible for device
patient	If the resource is affixed to a person
locationAddress	The location address of the device
use	Identifies the purpose of this address. Location address use (Home address, work place, direct, temporary address, physical visit address, postal address, postal and physical address)
useablePeriod	A valid time range for information about if and when the location address can be used for a given purpose
direction	A textual description how to get the specific location address
address part	A part that may have a type-tag signifying its role in the address. Typical parts that exist in