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Health informatics — Electronic health record communication —

Part 3: Reference archetypes and term lists

Informatique de santé — Communication du dossier de santé informatisé —

Partie 3: Archétypes de référence et listes de termes

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

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

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

0.1 General

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

0.2 Preface

ISO 13606-3 defines two kinds of specifications.

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

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

   — null_flavor;

   — access policies;

   — demographic entities;

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

0.3 Term Lists

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

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

0.4 Reference archetypes

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

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

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

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

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

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

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

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

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

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

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

Health informatics — Electronic health record communication —

Part 3: Reference archetypes and term lists

1 Scope

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

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

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

2 Normative references

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

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

3 Terms and definitions

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

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

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

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

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

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

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

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

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

[SOURCE: ISO 13940:2015]

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

4 Abbreviations

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

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

5 Conformance

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

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

6 Term lists

6.1 Introduction

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

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

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	*healthcare actor* with a *person role;* who seeks to receive, is receiving, or has received healthcare
DS01	relative of subject of care	*person role* being any human relative, without limitation to biological or adoptive relatives
DS02	next of kin	*person role* being either the closest living relative of *the subject of care* 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 foetus or neonate, if being described in the EHR of a baby (e.g. during pregnancy)
DS05	donor	*person role* being the donor of an organ or body specimen being described by an ENTRY in the EHR of the recipient
DS06	unrelated person	*person role* being any other person not related to the subject of care, such as an employer, friend, carer
DS07	healthcare third party	*healthcare actor* (organization or person) other than a *healthcare provider* or the *subject of care*
DS08	subject of care proxy	*healthcare third party* having person role with the right to take decisions on behalf of the subject of care

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

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** ISO 13606-1**.**

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. 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

Code	Meaning	Description
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.

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 link_description

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.

The list from the previous version of this document 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 ISO 13606-1, terms to link a RECORD_COMPONENT to an attestation or to link two attestations, and terms corresponding to Contsys associations that were not covered in the original term list.

6.5.1 Termlist RELATED_TO, Class LINK, attribute link_description

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 link_description

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.

Code	Meaning	Description
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 link_description

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.

Code	Meaning	Description
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, progression)	The source component documents a clinical situation that is a temporal successor to the target component (expected or unexpected, intended 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”.

Recognising that it is desirable to represent uncertainty and negation for ‘clinical links’ (‘possibly caused by’, ‘is not a contraindication for’), such advanced expressivity is not supported by the current vocabulary and class. Work continues to explore this topic.

6.5.4 Termlist SAME_PLAN, Class LINK, attribute link_description

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 link_description

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. 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. 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 180-4: Secure Hash Standard. As of August 2015.
SHA256	secure hash algorithm - 256	This algorithm is defined in FIPS PUB 180-4: Secure Hash Standard. As of August 2015.

7 Reference archetype for null_flavor

7.1 Archetype name: Null_flavor

Identifier:

Scope: This ELEMENT archetype shall 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: ISO 13606-3, 6.7

Method for applying the standard(s):

This ELEMENT reference archetype replicates the term list given in 6.7.

Mind map:

URL: http://en13606.org/specifications.html

Attribute description:

This is given in 6.7.

8 Reference archetype for the access policy COMPOSITION

8.1 Archetype name: Access_policy_rule

Identifier: ISO-EN13606-PART4_COMPOSITION.Access_policy_rule.v1

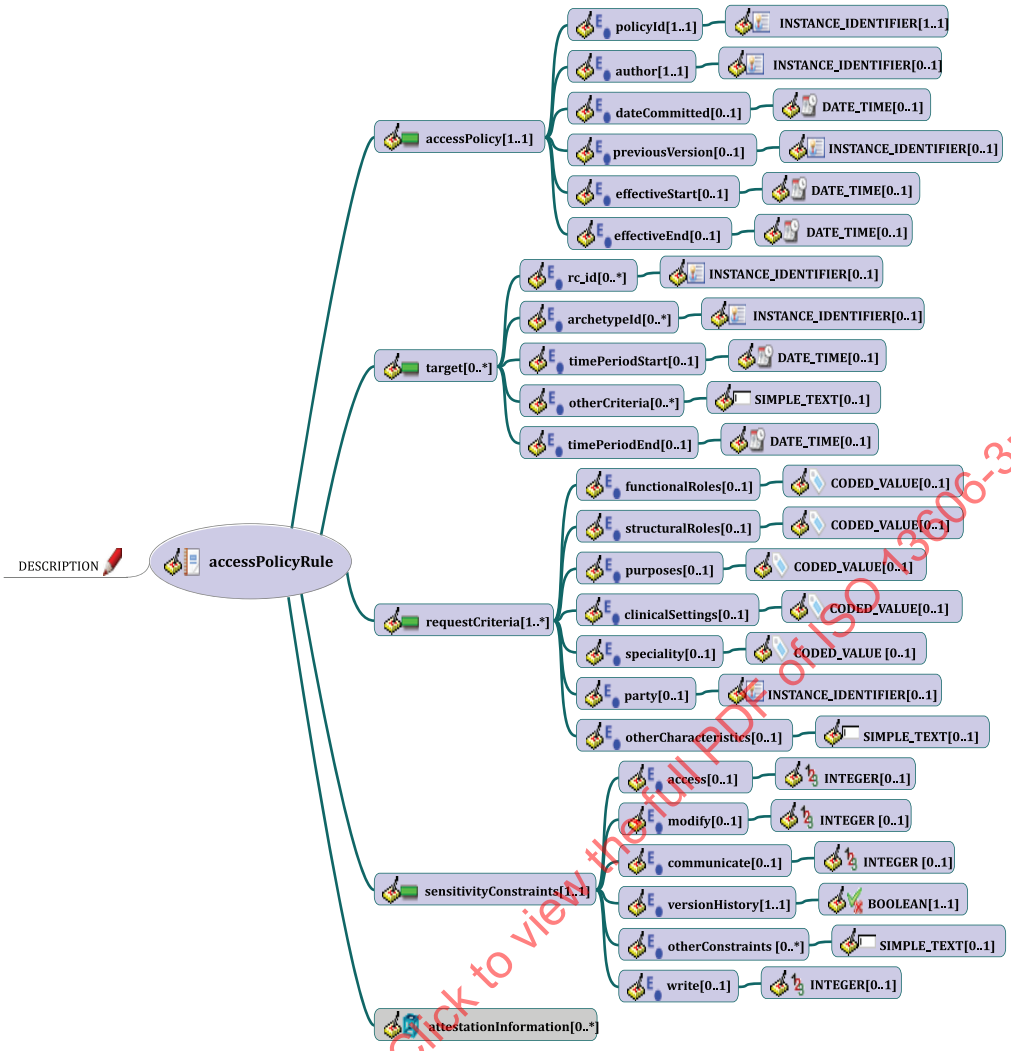
Scope: A COMPOSITION reference archetype for communicating access policy information as part of an EHR_EXTRACT. This reference archetype shall be used or specialized for representing an access policy COMPOSITION.

Standards incorporated: ISO 13606-4, 7.2

Method for applying the standard(s):

This reference archetype, when used to structure the RECORD_COMPONENT hierarchy of a COMPOSITION according to ISO 13606-1, conforms to the UML access policy model defined in 7.2 of ISO 13606-4.

Mind map:



URL: http://en13606.org/specifications.html

Attribute description:

This is given in 7.2 of ISO 13606-4.

9 Reference archetypes for demographic entities

The datatypes for each ELEMENT node of the reference archetypes included in this clause are shown in the mind map diagrams. These datatypes correspond to those defined in ISO 13606-1.

9.1 Archetype name: EntityIdentifier

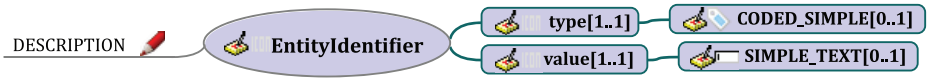
Identifier: ISO-EN13606-DEMOGRAPHIC_CLUSTER.EntityIdentifier.v1

Scope: A cluster for identifiers of an entity. This reference archetype may be used or specialized to represent EntityIdentifier within appropriate demographic archetypes.

Standards incorporated: None

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

Mind map:



URL: http://en13606.org/specifications.html

Attribute description:

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

9.2 Archetype name: useablePeriod

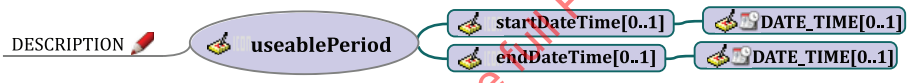
Identifier: ISO-EN13606-DEMOGRAPHIC_CLUSTER.useablePeriod.v2

Scope: A cluster for period of use of a property. This reference archetype may be used or specialized to represent useablePeriod within appropriate demographic archetypes.

Standards: -

Method: -

Mind map:



URL: http://en13606.org/specifications.html

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. This reference archetype may be used or specialized to represent LocationAddress within appropriate demographic archetypes.

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 shall 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)

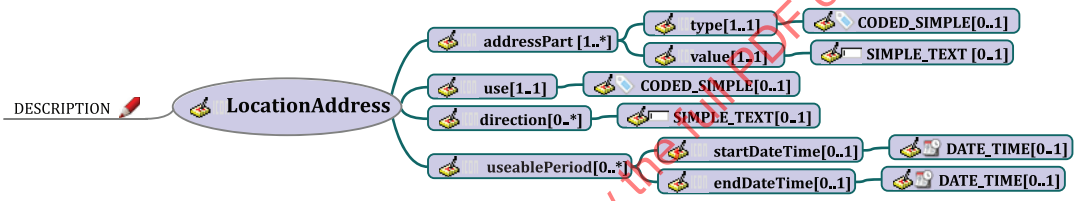
AD (Address)

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: http://en13606.org/specifications.html

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. This reference archetype may be used or specialized to represent TelecommunicationAddress within appropriate demographic archetypes.

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

TEL.PERSON

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

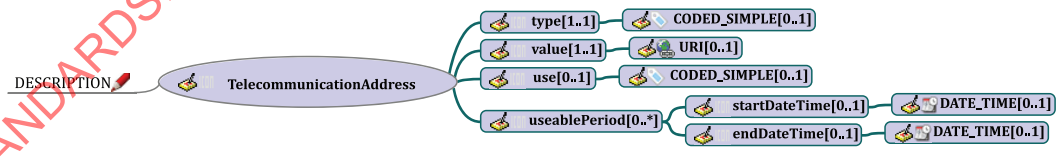
TEL.PHONE

TEL.PHONE constrains TEL.PERSON so it shall refer to some telephone based communication system with a person. The URL scheme shall 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 shall be mailto.

Mind map:



URL: http://en13606.org/specifications.html

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. This reference archetype may be used or specialized to represent Address within appropriate demographic archetypes.

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

TEL.PERSON

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

TEL.PHONE

TEL.PHONE constrains TEL.PERSON so it shall refer to some telephone based communication system with a person. The URL scheme shall 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 shall 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 shall 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)

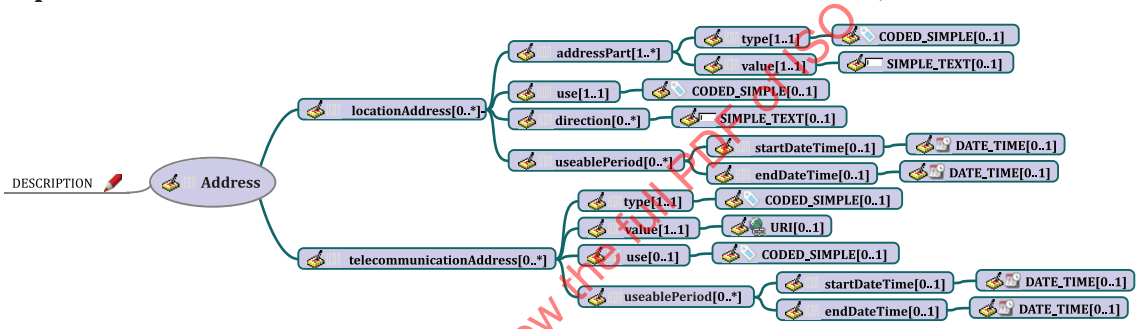
AD (Address)

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: http://en13606.org/specifications.html

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. This reference archetype may be used or specialized to represent Namepart within appropriate demographic archetypes.

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 shall 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: http://en13606.org/specifications.html

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. This reference archetype may be used or specialized to represent PersonName within appropriate demographic archetypes.

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.

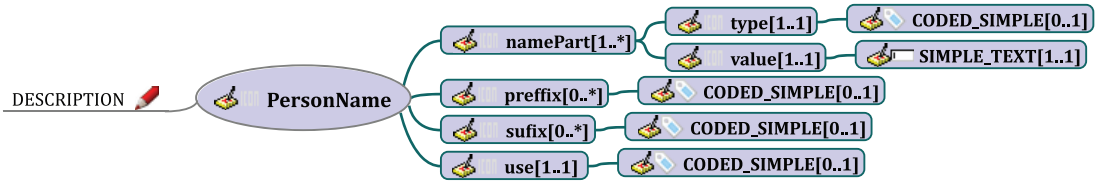
The possible values of the “use” attribute are (C, OR, T, I, P, A, R, OLD, DN, M, SRCH, PHON, ABC, SYL, IDE).

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: http://en13606.org/specifications.html

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)
preffix	Mr, Ms
suffix	PhD, Senior

9.8 Archetype name: Person

Identifier: ISO-EN13606-DEMOGRAPHIC_ENTITY.Person.v3

Scope: Human being regarded as an individual. This reference archetype may be used or specialized to represent Person within appropriate demographic archetypes.

Standards incorporated: 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.

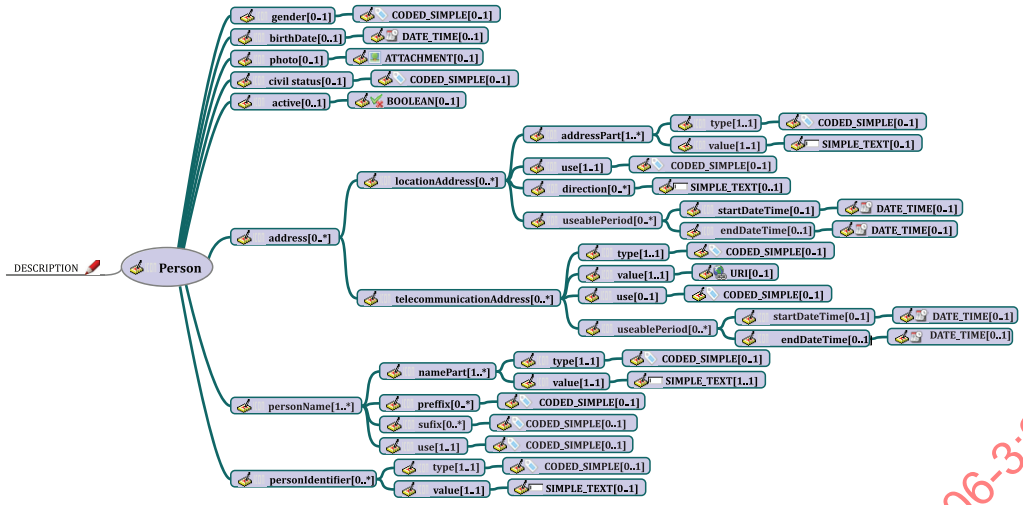
The possible values of the "use" attribute are (C, OR, T, I, P, A, R, OLD, DN, M, SRCH, PHON, ABC, SYL, IDE).

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: http://en13606.org/specifications.html

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. This reference archetype may be used or specialized to represent HealthcareOrganization within appropriate demographic archetypes.

Standards incorporated: ISO 13940, ISO 21090

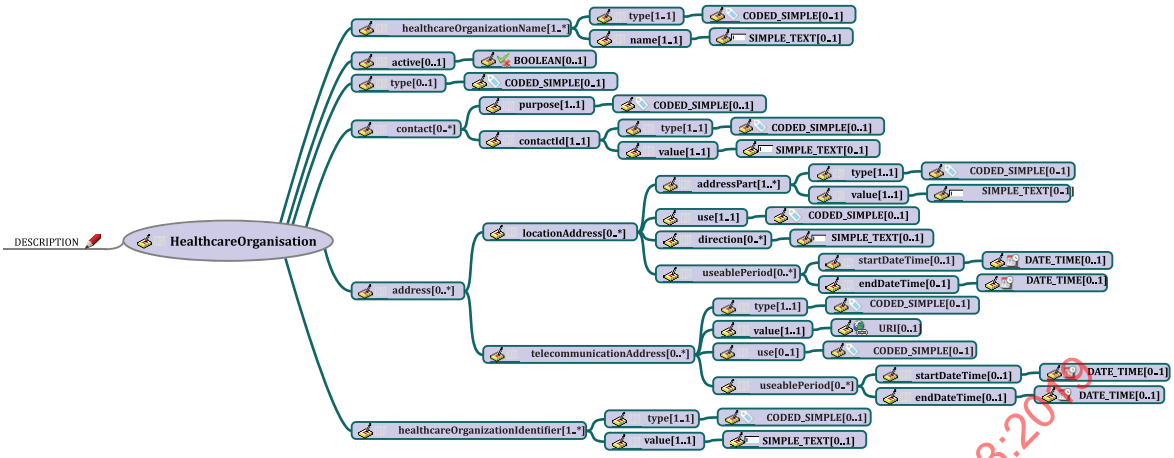
Method for applying the standard(s)

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: http://en13606.org/specifications.html

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

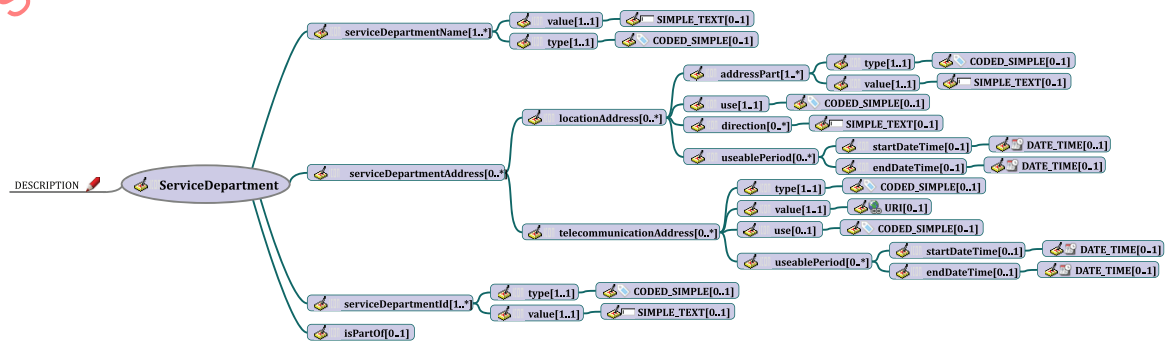
Identifier: ISO-EN13606-DEMOGRAPHIC_ENTITY.ServiceDepartment.v3

Scope: A department of the healthcare service. This reference archetype may be used or specialized to represent ServiceDepartment within appropriate demographic archetypes.

Standards incorporated: None

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

Mind map:



URL: http://en13606.org/specifications.html

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. This reference archetype may be used or specialized to represent HealthcarePersonnel within appropriate demographic archetypes.

Standards incorporated: 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.

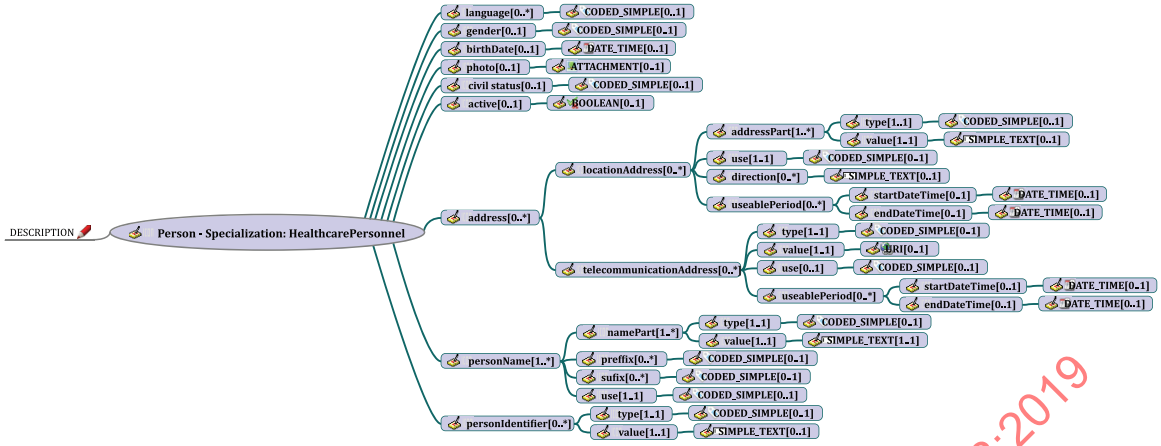
The possible values of the “use” attribute are (C, OR, T, I, P, A, R, OLD, DN, M, SRCH, PHON, ABC, SYL, IDE).

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: http://en13606.org/specifications.html

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
healthcareOrganization	The healthcare organization that the healthcare personnel having a role in

9.12 Archetype name: MedicalDevice

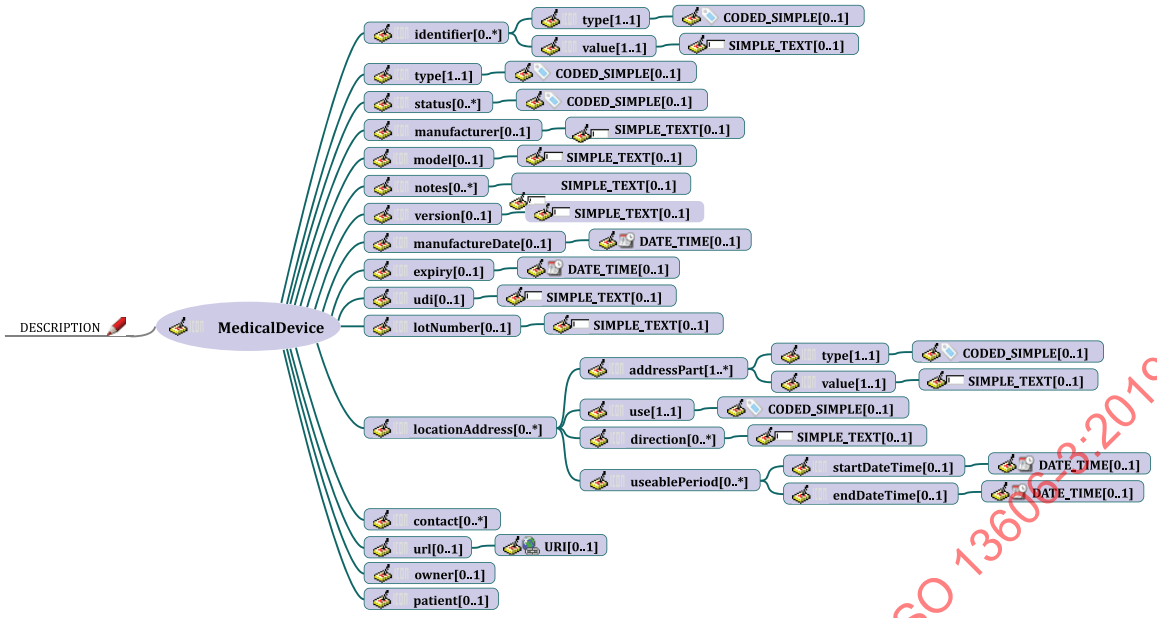
Identifier: ISO-EN13606-DEMOGRAPHIC_ENTITY.MedicalDevice.v1

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. This reference archetype may be used or specialized to represent MedicalDevice within appropriate demographic archetypes.

Standards incorporated: None

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

Mind map:



URL: http://en13606.org/specifications.html

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

Attribute	Description
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

9.13 Archetype name: SubjectOfInformation

Identifier: ISO-EN13606-DEMOGRAPHIC_CLUSTER.SubjectOfInformation.v1

Scope: Subject of information. This reference archetype may be used or specialized to represent SubjectOfInformation within appropriate demographic archetypes.

Standards incorporated: None

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

Mind map:

URL: http://en13606.org/specifications.html

Attribute description:

Attribute	Description
person	Identify the subject of information
relationship	Kind of relationship

9.14 Archetype name: Contact

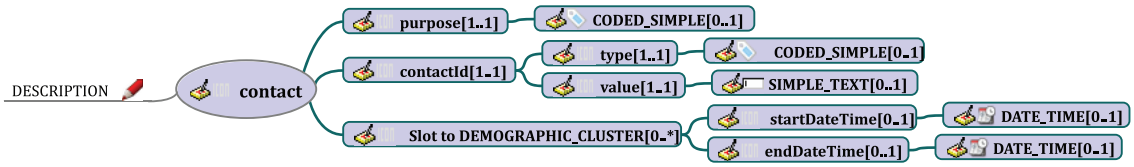
Identifier: ISO-EN13606-DEMOGRAPHIC_CLUSTER.Contact.v1

Scope: Interaction between a subject of care and one or more healthcare personnel. This reference archetype may be used or specialized to represent Contact within appropriate demographic archetypes.

Standards incorporated: None

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

Mind map:



URL: http://en13606.org/specifications.html

Attribute description:

Attribute	Description
contactIdentifier	The contact identifier
purpose	The type of the contact
contact period	The period of time the contact takes place

9.15 Archetype name: HealthcareActivityParticipation

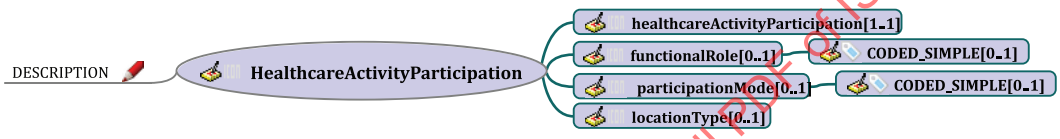
Identifier: DEMOGRAPHIC_CLUSTER.HealthcareActivityParticipation.v1

Scope: Information of the healthcare activity participation. This reference archetype may be used or specialized to represent HealthcareActivityParticipation within appropriate demographic archetypes.

Standards incorporated: None

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

Mind map:



URL: http://en13606.org/specifications.html

Attribute description:

Attribute	Description
performingHealthcareAgent	The actor performing the documented healthcare activity element. The identification will be to an entity (person, medical device, software, organization) for which there is a defined demographic entity, included in the demographics extract. The Contsys definition of subject of care (healthcare actor with a person role, who seeks to receive, is receiving, or has received healthcare), indicates that subject of care is a structural role since it is a permanent role (... has received healthcare). But during the performance of a specific healthcare activity, the subject of care will also have a functional role. In most situations, the term subject of care will also be used for this functional role. This means that if a person performs a self-care activity, it is the structural role subject of care that \"qualifies\" the person to perform the activity. And the person does also have two different functional roles in the self-care activity, e.g. one as \"administrator of medicine\" and one as subject of care.
functionalRole	A coded representation of the function or role that was performed. The functional role played by the actor in the healthcare activity, such as performer, observer, authoriser.
participationMode	The mode of participating in the activity.

9.16 Archetype name: HealthcareActivityFacility

Identifier: ISO-EN13606-DEMOGRAPHIC_CLUSTER.HealthcareActivityFacility.v1

Scope: The organization at which the role was performed. This reference archetype may be used or specialized to represent HealthcareActivityFacility within appropriate demographic archetypes.

Standards incorporated: None

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

Mind map:

URL: http://en13606.org/specifications.html

Attribute description:

Attribute	Description
healthcareOrganization	Healthcare organization at which the role was performed. The healthcare facility at which care is provided, if it is not the default facility where the performer is based. (In both of those cases the identification will be to an entity (person, medical device, software, organization) for which there is a defined demographic entity, included in the demographics extract.
locationType	The type of service location at which the role was performed. The type of setting where the activity took place e.g. home, ambulance, roadside, hospital, GP clinic, nursing home, etc.

9.17 Archetype name: HealthcareActivityFramework

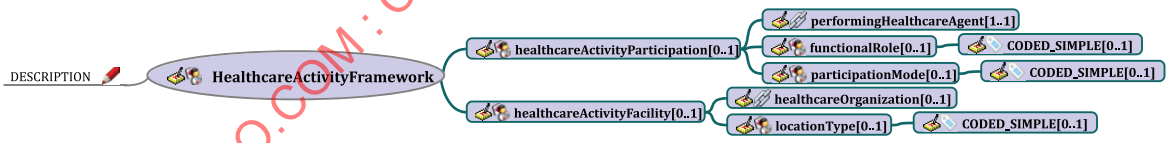
Identifier: ISO-EN13606-DEMOGRAPHIC_ENTITY.HealthcareActivityFramework.v1

Scope: Should be used for the other participant relationship to COMPOSITION. This reference archetype may be used or specialized to represent HealthcareActivityFramework within appropriate demographic archetypes.

Standards incorporated: None

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

Mind map:



URL: http://en13606.org/specifications.html

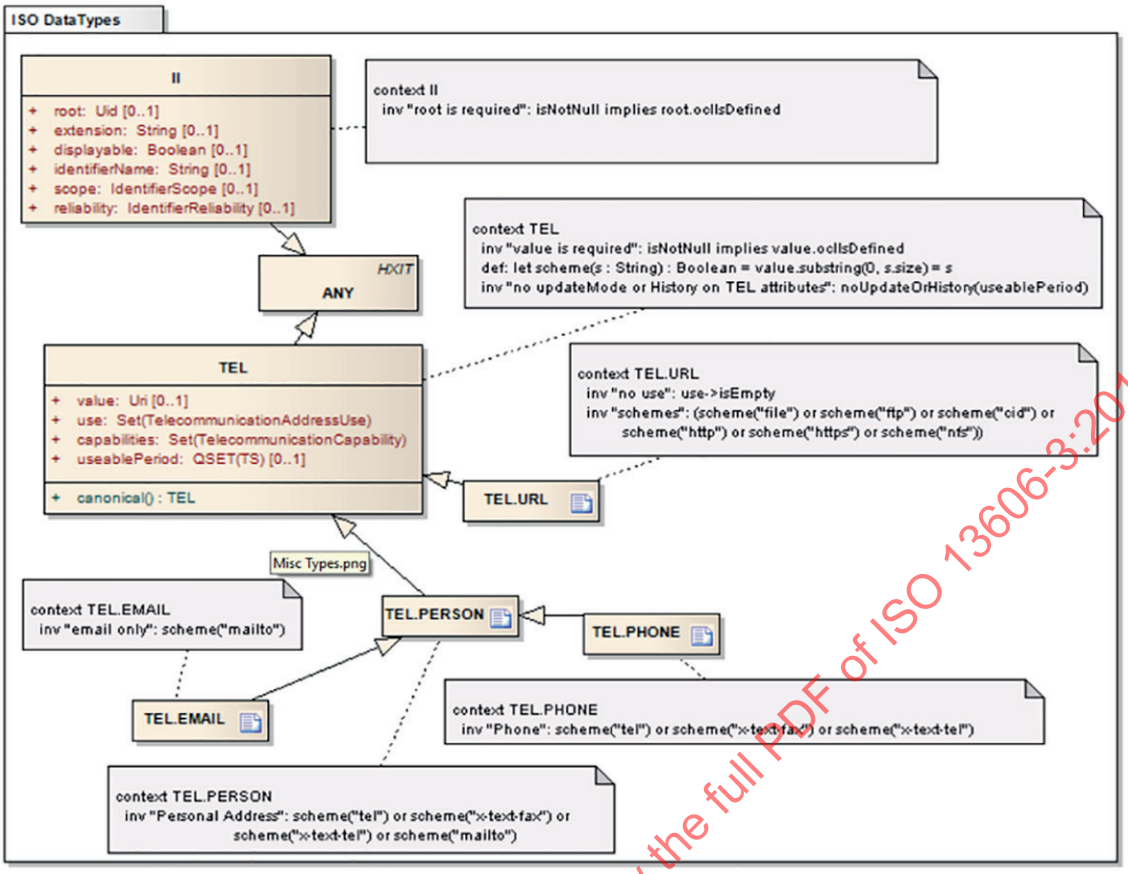
Attribute description:

Attribute	Description
healthcareActivityFacility	The organization at which the role was performed
healthcareActivityParticipation	Information of the healthcare activity participation

9.18 Summary of demographic-related data types in ISO 21090

9.18.1 Identification and Location Datatypes

These datatypes provide support for identifying objects, records, and things, and specifically for URLs, URIs and telecommunication addresses.



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

TEL.PERSON

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

TEL.PHONE

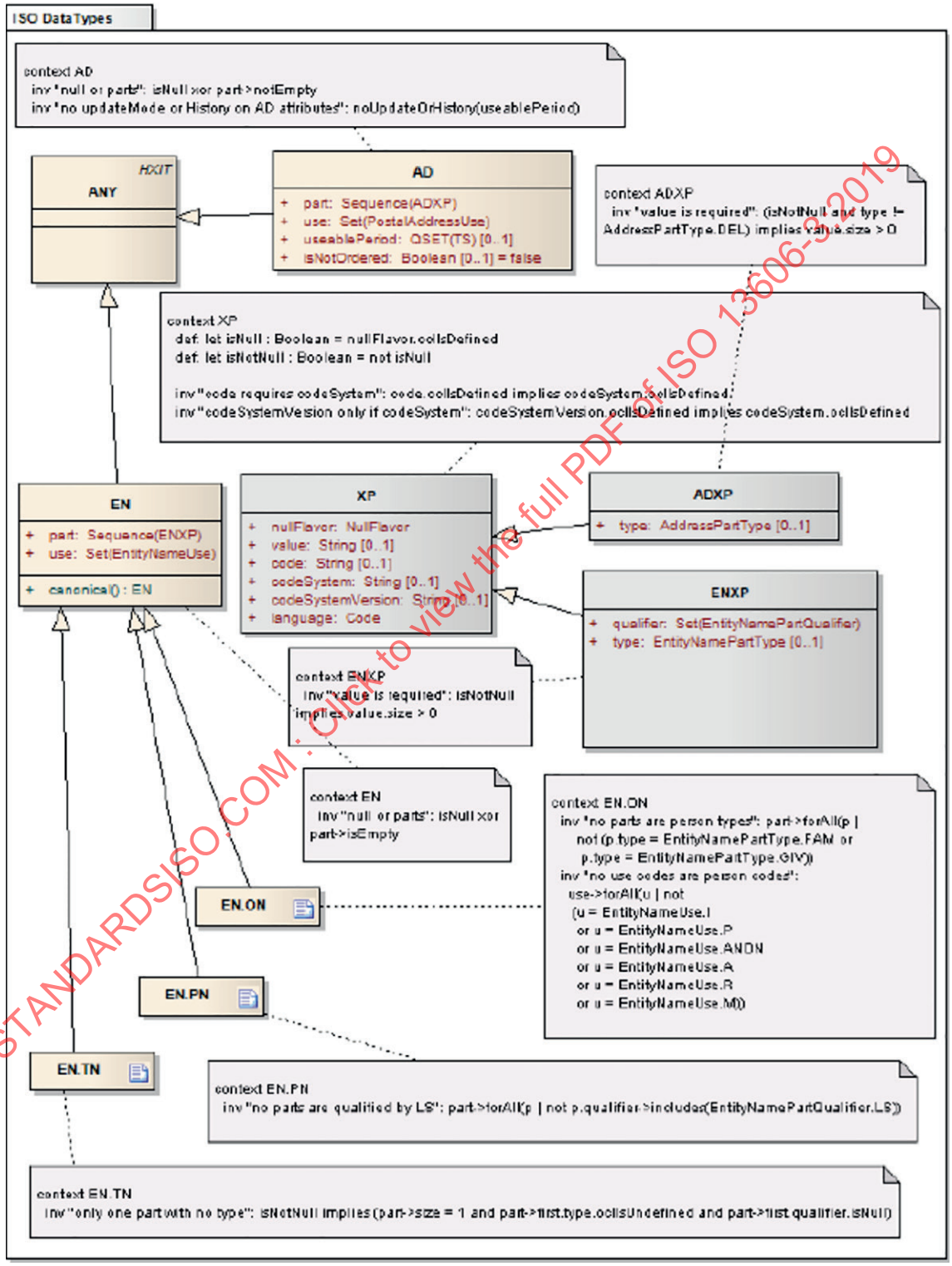
TEL.PHONE constrains TEL.PERSON so it shall refer to some telephone based communication system with a person. The URL scheme shall be tel, x-text-fax, or x-text-tel.

TEL.EMAIL

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

9.18.2 Name and Address Datatypes

These datatypes provide support for names and addresses.



XP (Name or Address Part)

A part of a name or address. Each part is a character string that may be coded, and that also may have a nullFlavor. The string content shall 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).

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).

EN (Entity Name)

A name for a person, organization, place or thing.

Examples: "Jim Bob Walton, Jr.", "Health Level Seven, Inc.", "Lake Tahoe", etc. An entity name may be as simple as a character string or may consist of several entity name parts, such as, "Jim", "Bob", "Walton", and "Jr.", "Health Level Seven" and "Inc.".

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.TN (Trivial Name)

A restriction of EN that is effectively a simple string used for a simple name for things and places. Trivial names are typically used for places and things, such as Lake Erie or Washington-Reagan National Airport.

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.

EN.ON (Organization Name)

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

10 Reference archetypes for medicinal product

10.1 Archetype name: MedicinalProduct

Subsidiary archetypes:

1) CEN-EN13606-CLUSTER.MedicinalProduct.v1.adl
2) CEN-EN13606-CLUSTER.Ingredient.v1.adl
3) CEN-EN13606-CLUSTER.PharmaceuticalProduct.v1.adl
4) CEN-EN13606-CLUSTER.RegulatedmedicinalProductt.v1.adl
5) CEN-EN13606-CLUSTER.PackagedMedicinalProduct.v1.adl

Scope: Identifying data elements and descriptive data elements of Medicinal Product based on ISO IDMP. The data are organized in a Detailed Clinical Model for the Medicinal Product, which consists of four main parts: Substance ID, Pharmaceutical Product ID, Medicinal Product ID and Package ID. The overall structure and each component are presented in a separate mind map for ease of reading.

Standards

— ISO 11615, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information

— ISO 11616, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical medicinal product

— ISO 11238, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances

— ISO 11239, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging

— ISO 11240, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement

— ISO TS 13972:2015. Health informatics — Detailed clinical models, characteristics and processes

Source specification

The reference archetype specification is derived from the following Detailed Clinical Model shown in Figure 1. The model consists of four sections, each representing one identifying data element and for that component the additional descriptive data elements. This reference archetype hence consists of four sections, each depicted as a mind map, and table with the details. Given that in particular the controlled terminologies for IDMP are determined at this time, not all attributes can be described in full in this version.

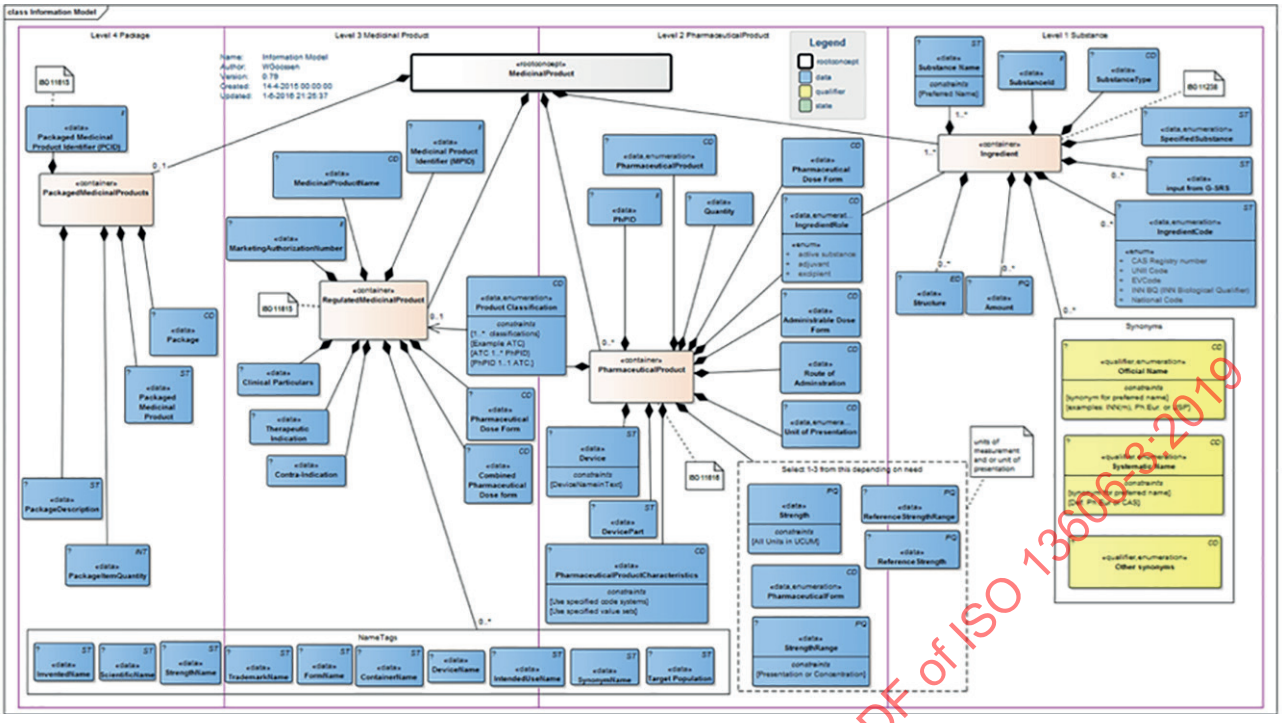


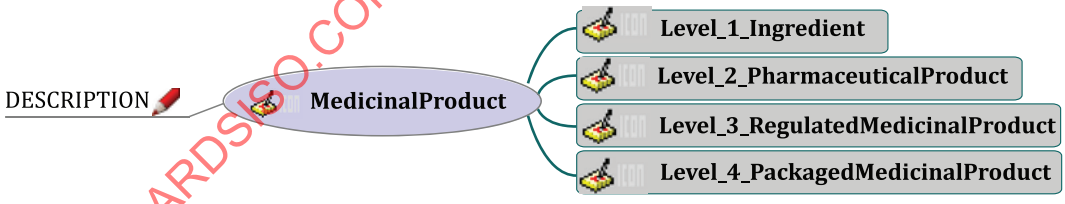
Figure 1 — UML representation of the Detailed Clinical Model for Medicinal Product

Method for applying the standard(s)

This reference archetype conforms to the following properties.

Medicinal Product as the overall structure

The above model is described in short in the mind map below which points to the four main sections: ingredient, pharmaceutical product, regulated medicinal product and packaged medicinal product. Next, each section is described in more detail.



URL: http://en13606.org/specifications.html

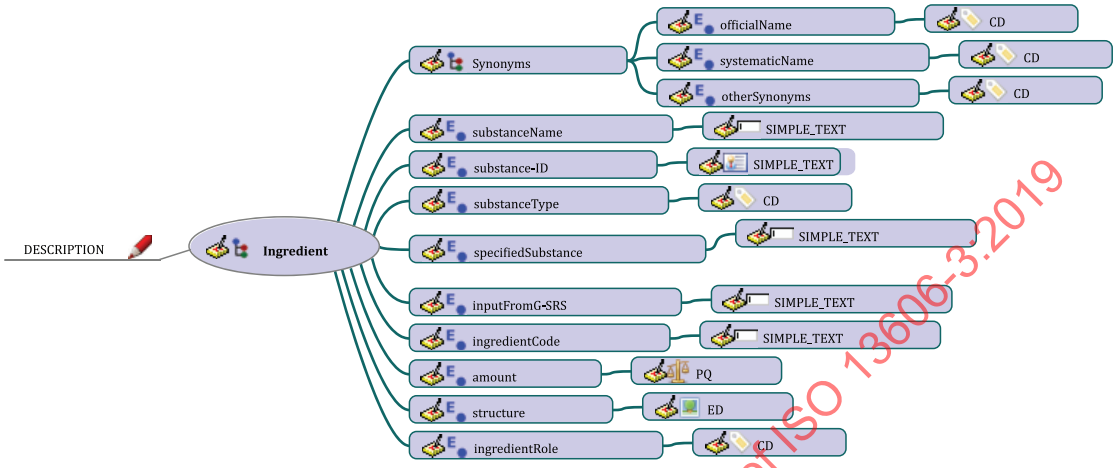
Attribute description:

Attribute	Description
Medicinal Product	Root concept that specifies the overall topic for the reference archetype.
Ingredient	Specification of the data elements for substances
Pharmaceutical Product Identifier PhPID	Unique string to refer to one specific Pharmaceutical Product
(Regulated) Medicinal Product Identifier MPID	Unique string to refer to one specific Medicinal Product
PackagedMedicinalProduct	Specifies information about the packaging and container(s) of a medicinal product and any associated device(s), which are an integral part or provided in combination with a medicinal product, as supplied by the manufacturer for sale and distribution.

Part 1: Ingredient

Part one of the Medicinal Product is shown on the right side of the model and pertains to all the details of the substances that are used in medicinal products.

Mind map ingredient/substance:



URL: http://en13606.org/specifications.html

Attribute description:

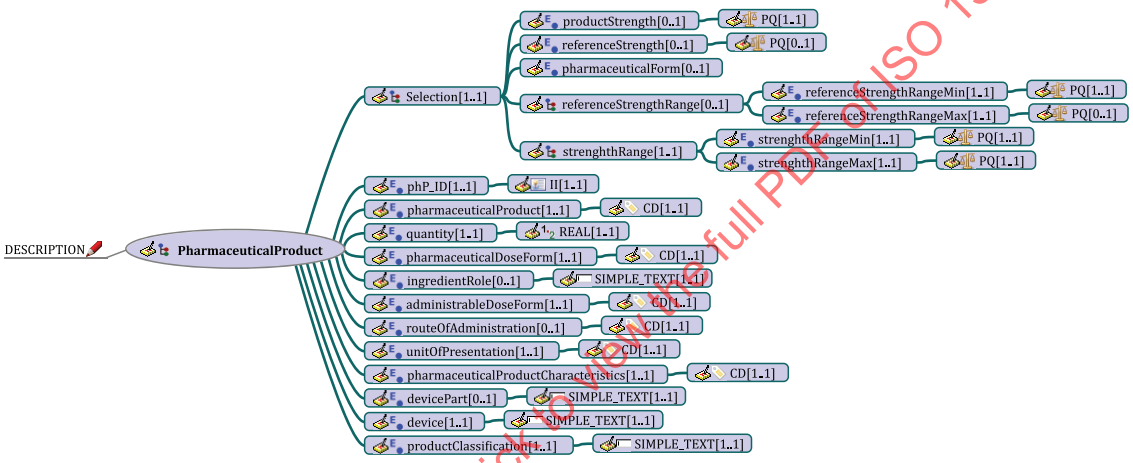
Attribute	Description
Substance ID	Each substance and specified substance shall have only one permanently associated unique identifier that shall not indicate the order of submission to the system.
Substance Name	Preferred Name for the substance, coming from the Global - Substance Registration System and is the Preferred Name
Synonyms	Alternate name for Substance. Official names are typically non-proprietary names used in a given jurisdiction and domain to refer to a specific substance. Can be described in various systems or formats such as official and systematic.
Official Name	INN(m) , Definition (Systematic name) used in a Pharmacopeial monograph or in Martindale.
Systematic Name	CAS Registry Name (CAS = Chemical Abstract Service, facilitated by the STN Easy database, Karlsruhe).
Other synonyms	Any other synonym for the same substance
Substance Type	Substance Type (ISO 11238, 3.6 Types of substances). Substances shall be single substances, mixture substances or specified substances. If it is possible to represent a substance as a single substance or a mixture substance, the substance shall be represented as a single substance.
Specified Substance	A component is an intended constituent of a Specified Substance (Group1) material. A multi-substance material is defined as a group 1 Specified Substance and is a combination of its constituents which are substances in their own right.
input from G-SRS	Global - Substance Registration System documentation on substances which can be queried upon demand and added to substance data.
Ingredient Code	Substance Name (ISO 11238, 3.4 Naming of substances). A least one substance name or company code shall be associated with each substance. Examples for Codes: CAS Registry number; UNII-Code (= FDA-SRS-Code); EVCode (Old code from EMA).

Attribute	Description
Amount	The quantitative or qualitative values that are associated with a variety of elements. The same format will be used for all quantitative, semi-quantitative and qualitative values. Molecular Weight for example.
Structure	Graphical or textual representation of the underlying molecular features. For chemicals this shall be the entire structure. For polymers, proteins and nucleic acids, this shall display pendant entities with defined molecular structure. For instance Molecular Formula in accordance with the Hill System.
IngredientRole	It is important for each substance to know its role in a pharmaceutical product: active ingredient, expedient or adjuvant for example.

Part 2: Pharmaceutical Product

Part two of the Medicinal Product is shown on the right middle part of the model and pertains to all the details of the pharmaceutical product.

Mind map ingredient/substance:



URL: http://en13606.org/specifications.html

Attribute description:

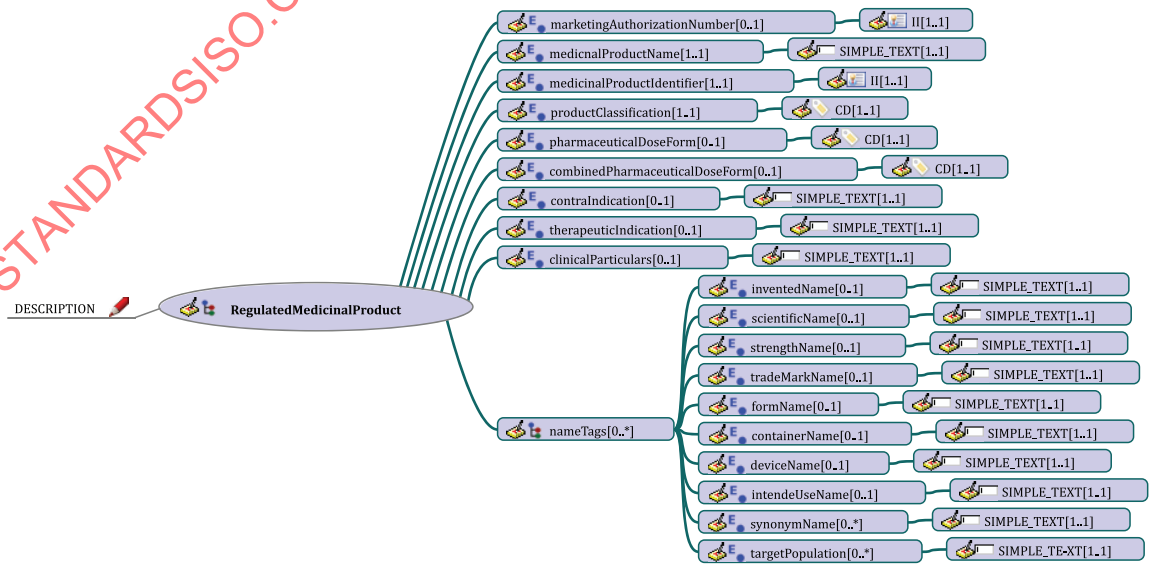
Attribute	Description
Pharmaceutical Product Identifier PhPID	Unique string to refer to one specific Pharmaceutical Product
Pharmaceutical Product	Qualitative and quantitative composition of a medicinal product in the dose form authorized for administration by a regulatory authority, and as represented with any corresponding regulated product information.
Selection	Option to include one to more of the following underlying specifications about strengths and dose form.
Strength	The content of the active substance/specified substance description expressed quantitatively (e.g. per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical form or unit of presentation) (ISO/FDIS 11616:2012).
Reference Strength	quantifying the active moiety relationship as amount
Pharmaceutical Dose Form	physical manifestation of a product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient
Reference Strength Range	a quantity of the substance/specified substance present in a given quantity of the pharmaceutical product. Can be expressed as referenceStrengthRangeMin and/or referenceStrengthMax

Attribute	Description
Strength Range	The difference between the largest and smallest values of quantity of the substance/specified substance present in a given quantity of the pharmaceutical product.
Quantity	The count or number of the pharmaceutical product value (number and unit (reference), together expressing magnitude of a quantity).
IngredientRole	It is important for each substance to know its role in a pharmaceutical product: active ingredient, expedient or adjuvant for example.
Administrable dose form	Pharmaceutical dose form as administered to the patient, after any necessary transformation of the packaged pharmaceutical dose form has been carried out.
Route of Administration	The path by which the pharmaceutical product is taken into or makes contact with the body.
Unit of Presentation	The discrete unit in which a pharmaceutical product is presented to describe strength or quantity in cases where a quantitative unit of measurement is not appropriate.
Pharmaceutical Product Characteristics	Various characteristics of the Pharmaceutical Product, such as its onset of action.
(Medical) Device	A pharmaceutical product may refer to a drug that is associated with a medical device (e.g. drug/device, biologic/device), e.g. to store or to administer it.
Device Part	Part of a medical device, e.g. a needle in a prepared injectable fluid syringe with the medication in it.
Product Classification	The medicinal product can be classified according to various classification systems, which may be jurisdictional or international. Example ATC

Part 3: Regulated Medicinal Product

Part three of the Medicinal Product is shown on the right middle part of the model and pertains to all the details of the pharmaceutical product.

Mind map Regulated Medicinal Product:



URL: http://en13606.org/specifications.html

Attribute description:

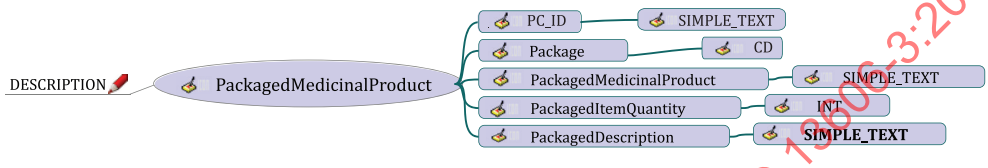
Attribute	Description
(Regulated) Medicinal Product Identifier MPID	Unique string to refer to one specific Medicinal Product Formal definition: Medicinal Product Identifier (MPID) is a unique identifier allocated to a medicinal product supplementary to any existing authorization number as described by a Medicines Regulatory Agency in a jurisdiction.
Medicinal Product Name	name as authorized by a Medicines Regulatory Agency
Marketing Authorization Number	identifier assigned by a Medicines Regulatory Agency to a Medicinal Product
Product Classification	The medicinal product can be classified according to various classification systems, which may be jurisdictional or international. Example ATC
Clinical Particulars	Specific information about the clinical characteristics of the medicinal product as described in line with the regulated product information.
Therapeutical Indication	the authorized indication(s) for the Medicinal Product in accordance with the regulated product information.
Contra-Indication	This class shall be used to describe the authorised contra-indication(s) for the Medicinal Product as described in the regulated product information.
dose form dosage form pharmaceutical dose form	physical manifestation of a Medicinal Product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient.
combined pharmaceutical dose form	The combined pharmaceutical dose form is a single term to describe two or more manufactured items that are intended to be combined in a specific way to produce a single pharmaceutical product; it includes information on the manufactured dose form of each manufactured item and the administrable dose form of the pharmaceutical product. If the Medicinal Product requires description of a combined pharmaceutical dose form, it can be specified here using a term and a term identifier as defined in ISO 11239 and the resulting terminology shall be specified.
Name Tags	The following descriptions or names can be added
Invented Name	name for an innovative Medicinal Product as authorized by a Medicines Regulatory Agency in a jurisdiction
Scientific Name	The scientific or common (i.e. generic) name of the Medicinal Product without any other descriptors can be specified as text, where applicable.
Strength Name	Strength reflected in the Medicinal Product Name, specified as text, where applicable.
Trademark Name	Trademark reflected in the Medicinal Product Name
Form Name	pharmaceutical dose form reflected in the Medicinal Product Name
Container Name	The container or pack reflected in the Medicinal Product Name
Device Name	The device reflected in the Medicinal Product Name

Attribute	Description
Intended Use Name	Intended Use reflected in the Medicinal Product Name
Synonym Name	Alternative name for the same Medicinal Product
Target Population	The target population reflected in the Medicinal Product Name

Part 4: Packaged Medicinal Product

Part four of the Medicinal Product is shown on the left part of the model and pertains to all the details of the packaged medicinal product.

Mind map Regulated Medicinal Product:



URL: http://en13606.org/specifications.html

Attribute description:

Attribute	Description
Packaged Medicinal Product Identifier PC_ID	Unique string to refer to one specific Packaged Medicinal Product. Formal Definition: Medicinal Product Package Identifier, PCID is a unique identifier allocated to a packaged medicinal product supplementary to any existing authorization number as ascribed by a Medicines Regulatory Agency in a jurisdiction.
Package	Package Item (Container) type shall be specified to describe the physical type of the container of the medicine in accordance with ISO 11239.
Packaged Medicinal Product	Specifies information about the packaging and container(s) of a medicinal product and any associated device(s), which are an integral part or provided in combination with a medicinal product, as supplied by the manufacturer for sale and distribution.
Packaged Item Quantity	Specification of the quantity (or count number) of the package item.
Package Description	A textual description of the Packaged Medicinal Product shall be provided.

11 Reference archetypes for clinical information specifications

11.1 General

The examples of clinical reference archetypes presented in this clause are based on the clinical reference information structures presented in Clause 12. The clinical reference information structures in Clause 12 are developed out from the clinical concepts as they are defined in ISO 13940 (Contsys). This means that the clinical reference archetypes presented here are conformant to Contsys.

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

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

The clinical reference archetypes presented in this clause are limited to a few examples for representations of the most basic clinical concepts. A comprehensive set of clinical reference information

structures for representation of all needed clinical information is given in Clause 12. Clinical reference archetypes can easily be developed based on the clinical reference information structures.

11.2 Archetype name: Health condition

Identifier: ISO-EN13606_CLUSTER.HealthCondition.v1.adl

Scope: *Health condition* is in ISO 13940:2015 an abstract concept defined as "observed or potential observable aspects of the health state at a given time".

Health state is defined as "physical and mental functions, body structure, personal factors, activity, participation and environmental aspects as the composite health of a subject of care". The definition of health state is based on the WHO classification ICF and the health components described in this. Health conditions include both observed and potential observable aspects of a health state.

Observed condition is in ISO 13940 an observed aspect of a health state and can be specialized as professionally assessed condition and/or resultant condition.

Professionally assessed condition is an observed condition that is assessed by a healthcare professional concerning certain specific factors.

Resultant condition is an observed condition observed after performance of a direct healthcare activity element (healthcare investigation or healthcare treatment). Resultant conditions are considered to include the FHIR resource "observation".

Potential condition is a not yet observed aspect of a health state that for some reasons assessed possible to become observed in the future. Potential condition can be specialized as considered- *risk-, target- and prognostic conditions*.

Health condition can be generalized as health issues (and further to healthcare matters).

The information structure for "Health condition" specifies common information concerning aspects of a health state. These are successive specializations of health condition that are considered relevant to keep information about. The two abstract concepts health condition and potential condition are not included as types of health conditions.

The information structure also includes specification of associations to other health conditions. For example can one observed condition be one of several criteria for a more composite professionally assessed condition. One health condition can alternatively be a complication of another. Relations to healthcare activity elements can also be specified by this information structure.

Standards:

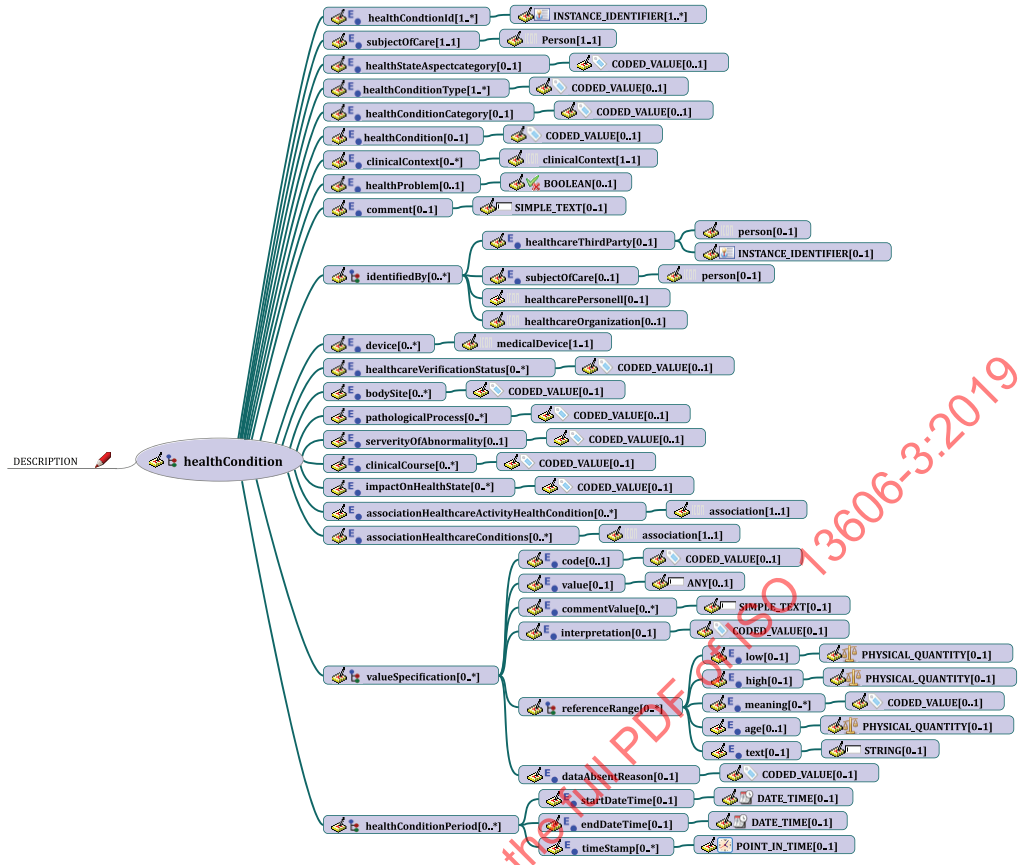
— ISO 13940:2015 Health informatics — System of concepts to support continuity of care

— HL7 FHIR: Observation resource, Condition resource.

Method for applying the standard(s)

This reference archetype conforms to the ISO 13940:2015 properties as indicated below.

Mind map:



URL: http://en13606.org/specifications.html

Attribute description:

Attribute	Description
health condition id	A unique identifier for the health condition instance. Allows health conditions to be distinguished and referenced. FHIR:condtion.identifier**
subject of care	This attribute is inherited from the relation between subject of care and Healthcare matter. Indentifies the subject of care/patient who the health condtion is associated with. FHIR:condition.patient** FHIR.observation.subject (patient, group, location, device)
health state aspect category	Code for the aspect of health state included in the health condition as defined by the health components in ICF. The category can be specified by the four position code in ICF i.e. the body function ”heart functions ICF b410. FHIR: Observation.category*
health condition type	Code for the type of health condition. Types of health conditions are all specializations of the abstract concept “health condition” in ISO 13940 (see introduction to this reference information structure). FHIR resource observation corresponds to resultant condition.

Attribute	Description
health condition category	Code for the category of condition based on FHIR condition category. Complaint - The patient considers the condition an issue to be addressed Symptom - A symptom of a condition (as might be mentioned in a review of systems) Finding - An observation made by a healthcare provider Diagnosis - This is a judgment made by a healthcare provider that the patient has a particular disease or condition FHIR:condition.category** http://hl7.org/fhir/ValueSet/condition-category
health condition	Code for the health condition. This attribute specifies the health condition from several perspectives. One is by classifications and terminologies, another is by value specifications from so called "assessment scales" like Apgar scores for newborns. Examples of classifications are ICD, ICF, SNOMED CT The health condition can be further specialized according to the "health state aspect and value specifications". FHIR: condition.code**
clinical context	This attribute refers to the cluster for clinical context specification Specifies clinical and/or administrative context, e.g. which clinical process concern and which step in the clinical process the health condition relates to FHIR: includes attribute for encounter
health problem	Specifies if the health condition is considered to be a problem concerning the health state. The consideration can be done by the subjert of care and/or by a healthcare professional FHIR:not included
comment	Textual comment on the health condition FHIR:condtion.notes** FHIR:observation.comments**
identified by	This attribute is inherited from the relation between healthcare actor and healthcare matter. Identity and name for the healthcare actor(s) who identified/noticed the condition. The identifier can be the subject of care, healthcare personnel, healthcare third party and the responsibility/task could also be specified by the healthcare organisation within which assignment the condition was identified. FHIR: condition.asserter(practioner or patient)**
device	Identification for the equipment/device that has generated the observation data FHIR: observation.device**

Attribute	Description
health condition period	This attribute is a specialization of the concept health related period. Time interval/period during which a healthcare professional, the subject of care or other healthcare actor (from identified by above) has noticed a specific health condition. A health condition period can be specified for all types of health conditions. For potential conditions this will be by an assessment. For lab test etc. where a sample or specimen is taken from the subject of care the time for the observation should be when the sample was taken. FHIR: condition.onset (datetime, age, period,range, string)** FHIR: condition.abatement datetime, age, period, range,string, Boolean)** FHIR: observation effective (datetime,period)** FHIR: observation.issued**
condition verification status	Specifying the level of verification of the health condition as assessed by the identifier. From FHIR "condition verification status". FHIR: Provisional, differential, confirmed, refuted entered-in-error and unknown
body site	Code for the anatomical localization of the health state aspect E.g. a blood pressure measured externally on right upper arm, a tumour in the lower abdomen etc. FHIR: body site
pathological process	Specifying the mechanism behind the abnormal findings for body structure or body function (e.g. autoimmune process behind diabetes type I) When the pathological process is specified as the reason for the condition by a healthcare professional the health condition is a "professionally assessed condition".
severity of abnormality	Specifying the level of abnormality of the health aspect, e.g. reduced calibre of a vessel to 25 % of normal When the severity is specified by a healthcare professional the health condition is a "professionally assessed condition".
clinical course	Specifying the probable (by medical knowledge) future course of the health condition. When the clinical course is specified by a healthcare professional the health condition is a "professionally assessed condition".
impact on health state	Specifying the impact on the health state of a health condition When the impact on the health state is specified by a healthcare professional the health condition is a "professionally assessed condition".
association healthcare activity health condition	Specifies the relation/association of the health condition to a specific healthcare activity element, e.g. as a motivation for or as a result of a healthcare activity element E.g. high blood pressure as a motivation for pharmacological treatment or a genetic profile as a health condition associated to choice of a specific medical product in a pharmacological treatment activity. FHIR.observation.related

Attribute	Description
association health conditions	Specifies the associations between the specified health condition and another health condition. The relation can be the health condition being criteria for a more composite condition or being a resulting condition from a risk condition after an occurred event etc. Another important relationship is that a health condition can be a complication to a primary health condition. A health condition evolution is “an association health condition” for the successive change of a condition over time. Criteria for a composite health condition which in FHIR is called evidence is another “association health condition”. E.g. breathlessness as criteria for heart failure or a stroke as a complication to high blood pressure. FHIR.observation.related ?
Code	Specifies the code that describes the value of the health condition. Sometimes this is called the observation "code". FHIR:observation .component.code**
value	The value of the actual health condition (expressed in units) at a certain occasion. The values can be specified by so called “assessment scales” like Apgar score for newborns. FHIR:observation.value, component. value**. Value of health conditions/observations as criteria and summary from assessment scales.
comment value	Textual comment on the value of the health condition FHIR –not included**
reference range	Specifies the interval of values which are considered in the interpretation of the value. FHIR reference values for low and high etc.
Low	Low Range, shall have at least a low or a high or text
High	High Range, shall have at least a low or a high or text
Meaning	Reference range qualifier
Range	Applicable age range
Text	Text based reference range in an observation, shall have at least a low or a high or text
interpretation	Represents a signal from the healthcare actor that the value is to be especially noticed, e.g. marked as pathological or borderline pathological FHIR:observation.interpretation**
data absent reason	Provides a reason why the expected value in the element. An example of reason is that the value is exceptional high and not within a trustworthy reference range. FHIR “data absent reason”.

11.3 Archetype name: Healthcare activity element

Identifier: ISO-EN13606_CLUSTER.HealthcareActivityElement.v1.adl

Scope: In ISO 13940, “*Healthcare activity*” is defined as “activity intended directly or indirectly to improve or maintain a health state”. The types of healthcare activities are defined out from the actor performing the activity (*healthcare provider-, self-care- and healthcare third party activity)*.

Healthcare activity is a complex concept that can be subdivided into *healthcare activity elements* that also represent the purposes of the performance The two main purposes are to clarify aspects of the health

state of a subject of care -*healthcare investigations*- or to improve/maintain the health state -*healthcare treatment* Healthcare investigations and healthcare treatments directly involve the subject of care and are thereby also called direct healthcare activity elements. Healthcare activity elements that are only indirectly involving the subject of care are, -*healthcare assessments, -evaluations, -communication, resource management* and *healthcare activity management including healthcare planning* for changing the status of a direct activity element.

Healthcare treatment is a direct healthcare activity element aiming to influence some aspect(s) of the health state of a subject of care.

Healthcare investigation is a direct healthcare activity element that gives the prerequisites for observations of one or several aspects of a person's health state (observed conditions). The observed conditions as results of investigations (resultant condition) provide the basis for assessments of pathophysiological genesis, severity or consequence for a person's health state (expressed as professionally assessed conditions).

In clinical practice information about investigations and treatments are fundamental and are for this reason the basis for the information structure concerning healthcare activity element.

Information structures as requirements/patterns for specifying reference- and clinical archetypes are defined and included to comprehensively cover all need for information in an EHR.

All categories of healthcare activity elements share a number of characteristics to keep information about. The common structure for healthcare activity element includes all attributes needed for the two direct activity elements – investigations and treatments. Several attributes relevant for indirect healthcare activity elements are included in the common structure. Further attributes are however needed for indirect activity elements as complements. For these reasons specific structure are included for:

— healthcare activity element – general and complete for healthcare investigations and healthcare treatments;

— healthcare assessment;

— healthcare evaluation;

— healthcare activity management including healthcare planning.

Healthcare assessment is specified as three specialisations for:

— assessment to conclude or exclude health conditions;

— healthcare needs assessment;

— clinical risk assessment.

Standards:

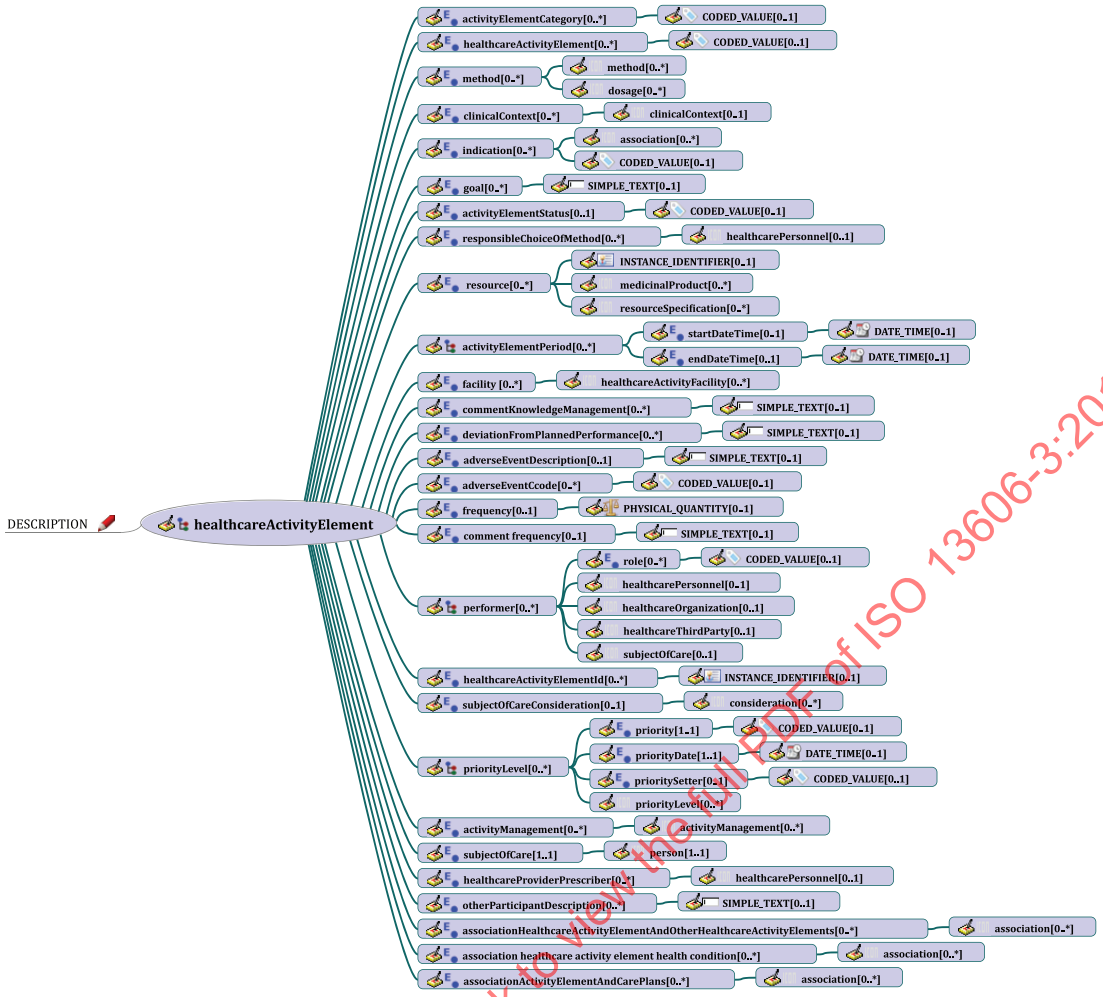
— ISO 13940:2015 Health informatics — System of concepts to support continuity of care

— HL7 FHIR: Procedure resource

Method for applying the standard(s)

This reference archetype formalizes the representation of the ISO 13940:2015 concepts as indicated below.

Mind map:



URL: http://en13606.org/specifications.html

Attribute description:

Attribute	Description
healthcare activity element id	A unique identifier for the healthcare activity element instance. Allows the healthcare activity element to be distinguished and referenced.
activity element category	Specifies the category of the activity element categorized by the main purpose. Corresponding to “procedure type” in FHIR.
healthcare activity element	Code for the healthcare activity element. Different code systems and classifications can be used.
method	In accordance with the “method specification” Specification of the method to be used for performance of the healthcare investigation or healthcare treatment, e.g. a laboratory test, a CT-scan etc. for healthcare investigations and open surgery or pharmacological treatment for healthcare treatments.
clinical context	This attribute refers to the cluster for clinical context Specifies the clinical and/or administrative context, e.g. which clinical process concern and which step in the clinical process the activity element is included in

Attribute	Description
indication	Specifying the indication/motif for or against performing the activity element. Indications can also be specified as an association healthcare activity element – health condition or an association healthcare activity – healthcare activity.
goal	Specification of the goal for the activity element e.g. to exclude a considered condition as breast cancer or to verify a myocardial infarction for healthcare investigations and removal of a tumour or lowering blood pressure for a healthcare treatment. The goal can be specified as a target condition in an association healthcare activity element – health condition. Goals other than different types of health conditions can also be identified i.e. degree of subject of care satisfaction or a certain degree of effectiveness.
activity element status	Code and text for the current status of an activity element Only current status is shown, history is shown in the compound format healthcare activity management. Instruction state machine from open EHR can be used
resource	According to the cluster "resource". Specification of the resources that are planned, booked and used for performance of the activity element. Should include both personal (e.g. an hour nurse) and material (e.g. an ultrasonic scanner or a medicinal product)
activity element period	This attribute is a specialization of the concept "health related period". Specifies the time (moment or time interval) for the performance of the activity element
facility	According to the demographics. Specification of the place/site/room where the healthcare activity element is performed, e.g. a laboratory, a hospital ward, a surgical theatre etc.
comment knowledge management	Information linked to the knowledge management that is applied for performance of the activity element Protocols, guidelines etc. can include specifications for application of knowledge
deviation from planned performance	Description of deviation from the decided and planned performance of the activity element e.g. change of method for performance
adverse event description	Description of unforeseen event during the healthcare activity period that has impact on activity management, performance and/or the resulting conditions
adverse event code	Code and text for the unforeseen event during the healthcare activity period
frequency	Number of instances per time unit for performance of the activity element e.g. once every 4th week
comment frequency	Possible further information for clarifying the frequency
performer	Identity and/or name of the healthcare actor who is planned to perform, is performing or has performed the activity element. The performer can be the subject of care (self-care activity), healthcare personnel (healthcare provider activity), healthcare third party and the responsibility/task could also be specified by the healthcare organisation within which assignment the condition was identified. National or local person registers

Attribute	Description
role	A code that identifies a role of the performer of the healthcare activity element The role of the performer also determines the type of activity that is performed — healthcare provider activity — self-care activity — healthcare third party activity — automated activity Related to FHIR:procedure.performer.role**
subject of care consideration	According to the cluster “consideration”. The subject of care considers and takes position to the provider’s commitment to perform the activity element. The outcome is either an informed consent that includes who, where and by whom the activity will be performed or a dissent. Informed consent or dissent should be registered to achieve the activity state ”active”
priority level	The priority level for the performance of the activity element within a certain time interval Priority set by whom and when should be registered before the activity element achieves the status “active”. E.g. within a specified time limit or a code system for acute, planned etc. Priority level can be further specified in accordance with the cluster for “priority level”
priority	Code and text that describes the priority of performance of the activity/activity element
priority date	Date or dates when prioritization is decided
priority setter	Code and text for the role of the person specifying the priority level
activity management	According to the cluster “activity management”. Specifies the indirect activity elements performed to change the status of the direct healthcare activity element
subject of care	This attribute is inherited from the relation between subject of care and Healthcare matter. Indicates the subject of care/patient who the health activity element is associated with FHIR:procedure.patient**
healthcare provider prescriber	Specifies which healthcare provider that with or without an explicit healthcare needs assessment prescribed the activity element. The information is valid for all healthcare provider- and all prescribed self-care activity elements E.g. a person having a healthcare professional role, a healthcare organisation or a professional team
other participant description	Description of other actor who is involved in the activity element. Can be e.g. the subject of care, a next of kin, other healthcare third party
responsible for choice of method	This attribute is a specialization of the concept “healthcare mandate”. Identification and name for the healthcare professional and unit within which assignment deciding which method to use for performing the activity element

Attribute	Description
association healthcare activity element and other healthcare activity elements	According to the cluster “association”. Specification of associations of the activity elements to other activity elements. The association include activity elements that are consequences of another activity element e.g. removal of sutures after a surgical operation. Specifies i.e. dependencies between activity elements where performance of one element is a consequence of another
association healthcare activity element health condition	According to the cluster “association”. Specification of the association between the activity element and health condition(s) (observed or potential conditions) e.g. as specifying the indication, a complication to and/or the result of an activity element e.g. association between a high blood pressure and a healthcare treatment with an antihypertensive drug. FHIR:procedure. Complication**
association activity element and care plans	Specifies the associations between the activity element and one or several care plans. Examples of care plans that the activity element is included in: Care plan for a clinical process for specified health issues etc.

11.4 Archetype name: ClinicalContext

Identifier: ISO-EN13606_CLUSTER.ClinicalContext.v1.adl

Scope: Clinical processes are the basis for the provision of healthcare services with continuity of care. The system of concepts in ISO 13940 includes an informative generic model of the clinical process. Definitions of the core concepts specify the clinical content. Health conditions/-problems and healthcare activity elements are the most important concepts concerning content in the clinical process. *Clinical context* describes how phenomenon and information concerning content are related to the phases of the clinical process for individual subjects of care.

In ISO 13940 a *health thread* is defined as “defined association between healthcare matters as determined by one or more healthcare actors”. A health thread can include healthcare investigations and -treatments, health conditions, healthcare activity planning, -activity management, -evaluations and –assessments.

A *clinical process interest* is a health thread for a specific instance of a clinical process.

A *health concern* is a “health record extract that includes all health record components associated with a health thread for a specific concern”. A concern is gathered information to support continuity of care for a subject of care. Thereby, all information needed for continuity of care for an individual subject of care can be covered by a health concern for a specified health thread.

One basic and fundamental type of health concern is a *clinical process concern,* which accordingly includes information documented in an EHR concerning a specific clinical process interest for a subject of care. Thereby, all information needed for continuity of care for a specific clinical process can be covered by a clinical process concern.

Clinical context is a *clinical process concern* where the information concerning clinical phenomenon in a clinical process interest are related to the phases of an instantiated clinical process. The information structure for clinical context includes attributes to specify how a clinical process concern relates to the phases defined in the general clinical process model.

This structure for clinical context is focused on the relations to a clinical process. However there are other types of clinical contexts that also could be relevant to document.

Standards:

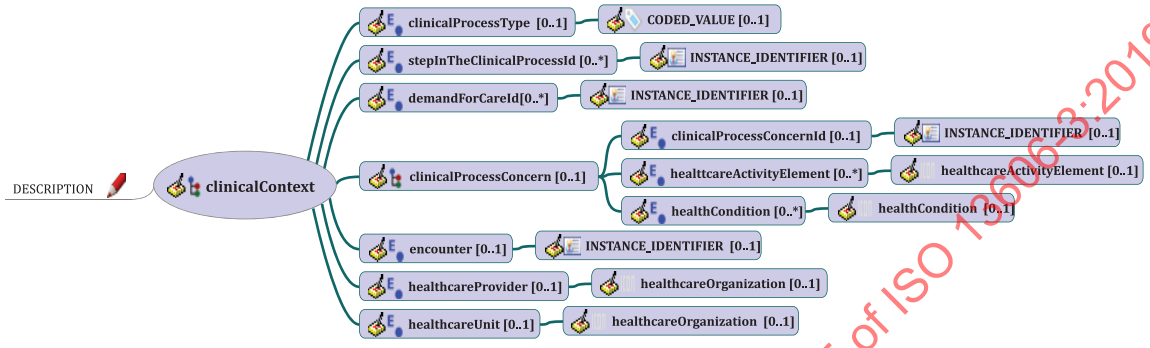
— ISO 13940:2015 Health informatics — System of concepts to support continuity of care

— HL7 FHIR: Observation resource, Condition resource.

Method for applying the standard(s)

This reference archetype conforms to the ISO 13940:2015 properties as indicated below.

Mind map:



URL: http://en13606.org/specifications.html

Attribute description:

Attribute	Description
clinical process type	Specifying the type of clinical process that the concern holds information about. Clinical processes are recommended to be categorized by the main health problem or problems the process handles
step in the clinical process id	This attribute is a specialization of the concept “health related period”. Specifying the step/phase of the clinical process that the information in the clinical process concern is about. The steps of the clinical process can be defined by a structured analysis of the specific type of clinical process based on the clinical process model in ISO 13940. The steps are: demand for care healthcare needs assessment for investigations care plan for investigations (planning, performing and evaluation) healthcare needs assessment for treatment care plan for treatment (planning, performing and evaluation) clinical process evaluation
demand for care id	Identity of the demand for care, that has initiated the clinical process included in the clinical process concern. A demand for care initiates a clinical process. In a health record a repository of demands for care is needed for traceability to clinical processes and clinical process concerns.
clinical process concern	According to cluster for clinical process concern. Identity of the specific clinical process concern. In a health record the clinical process concerns should be possible to identify by a specific clinical process concern repository, which also is a basic component of a patient summary.
clinical process concern id	Identity of the specific clinical process concern. In a health record the information in clinical process concerns should be possible to identify by a specific clinical process concern repository, which also is a basic component of a professional health record overview

Attribute	Description
healthcare activity element	Specified by "healthcare activity element". Specifying the healthcare activity elements included in the care plan for the clinical process. Investigations and treatments can be coded by Snomed CT procedures or by national/local code systems
health conditions	Specified by "health condition". Specifying the health conditions identified/noticed by the healthcare actors during the clinical process. E.G. classifications as ICF or ICD alternatively Snomed CT clinical findings can be used
Encounter	Specifies the current encounter/visit/hospital stay that is documented in the specified clinical process concern. FHIR encounter
healthcare provider	Specifying the healthcare provider which by a healthcare mandate is responsible for the complete and/or current part of the clinical process.
healthcare unit	Specifying the healthcare unit which by a healthcare mandate is responsible for the complete and/or current part of the clinical process.

11.5 Archetype name: Activity management

Identifier: ISO-EN13606_CLUSTER.ActivityManagement.v1.adl

Scope: *Healthcare activity management* is defined as "healthcare activity element during which the status of healthcare activities in a care plan are changed". Statuses can be changed by indirect and/or direct healthcare activity elements. Examples of indirect activity elements able to change statuses are healthcare planning, healthcare needs assessment and healthcare evaluation. Performance of a direct healthcare activity element also changes the status.

In ISO 13940 *healthcare planning* is defined as: "element of healthcare activity management where a care plan is created or modified". A "*care plan*" is defined as "dynamic, personalized plan including identified needed healthcare activities, health objectives and healthcare goals, relating to one or more specified health issues in a healthcare process".

A care plan is created when the first healthcare activity element is registered as having the status "planned".

A care plan includes direct healthcare activity elements for investigations and treatments (regardless the status of the activity element) in a healthcare process (a part of or a complete clinical process).

Status of an activity element can e.g. be categorized in accordance with the Instruction state machine from open EHR where the main statuses are planned, scheduled, active, completed, complemented by, aborted, cancelled or suspended.

Activity planning is specified according to the cluster for healthcare activity management. Input to activity planning is the result of a healthcare needs assessment. The information structure for care plan includes an attribute for healthcare needs assessment.

The archetype (or cluster in the clinical reference information structure) for activity management is linked to the direct healthcare activity elements by constituting an attribute in these.

Standards:

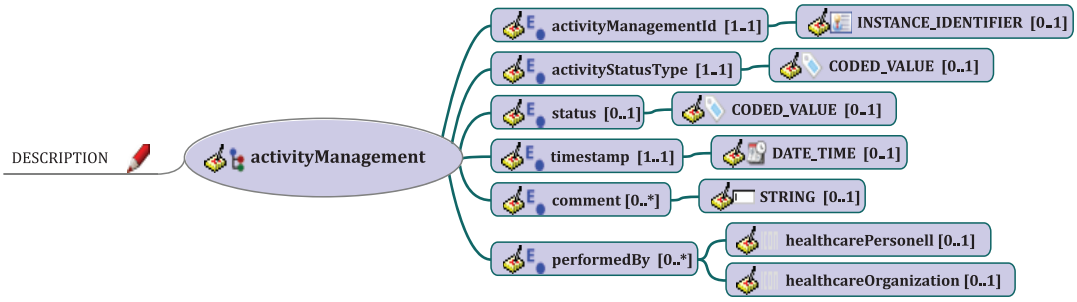
— ISO 13940:2015 Health informatics — System of concepts to support continuity of care

— HL7 FHIR: Observation resource, Condition resource

Method for applying the standard(s)

This reference archetype conforms to the ISO 13940:2015 properties as indicated below.

Mind map:



URL: http://en13606.org/specifications.html

Attribute description:

Attribute	Description
activity management_id	Identity of the activity management. Unique identifier. Generated in the local/source system
activity status type	Code and text that describes the type of activity status affected
Status	Code and text for the status of the activity/activity element E.g. specified according to the "Instruction state machine" of open EHR
Timestamp	Time and date when the status was changed
Comment	Comment to activity management that changed the status
performed by	This attribute is a specialization of the concept "healthcare mandate". Identification and name of the health care personnel and/or organisation on whose behalf the changed status was generated

11.6 Archetype name: Association

Identifier: ISO-EN13606_CLUSTER.Association.v1.adl

Scope: "Association" specifies information concerning associations between different health conditions (including potential conditions), included in a health condition thread and associations between health conditions and healthcare activity elements. Associations between healthcare activity elements are also included.

An example of *association health conditions* is that a number of observed conditions can constitute criteria for a professionally assessed condition or a working diagnosis.

"*Associations health condition healthcare activity elements*" specifies information in a health thread concerning the associations between healthcare activity elements and health conditions. Examples are that a healthcare investigation can be motivated by a considered condition and a resultant condition can be an outcome of a healthcare treatment.

Standards:

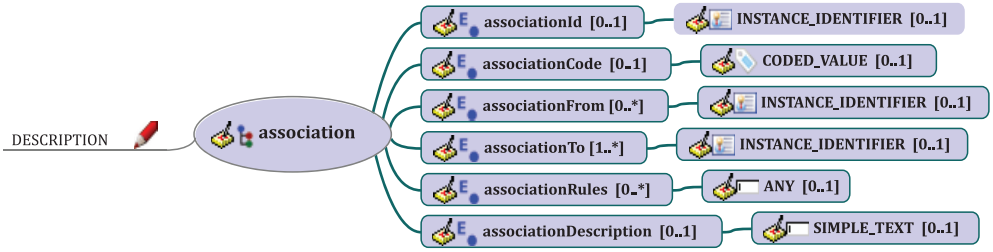
— ISO 13940:2015 Health informatics — System of concepts to support continuity of care

— HL7 FHIR: Observation resource, Condition resource

Method for applying the standard(s)

This reference archetype conforms to the ISO 13940:2015 properties as indicated below.

Mind map:



URL: http://en13606.org/specifications.html

Attribute description:

Attribute	Description
association id	Description and/or identity of the association. Specifying the type of association i.e. being a criteria for, a complication to, a risk for etc. Unique identifier. Generated in the source system
association code	Code and text for the type of association between the associated concepts, e.g. symptom of, criteria for, consequence of etc.
association from	Identification of the concept the association is from
association to	Identification for the concept the association is to
association rules	Description of the rules for the association
association description	Textual comment of the association

11.7 Archetype name: Consideration

Identifier: ISO-EN13606_CLUSTER.Consideration.v1.adl

Scope: Consideration describes the patient's position taken to a proposed healthcare activity element or a professional assessment. The subject of care or an authorized representative of the subject of care (subject of care proxy) can execute a consideration.

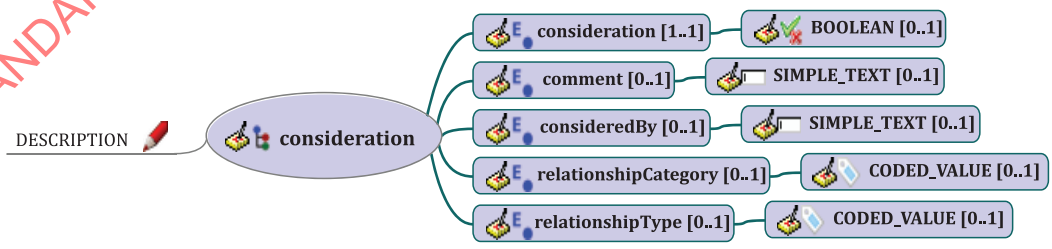
Standards:

— ISO 13940:2015 Health informatics — System of concepts to support continuity of care

Method for applying the standard(s)

This reference archetype conforms to the ISO 13940:2015 properties as indicated below.

Mind map:



URL: http://en13606.org/specifications.html

Attribute description:

Attribute	Description
consideration	Indicates if the patient consents or dissents a professional actor's proposed healthcare activity elements, assessment of healthcare activity needs, the health condition, prognosis, risks, etc.
comment	Subject of care comment.
considered by	Name of the person that made the consideration if other than the subject of care.
relationship category	Code and text for category of relationship between the subject of care and the authorized representative.
relationship type	Code and text indicating the type of relationship referred by category.

11.8 Archetype name: Dosage

Identifier: ISO-EN13606_CLUSTER.Dosage.v1.adl

Scope: "Dosage" specifies characteristics/information concerning the method for a pharmacological treatment by specifying amount and frequency for the administering of a medicinal product.

Standards:

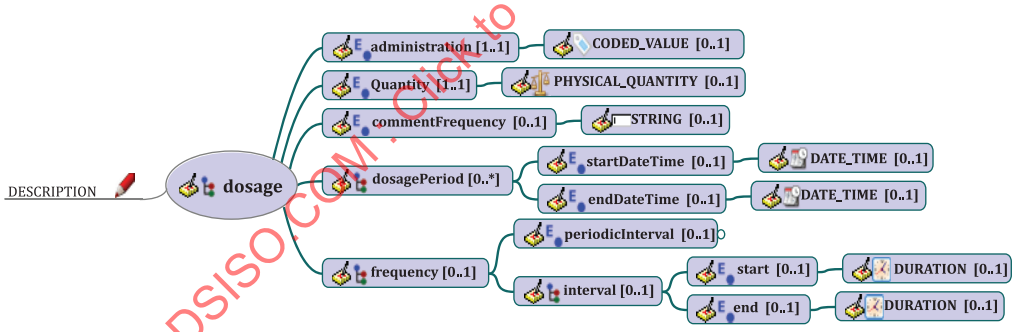
— ISO 13940:2015 Health informatics — System of concepts to support continuity of care

— HL7 FHIR MedicationAdministration resource

Method for applying the standard(s)

This reference archetype conforms to the ISO 13940:2015 properties as indicated below.

Mind map:



URL: http://en13606.org/specifications.html

Attribute description:

Attribute	Description
Administration	Specifies the method for administration of the medicinal product to the subject of care e.g. orally, intravenously.
Quantity	Specific the amount for each occasion e.g. 1 á 10 mg.
dosage period	Specifies the time interval for the given dosage.
frequency	Specification of the number of occasions per time interval for the administering each dose of the medicinal product e.g. every 8th hour, daily, once a week etc.
comment frequency	Further information to clarify the frequency.

11.9 Archetype name: Method

Identifier: ISO-EN13606_CLUSTER.Method.v1.adl

Scope: The information structure for "Method" specifies the method applied when performing a specific type of healthcare activity element. Method specifications can be described for any type of direct healthcare activity element (investigating, treatment or combinations) and is a detailed and structured description of how and with what resources a healthcare activity element is performed.

Standards:

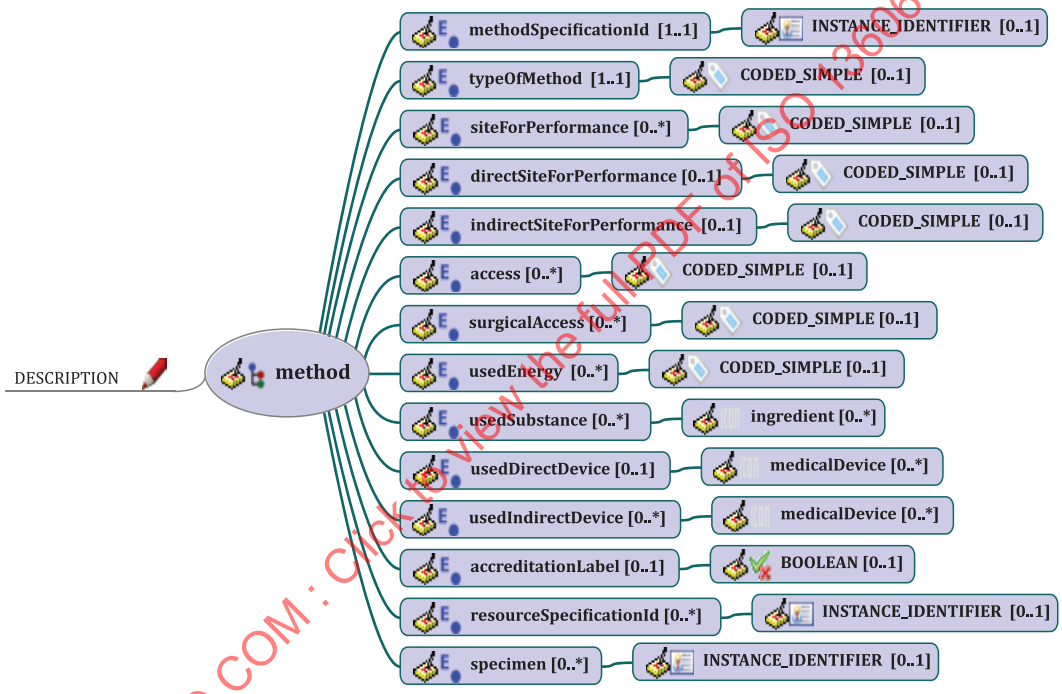
— ISO 13940:2015 Health informatics — System of concepts to support continuity of care

— HL7 FHIR: Observation resource

Method for applying the standard(s)

This reference archetype conforms to the ISO 13940:2015 properties as indicated below.

Mind map:



URL: http://en13606.org/specifications.html

Attribute description:

Attribute	Description
method specification_id	Identity for the method specification. Generated in the source system.
type of method	Code and text for the type of method used for performing the direct healthcare activity element. Examples of a method for a healthcare investigation are lab tests and x-ray examinations. Examples of types of methods for healthcare treatments are surgical operations and pharmacological treatments.
site for performance	Code and text for the site/place where the performer actually work with hands/equipment when performing the activity element. The site can be an anatomical structure but also an artefact (e.g. an implanted pacemaker that is adjusted).
direct site for performance	Code and text for the direct site for performance e.g. the precise organ site where a tissue sample is taken.
indirect site for performance	Code and text for indirect site for performance e.g. a blood vessel used to inject contrast for visualization of an organ.

Attribute	Description
access	Code and text for specifying the access to the site for performance e.g. transdermal puncture, through a catheter etc.
surgical access	Code and text for the surgical access/approach e.g. open surgery.
used energy	Code and text for the used energy e.g. ultrasound.
used substance	Code and text for the used substance e.g. injectable contrast.
used direct device	Code and text for the direct device used e.g. a fibrescope in a hepatic duct for inspection.
used indirect device	Code and text for the indirect device used e.g. a fibrescope in a hepatic duct used to get a tissue sample by a biopsy instrument through the fibrescope.
accreditation label	Specifies that the performer is accredited for performance of the method used.
resource specification id	Identification for the specified type of resource needed for performance of the method, e.g. a medicinal product or a medical device.
specimen	Specifying the analysis object.

12 Contsys-based clinical reference information structures as the basis for development of clinical archetypes

This clause specifies a reference information structure conformant to ISO 13940:2015 (Contsys). The aim is that this structure, when further tested and developed in the future, should be used as a comprehensive basis for development of clinical reference archetypes and for further specializations as specific clinical archetypes. The final portfolio of clinical reference archetypes conformant to Contsys may be published as a separate ISO standard or specification, or included as a revision of this document, or published by some other means, to be determined later.

12.1 Introduction

An overall aim for clinical information management is to contribute to quality of healthcare services. General quality management and information management can have synergistic effects on quality, if the approaches are coordinated. To achieve such coordination a common business model is needed. ISO 13940:2015 “System of concepts for continuity of care” (Contsys) comprises such a common model by systematically defined clinical concepts and a clinical process model.

Contsys aims to constitute a basis for both information management and quality management in general – as illustrated in Figure 2 below.

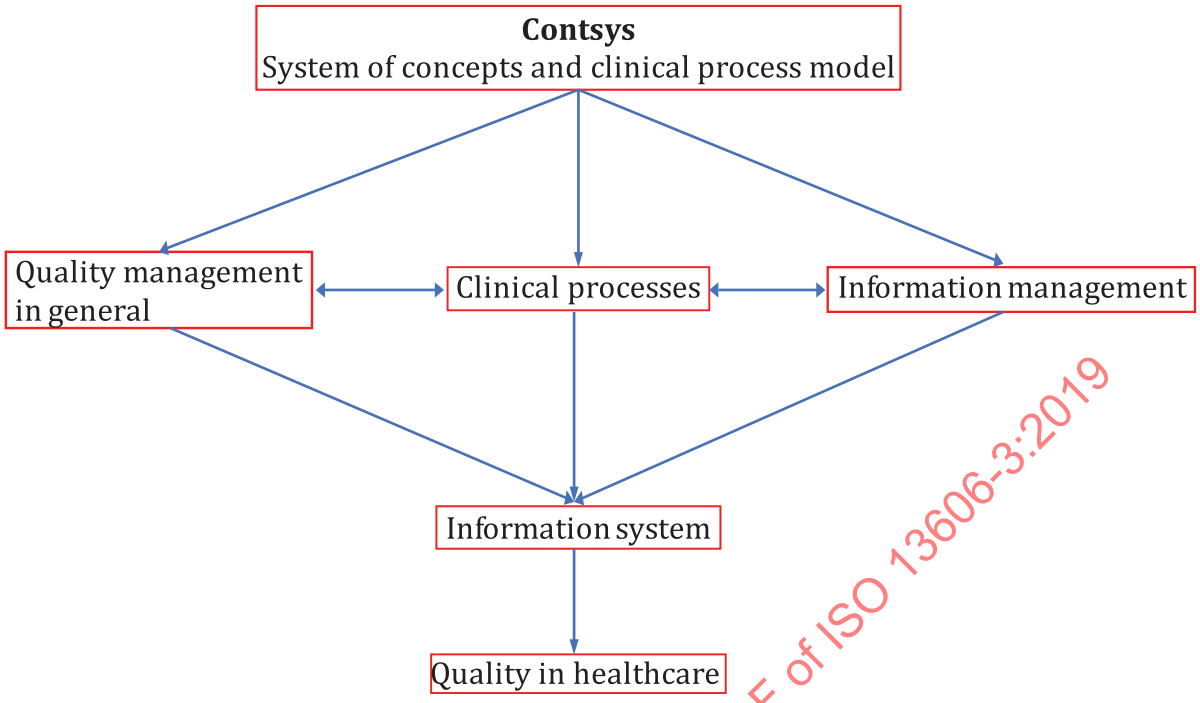


Figure 2 — High level information management and quality management view of Contsys

Semantic interoperability is a requirement for information management contributing to good quality care. Semantic interoperability requires clinical information to be systematically and unambiguously structured. The basis for the clinical information models needed to structure clinical information should be founded on models of the real phenomena in clinical practice.

Contsys includes comprehensive definitions of these clinical phenomena concerning clinical content and clinical context in relation to clinical processes.

Clinical information structures at a reference level based on Contsys can be applied as patterns for information specifications of clinical content and clinical context. One possibility is development of clinical archetypes at all levels of specializations (including reference- and detailed levels). The Contsys-based reference information structures can also be applied for any other method of choice for systematic and traceable structuring of clinical information. Thereby the information structures at the reference level can constitute the basis required for harmonization of different approaches for specifying clinical information to achieve semantic interoperability. This approach for concurrent and coordinated use of standards in health informatics includes how to concretize and apply Contsys as the conceptual and contextual base for information management.

The starting point for specifying clinical information should be the needs and premises from the clinical perspective. The clinical perspective includes by definition the interaction of subjects of care/patients and healthcare professionals aiming to maintain or improve a patient's health state by performing healthcare activities. The basic information structures presented below use the definitions of clinical concepts and the clinical process model in Contsys for defining requirements/characteristics/attributes and patterns for creating clinical reference archetypes and clinical archetypes at more specialized levels. The clinical information structures aim to include both the medical/professional and the subject of care/patient perspectives/domains.

Each clinical concept in ISO 13940:2015 (Contsys) has been elaborated based on the definition, relations and explanations in notes given in the standard. The attributes of the clinical reference information structures are thus mainly based on ISO 13940. Some further attributes have been added to harmonize with e.g. FHIR resources.

The result is clinical reference information structures for concepts defined in Contsys including a gross list of attributes for each concept. The gross list is intended to be comprehensive and cover all needs

for clinical information in different specializations and applications. This approach reflects the general idea to include all needed types of attributes and constrain the number applied when specializing clinical archetypes for instantiation.

12.1.1 Criteria/characteristics

Criteria for defining these clinical information structures have been to be:

— Conformant to the clinical process model in Contsys;

— Conformant to the definitions of clinical concepts in Contsys;

— Conformant to the relations between concepts in Contsys;

— Covering possibilities to specialize all needed clinical information in clinical practice;

— Fulfilling requirements for specializations/generalizations and traceability;

— "Human readable" and presented in UML (no other formal modelling style);

— Conformant to requirements related to clinical process management in EN 15224;

— Developed in a stepwise method where the attributes are validated on the basis of analyses of the clinical process perspective.

12.1.2 Basic concepts as bases for the Contsys-based information structure

The clinical reference information structure presented in this Clause is based on clinical concepts as they are defined in Contsys. These concepts are used as "building blocks"/classes of the information structure. The concepts are commented on in each class of the structure but as an overview the most basic concept definitions are presented in the table below.

Concept	Definition
Health condition	observed or potential observable aspects of the *health state* at a given time.
Observed condition	*health condition* observed by a *healthcare actor.*
Potential health condition	"possible future or current health condition described by a healthcare actor" There are four types of health conditions to be potentially observable (currently or in the future): considered-, risk-, target- and prognostic conditions.
Healthcare activity	"activity intended directly or indirectly to improve or maintain a *health state".*
Healthcare activity element	"element of *healthcare activity* that addresses one type of purpose". The different purposes could be direct (*healthcare investigation* and *healthcare treatment* that directly involves the *subject of care*) or indirect (*healthcare assessment*, *healthcare evaluation*, *healthcare documenting* or *healthcare activity management* that do not necessarily directly involve the *subject of care*.
Care plan	"dynamic, personalized plan including identified *needed healthcare activity, health objectives* and *healthcare goals*, relating to one or more specified *health issues* in *a healthcare process".*
Clinical context	a *clinical process concern* where the information concerning clinical phenomenon in a *clinical process* are related to the phases of a clinical process described by the model of the clinical process.

12.1.3 Method for development of Contsys-based clinical reference information structures

Contsys includes textual definitions of concepts, clarifies the relations between them and present them in UML diagrams. The concepts are structured in an ontological approach. The top node is generic and several levels of specializations are defined.

In general, this development of information structures based on Contsys has aimed to reuse as much experience as possible from existing reference information models. Other inputs have been conceptual models like ICF health components and SNOMED CT concept model. Attributes that are included in other specification approaches such as FHIR resources and open EHR have also been added.

Figure 3 gives an overview of the different inputs for specifying the reference structures.

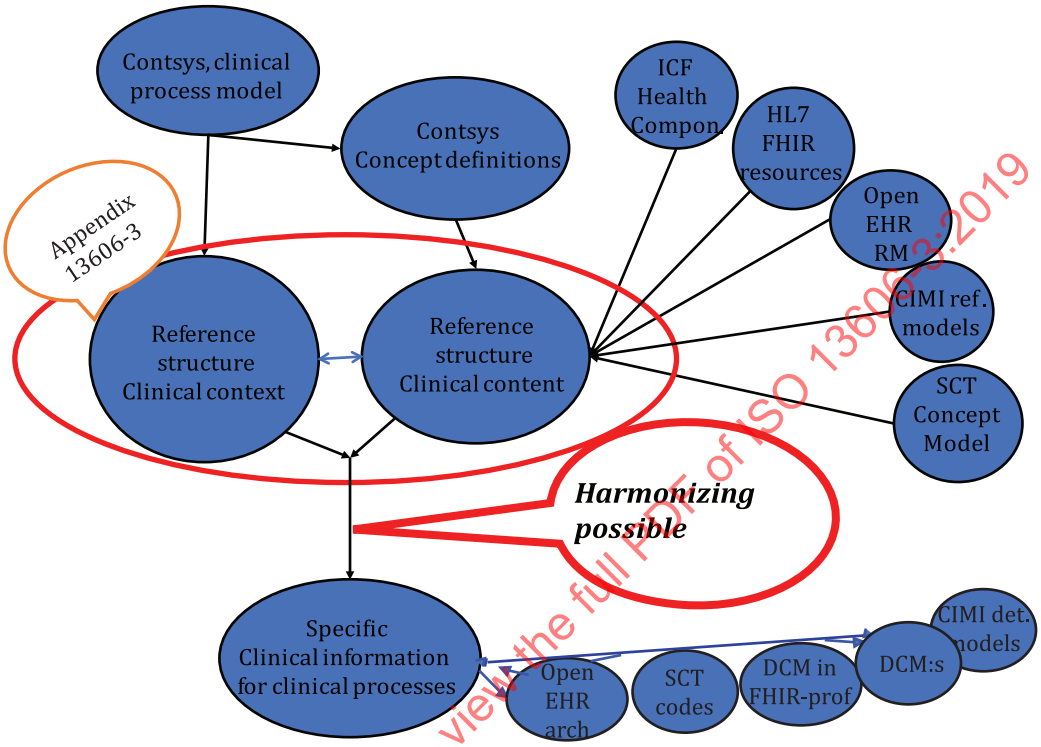


Figure 3 — Overview of the method used to constitute the reference information structures.

12.1.4 Steps in defining the information structures

The first step in the development of the clinical reference information structures was to identify which concepts in Contsys that should constitute information classes. The inputs shown above and the clinical process model guide these choices. One aim with the selection of clinical concepts for the information structures is to include as few as possible but still be comprehensive for all needs for clinical information. Two main concepts are dominating the clinical perspective:

— Health conditions describing the patient's state of health and the value added to that state by the provision of healthcare;

— Healthcare activities directly or indirectly adding value to the health state of the patient.

The second step has been to choose the level of specialization/abstraction of the concepts to be included as information classes. The aims for this choice have been to be generic enough to cover all needed specializations for information but yet be as concrete as possible. Also for this the different inputs and clinical process model give guidance. For example, health condition is a specialization of health issue which is a specialization of Healthcare matter in Contsys. Health condition is an abstract concept that is the parent to all types of conditions that are meaningful to specify clinical information for. Health condition was chosen as the appropriate level to include.

Concerning healthcare activities there are different purposes for these in the provision of care. The concept in Contsys that includes the purpose is Healthcare activity element. This concept was also considered appropriate to select for inclusion.

The third step was to identify which characteristics of each concept that should be included as attributes to be included in the gross list in each information class. These characteristics are primarily found from the relations between the concepts in Contsys and in the notes/examples given there. Characteristics/attributes was also gathered from the existing models as shown in the figure above. The number of characteristics/attributes to include was deliberately not constrained – all attributes that could possibly be applied in information concerning any clinical situation were included. This means that far from all attributes will be applied when specializations for instantiation is made. Organizations that wish to communicate clinical information with high levels of interoperability could make agreements to apply any agreed set of attributes for information in e.g. a certain type of clinical process.

The fourth step was to combine concepts/information classes to be able to constitute meaningful information patterns for different clinical situations. The clinical process model and experiences from multiple analyses of information needs in clinical processes, as well as the different inputs mentioned in Figure 3 were the main basis for this step. The combinations are formulated in clusters for multiple reuse and in more complex structures for use in creating more composite templates.

In summary, the choices made in development of these information structures are closely related to the conceptual ontology of Contsys combined with inputs from existing information and conceptual models in healthcare. The resulting structures are developed from a relatively restricted number of clinical concepts in Contsys. Each concept/information class includes a relatively long list of optional attributes for defining specific clinical information in interoperable information systems. The degree of interoperability between and within these systems will be based on the common conceptual basis but also depend on the common choices of attributes.

12.2 Content of information structures

12.2.1 Structures for single concepts

Two main concepts are dominating the clinical perspective:

— Health conditions describing the patient's state of health and changes of that state encompassing the value added to that state by the provision of healthcare;

— Healthcare activities directly and/or indirectly adding value to the health state of the patient.

These two basic concepts are included as:

— Health condition, and

— Healthcare activity element categorized by the purpose of the healthcare activity.

Care plan is a central concept in the continuity of care motivating a separate information structure.

12.2.2 Structures for reuse in clinical situations — Clusters complementing structures for basic clinical concepts

— Activity management and healthcare planning.

— Associations; relations between:

  — different health conditions (including potential conditions), included in a health condition thread, and

  — associations to or between healthcare activity elements and care plans.

— Clinical context; the relation of the clinical content to the clinical process model.

— Clinical process concern; the complete information needed for the continuity of care for a comprehensive clinical process for a specific subject of care.

— Clinical risk; the components of risks for having an unintended effect on the health state of subjects of care.

— Consideration; the choice of subjects of care to consent or dissent to assessments and proposed healthcare activity elements.

— Knowledge base: the referred knowledge behind the applied knowledge management.

— Method specification: specification of the method used for healthcare investigations and healthcare treatments.

— Priority level; the assessment of the "acuteness" of an activity element to be performed.

— Version information.

12.2.3 Structures for compound documents in an EHR

In clinical practice certain combinations of structured information is commonly used in templates. For interoperability a common structure for such templates is beneficial.

Clinicians need access to summarized information concerning the health and healthcare of a subject of care.

Summarized information documented directly by the subject of care should also be possible to be documented in a structured way to be possible to use in the clinical work.

In Contsys a concept for "summarized healthcare information repository" is defined as: "*data repository* containing summarized *information* for *healthcare* coordination and the *continuity of care".* Concepts that are specializations of "health record" are also defined in Contsys;

"*Personal health record*" as " *health record* held and maintained by the *subject of care* or a *subject of care proxy"* and "*Professional health record* as " *health record* held under the responsibility of one *healthcare provider* and maintained by one or several *healthcare professionals.*

Compound structures representing overviews of content for both these types of health records are in this structure included as:

— Personal health record overview, and

— Professional health record overview.

12.2.4 Other comments

In Contsys references are made to ISO 9000:2015 for basic concepts concerning quality management. One important concept in Contsys related to quality and knowledge management of clinical processes is "core care plan", with the synonym "standardized care plan". This concept can be applied for knowledge management by applying documentation of knowledge based recommendations for which healthcare activity elements that should be used and included in the care plan to handle identified health problems. The definition of standardized care plan in Contsys is "reusable content and structure for a potential care plan for a specified set of circumstances".

An aspect of information management in the context of quality management is that knowledge management can be integrated in the information management. Information management is further an integrated part of quality management as defined in ISO 9001 and in the healthcare sector specific EN 15224 defining requirements for quality management systems in healthcare. Compound structures for such knowledge management integrated in information management are included in this clinical reference information structure for:

— Knowledge based healthcare activity planning of healthcare investigations,

— Knowledge based healthcare activity planning of healthcare treatments, and

— Knowledge based criteria for identifying health problems/specific health conditions.

Follow up of results and quality indicators as a base for quality management and improvement in general can also be integrated in the information management according to these information structures.

The clinical information structures presented include some attributes that are covered by the reference model in ISO 13606-1. These attributes are though included here for giving the comprehensive overview and also for possible alignment with other standards in health informatics.

Relations between concepts are an important aspect of the definition and clarification of the meaning of concepts in a system of concepts. To be conformant to Contsys in a traceable way the inheritance of relations from concepts higher in the ontological structure need to be specified. One example is that Healthcare matter has a relation to subject of care with multiplicity 1 saying that a healthcare matter always concerns a specific subject of care and is identified or stated by a specific healthcare actor. Those relations are inherited to health condition and such inheritances are, when included as attributes to i.e. health condition, clarified in the comment column for those attributes.

Pharmacological treatment or medication is one of the most commonly performed healthcare activity elements. This type of treatment is also important for patient safety and the information need to be carefully specified to be interoperable and fully understood by all actors. A specific information structure for pharmacological treatment is therefore included. However, the medicinal product as the main resource in pharmacological treatment is not specified here. A reference archetype for this is included in Clause 11 and the information structure here refers to that.

12.2.5 Format

Datatypes from HL7 FHIR https://www.hl7.org/fhir/DSTU2/datatypes.html#is used as format in these information structures. This will be changed to the 13606 datatypes in the further work.

12.3 Specializations of types of Health condition

The reference information structure for Health condition contain attributes that is needed for all of the different types of health condition. The intention is that the reference information structure should be specialized and only use the needed attributes for a specific situation/purpose. The specialization is done advantageously in several steps. The first step is to specialize the different types of health condition, according to the list. This specialization could then be specialized one or many times, depending on the specific needs.

Health condition	**{1..1}**	**Observed condition**	**Professionally assessed condition**	**Resultant condition**	**Considered condition**	**Risk condition**	**Target condition**	**Prognostic condition**
Health condition id	{0..*}	X	X	X	X	X	X	X
Health state aspect category	{0..1}	X	X	X	X	X	X	X
Health condition type	{1..*}	Observed	Professionally assessed	Resultant	Considered	Risk	Target	Prognostic
Health condition category	{0..1}	X	X	X	X	X	X	X
Health condition code	{0..*}	X	X	X	X	X	X	X
Clinical context	{0..*}	X	X	X	X	X	X	X
Health problem	{0..1}	X	X	X				
Identified by	{0..*}	X	X	X	X	X	X	X
Device	{0..*}	X	X	X	X	X	X	X
Health condition period	{0..*}	X	X	X	X	X	X	X

Health condition	{1..1}	Observed condition	Professionally assessed condition	Resultant condition	Considered condition	Risk condition	Target condition	Prognostic condition
Condition verification status	{0..*}	X	X		X	X	X	X
Body site	{0..*}	X	X	X	X	X	X	X
Pathological process	{0..*}		X					
Severity of abnormality	{0..1}		X					
Clinical course	{0..*}		X					
Impact on healthcare state	{0..*}		X					
Association to	{0..*}	X	X	X Activity {1..1}	X	X Clinical risk {1..*}	X Care plan {1..*}	X Health condition {1..*}
Value specification	{0..*}	X	X	X	X	X	X	X
Code	{0..1}	X	X	X	X	X	X	X
Value	{0..1}	X	X	X	X	X	X	X
Comment value	{0..*}	X	X	X	X	X	X	X
Interpretation	{0..1}	X	X	X	X	X	X	X
Reference range	{0..*}	X	X	X				
Data absent reason	{0..1}	X	X	X	X	X	X	X

12.4 Information structures for single concepts

12.4.1 Health condition

Figure 4 defines the information structure for Health Condition.

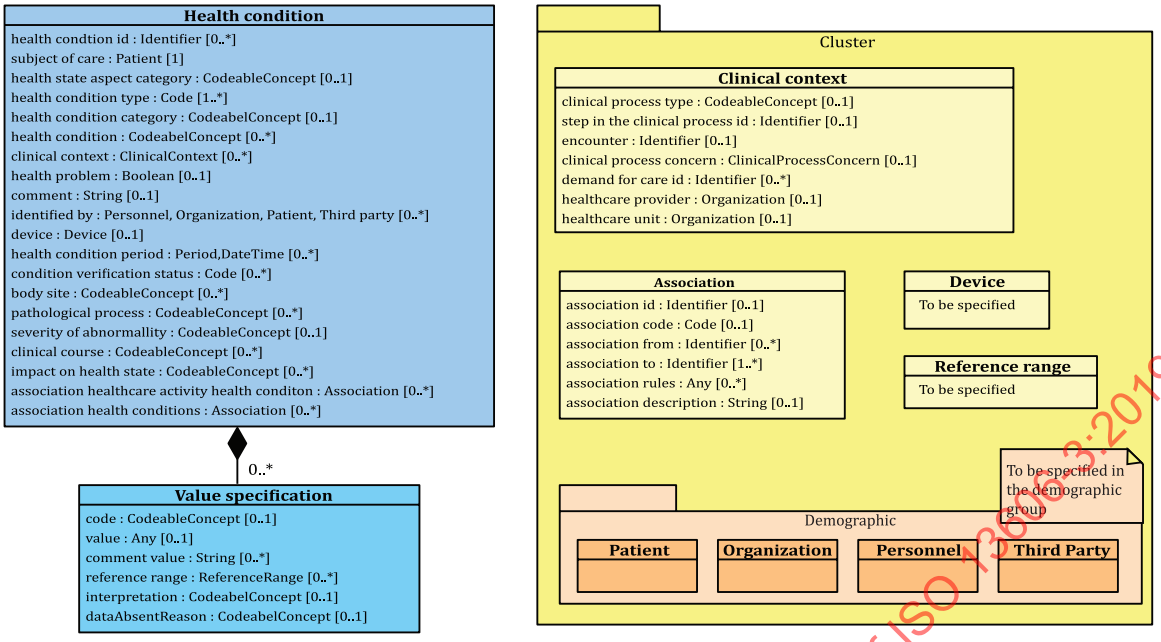


Figure 4 — UML diagrams of the clinical reference information structure for health condition

Scope: *Health condition* is in ISO 13940:2015 an abstract concept defined as "observed or potential observable aspects of the health state at a given time".

Health state is defined as "physical and mental functions, body structure, personal factors, activity, participation and environmental aspects as the composite health of a subject of care". The definition of health state is based on the WHO classification ICF and the health components described in this. Health conditions include both observed and potential observable aspects of a health state.

Observed condition is in ISO 13940 an observed aspect of a health state and can be specialized as professionally assessed condition and/or resultant condition.

Professionally assessed condition is an observed condition that is assessed by a healthcare professional concerning certain specific factors.

Resultant condition is an observed condition observed after performance of a direct healthcare activity element (healthcare investigation or healthcare treatment). Resultant conditions are considered to include the concept behind the FHIR resource "observation".

Potential condition is a not yet observed aspect of a health state that for some reasons assessed possible to become observed in the future. Potential condition can be specialized as considered- *risk-, target- and prognostic conditions*.

Health condition can be generalized as health issues (and further to healthcare matters).

The information structure for "Health condition" specifies common information concerning aspects of a health state. There are successive specializations of health condition that are considered relevant to keep information about in an EHR.

The different types of health condition are specified in an attribute. In this way the number of information structures for health conditions is reduced and redundancy is avoided.

The information structure for health condition also includes specification of associations to other health conditions. For example can one observed condition constitute one of several criteria for a more composite professionally assessed condition. One health condition can alternatively represent

a complication of another. Relations to healthcare activity elements can also be specified by this information structure.

Attribute	*Description and Comments*	*Format*	*Mult*	*Codelist and values*
health condition id	A unique identifier for the health condition instance. Allows health conditions to be distinguished and referenced. FHIR:condtion.identifier**	Identifier	0..*	
subject of care	*This attribute is inherited from the relation between subject of care and Healthcare matter.* Identifies the subject of care/patient who the health condtion is associated with. FHIR:condition.patient** FHIR.observation.subject (patient, group, location, device)	Patient (demographic)	1	
health state aspect category	Code for the aspect of health state included in the health condition as defined by the health components in ICF. The category can be specified by the four position code in ICF I.e. the body function “heart functions ICF b410. FHIR:Observation.category*	Codeable Concept	0..1	body function, body structure, activity, participation and environmental factors
health condition type	Code for the type of health condition. Types of health conditions are all specializations of the abstract concept “health condition” in ISO 13940 (see introduction to this reference information structure). FHIR resource observation corresponds to resultant condition.	Code	1..*	Observed-, professionally assessed-, resultant-, considered-, risk-, target- or prognostic condition
health condition category	Code for the category of condition based on FHIR condition category. Complaint - The patient considers the condition an issue to be addressed Symptom - A symptom of a condition (as might be mentioned in a review of systems) Finding - An observation made by a healthcare provider Diagnosis - This is a judgment made by a healthcare provider that the patient has a particular disease or condition FHIR:condition.category** http://hl7.org/fhir/ValueSet/condition-category	Codeable Concept	0..1	Complaint Symptom Finding Diagnosis
health condition	Code for the health condition. This attribute specifies the health condition from several perspectives. One is by classifications and terminologies, another is by value specifications from so called “assessment scales” like Apgar score for newborns. Examples of classifications are ICD, ICF, SNOMED CT The health condition can be further specialized according to the “health state aspect and value specifications”. FHIR: condition.code**	Codeable Concept	0..*	ICD ICF SNOMED CT Value from assessment scales

Attribute	*Description and Comments*	*Format*	*Mult*	*Codelist and values*
clinical context	This attribute refers to the cluster for clinical context specification Specifies clinical and/or administrative context, e.g. which clinical process concern and which step in the clinical process the health condition relates to FHIR: includes attribute for encounter	Clinical context	0..*	
health problem	Specifies if the health condition is considered to be a problem concerning the health state. The consideration can be done by the subject of care and/or by a health-care professional FHIR:not included	Boolean	0..1	Yes No
comment	Textual comment on the health condition FHIR: condtion.notes** FHIR:observation.comments**	String	0..1	
identified by	This attribute is inherited from the relation between healthcare actor and healthcare matter. Identity and name for the healthcare actor(s) who identified/noticed the condition. The identifier can be the subject of care, healthcare personnel, healthcare third party and the responsibility/task could also be specified by the healthcare organisation within which assignment the condition was identified. FHIR: condition.asserter(practioner or patient)**	Healthcare personnel Healthcare organization Subject of care Healthcare third party (demo-graphic)	0..*	
device	Identification for the equipment/device that has generated the observation data FHIR: observation.device**	Device	0..1	
health condition period	This attribute is a specialization of the concept health related period. Time interval/period during which a healthcare professional, the subject of care or other healthcare actor (from identified by above) has noticed a specific health condition. A health condition period can be specified for all types of health conditions. For potential conditions this will be by an assessment. For lab test etc. where a sample or specimen is taken from the subject of care the time for the observation should be when the sample was taken. FHIR: condtion.onset (datetime, age, period,range, string)** FHIR: condition.abatement datetime, age, period, range,string, Boolean)** FHIR: observation effective (datetime,period)** FHIR: observation.issued**	Period DateTime	0..*	

Attribute	*Description and Comments*	*Format*	*Mult*	*Codelist and values*
condition verification status	Specifying the level of verification of the health condition as assessed by the identifier. From FHIR "condition verification status". FHIR: Provisional, differential, confirmed, refuted entered-in-error and unknown	Code	0..*	Considered Alternatively considered Concluded Excluded Entered in error Unknown
body site	Code for the anatomical localization of the health state aspect E.g. a blood pressure measured externally on right upper arm, a tumour in the lower abdomen etc. FHIR: body site	Codeable Concept	0..*	ICF body structure SNOMED CT
pathological process	Specifying the mechanism behind the abnormal findings for body structure or body function (e.g. autoimmune process behind diabetes type I) When the pathological process is specified as the reason for the condition by a healthcare professional the health condition is a "professionally assessed condition".	Codeable Concept	0..*	ICF body function SNOMED CT
severity of abnormality	Specifying the level of abnormality of the health aspect, e.g. reduced calibre of a vessel to 25% of normal When the severity is specified by a healthcare professional, the health condition is a "professionally assessed condition".	Codeable Concept	0..1	ICF body function
clinical course	Specifying the probable (by medical knowledge) future course of the health condition. When the clinical course is specified by a healthcare professional, the health condition is a "professionally assessed condition".	Codeable Concept	0..*	

Attribute	*Description and Comments*	*Format*	*Mult*	*Codelist and values*
impact on health state	Specifying the impact on the health state of a health condition When the impact on the health state is specified by a healthcare professional, the health condition is a "professionally assessed condition".	Codeable Concept	0..*	
association healthcare activity health condition	Specifies the relation/association of the health condition to a specific healthcare activity element, e.g. as a motivation for or as a result of a healthcare activity element E.g. high blood pressure as a motivation for pharmacological treatment or a genetic profile as a health condition associated to choice of a specific medical product in a pharmacological treatment activity. FHIR.observation.related	association	0..*	
association health conditions	Specifies the associations between the specified health condition and another health condition. The relation can be the health condition being criteria for a more composite condition or being a resulting condition from a risk condition after an occurred event etc. Another important relationship is that a health condition can be a complication to a primary health condition. A health condition evolution is "an association health condition" for the successive change of a condition over time. Criteria for a composite health condition which in FHIR is called evidence is another "association health condition". E.g. breathlessness as criteria for heart failure or a stroke as a complication to high blood pressure. FHIR.observation.related?	association	0..*	

Value specification

Scope: "Health condition – Value specification" specifies information concerning the possible values of a health condition

Attribute	*Description and Comments*	*Format*	*Mult*	*Codelist and values*
Code	Specifies the code that describes the value of the health condition. Sometimes this is called the observation "code". FHIR:observation.component.code**	Codeable Concept	0..1	
value	The value of the actual health condition (expressed in units) at a certain occasion. The values can be specified by so called "assessment scales" like Apgar score for newborns. FHIR: observation.value, component.value**. Value of health conditions/observations as criteria and summary from assessment scales.	Quantity CodeableConcept string Range Ratio SampledData Attachment time dateTime Period	0..1	

comment value	Textual comment on the value of the health condition FHIR –not included**	String	0..*	
reference range	Specifies the interval of values which are considered in the interpretation of the value. FHIR reference values for low and high etc.	Reference range	0..*	
interpretation	Represents a signal from the healthcare actor that the value is to be especially noticed, e.g. marked as pathological or borderline pathological FHIR:observation.interpretation**	Codeable Concept	0..1	
data absent reason	Provides a reason why the expected value in the element. An example of reason is that the value is exceptional high and not within a trustworthy reference range. FHIR "data absent reason".	Codeable Concept	0..1	

ReferenceRange

Scope: Reference range is a part of the value specification of a health condition, normally an observed condition.

Attribute	Description
Low	Low Range, shall have at least a low or a high or text
High	High Range, shall have at least a low or a high or text
Meaning	Reference range qualifier
Range	Applicable age range
Text	Text based reference range in an observation, shall have at least a low or a high or text

12.5 Healthcare activity element

Figure 5 defines the information structure for healthcare activity element.

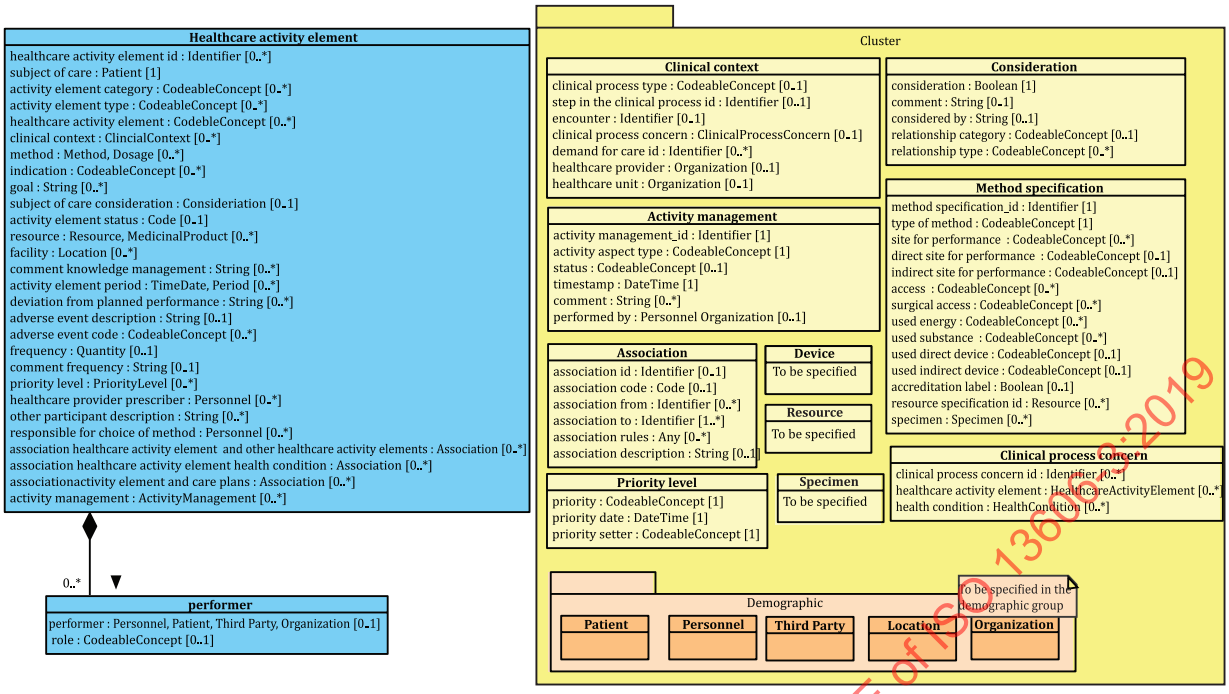


Figure 5 — UML diagrams of the clinical reference information structure for healthcare activity element

Scope: In ISO 13940, "*Healthcare activity*" is defined as "activity intended directly or indirectly to improve or maintain a health state". The types of healthcare activities are defined out from the type of actor performing the activity (*healthcare provider, self-care and healthcare third party activity)*.

Healthcare activity is a complex concept that can be subdivided into *healthcare activity elements* that also represent the purposes of the performance The two main purposes are to clarify aspects of the health state of a subject of care *healthcare investigations*- or to improve/maintain *healthcare treatment.*

Healthcare investigations and healthcare treatments directly involve the subject of care and are thereby also called direct healthcare activity elements. Healthcare activity elements that are only indirectly involving the subject of care are, *healthcare assessments, evaluations, communication, resource management* and *healthcare activity management including healthcare planning*.

Healthcare treatment is a direct healthcare activity element aiming to influence the health state of a subject of care.

Healthcare Investigation is a direct healthcare activity element that gives the prerequisites for observations of one or several aspects of a person's health state (observed conditions). The observed conditions as results of investigations (resultant condition) provide the basis for assessments of pathophysiological genesis, severity or consequence for a person's health state (expressed as professionally assessed conditions).

In clinical practice information about investigations and treatments are fundamental and are for this reason the basis for the information structure concerning healthcare activity element.

Information structures as requirements/patterns for specifying reference and specific clinical archetypes are defined and included to comprehensively cover the need for information in an EHR.

All categories of healthcare activity elements share a number of characteristics to keep information about. The common structure for healthcare activity element includes all attributes needed for the two direct activity elements – investigations and treatments. Several attributes relevant for indirect healthcare

activity elements are included in the common structure. Further attributes are however needed for indirect activity elements as complements. For these reasons specific structure are included for:

— healthcare activity element – general and complete for healthcare investigations and healthcare treatments;

— healthcare assessment;

— healthcare evaluation;

— healthcare activity management including healthcare planning.

Healthcare assessment is specified as three specializations for:

— assessment to conclude or exclude health conditions;

— healthcare needs assessment;

— clinical risk assessment.

Attribute	*Description and Comments*	*Format*	*Mult*	*Codelist and values*
healthcare activity element id	A unique identifier for the healthcare activity element instance. Allows the healthcare activity element to be distinguished and referenced.	Identifier	0..*	FHIR:Procedure. identifier*
subject of care	*This attribute is inherited from the relation between subject of care and Healthcare matter.* Indicates the subject of care/patient who the health activity element is associated with FHIR:procedure .patient**	Patient (demographic)	1	
activity element category	Specifies the category of the activity element categorized by the main purpose Corresponding to "procedure type" in FHIR.	Codeable Concept	0..*	Healthcare investigation, healthcare treatment, -planning, -assessment, -evaluation, -documenting, --communication, -activity management.
healthcare activity element	Code for the healthcare activity element Different code systems and classifications can be used.	Codeable Concept	0..*	SNOMED CT procedures and/or national/local classifications
clinical context	This attribute refers to the cluster for clinical context Specifies the clinical and/or administrative context, e.g. which clinical process concern and which step in the clinical process the activity element is included in	Clinical Context	0..*	
method	In accordance with the "method specification" Specification of the method to be used for performance of the healthcare investigation or healthcare treatment, e.g. a laboratory test, a CT-scan etc. for healthcare investigations and open surgery or pharmacological treatment for healthcare treatments.	Method Dosage	0..*	

Attribute	*Description and Comments*	*Format*	*Mult*	*Codelist and values*
indication	Specifying the indication/motif for or against performing the activity element. Indications can also be specified as an association healthcare activity element – health condition or an association healthcare activity – healthcare activity.	Codeable Concept	0..*	health conditions (observed, professionally assessed or potential conditions other healthcare activities
goal	Specification of the goal for the activity element e.g. to exclude a considered condition as breast cancer or to verify a myocardial infarction for healthcare investigations and removal of a tumour or lowering blood pressure for a healthcare treatment. The goal can be specified as a target condition in an association healthcare activity element – health condition. Goals other than different types of health conditions can also be identified i.e. degree of subject of care satisfaction or a certain degree of effectiveness.	String	0..*	
subject of care consideration	According to the cluster “consideration”. The subject of care considers and takes position to the provider’s commitment to perform the activity element. The outcome is either an informed consent that includes who, where and by whom the activity will be performed or a dissent. Informed consent or dissent should be registered to achieve the activity state ”active”	Consideration	0..*	Informed consent Dissent
activity element status	Code and text for the current status of an activity element Only current status is shown, history is shown in the compound format healthcare activity management. Instruction state machine from open EHR can be used	Code	0..1	planned- scheduled- active- completed
resource	According to the cluster “resource”. Specification of the resources that are planned, booked and used for performance of the activity element. Should include both personal (e.g. an hour nurse) and material (e.g. an ultrasonic scanner or a medicinal product)	Resource Medicinal product	0..*	
facility	According to the demographics. Specification of the place/site/room where the healthcare activity element is performed, e.g. a laboratory, a hospital ward, a surgical theatre etc.	Location	0..*	
comment knowledge management	Information linked to the knowledge management that is applied for performance of the activity element. Protocols, guidelines etc. can include specifications for application of knowledge	String	0..*	
activity element period	This attribute is a specialization of the concept “health related period”. Specifies the time (moment or time interval) for the performance of the activity element	DateTime Period	0..*	
deviation from planned performance	Description of deviation from the decided and planned performance of the activity element e.g. change of method for performance.	String	0..*	

Attribute	*Description and Comments*	*Format*	*Mult*	*Codelist and values*
adverse event description	Description of unforeseen event during the healthcare activity period that has impact on activity management, performance and/or the resulting conditions.	String	0..1	
adverse event code	Code and text for the unforeseen event during the healthcare activity period.	Codeable Concept	0..*	
frequency	Number of instances per time unit for performance of the activity element e.g. once every 4th week.	Quantity	0..1	
comment frequency	Possible further information for clarifying the frequency.	String	0..1	
priority level	The priority level for the performance of the activity element within a certain time interval Priority set by whom and when should be registered before the activity element achieves the status "active". E.g. within a specified time limit or a code system for acute, planned etc. Priority level can be further specified in accordance with the cluster for "priority level".	Priority level	0..*	
healthcare provider prescriber	Specifies which healthcare provider that with or without an explicit healthcare needs assessment prescribed the activity element. The information is valid for all healthcare provider- and all prescribed self-care activity elements E.g. a person having a healthcare professional role, a healthcare organisation or a professional team.	Healthcare personnel	0..*	
other participant description	Description of other actor who is involved in the activity element. It can be for example, the subject of care, a next of kin, other healthcare third party.	String	0..*	
responsible for choice of method	This attribute is a specialization of the concept "healthcare mandate". Identification and name for the healthcare professional and unit within which assignment deciding which method to use for performing the activity element.	Healthcare personnel	0..*	
association healthcare activity element and other healthcare activity elements	According to the cluster "association". Specification of associations of the activity elements to other activity elements. The association include activity elements that are consequences of another activity element e.g. removal of sutures after a surgical operation. Specifies i.e. dependencies between activity elements where performance of one element is a consequence of another.	Association	0..*	

Attribute	*Description and Comments*	*Format*	*Mult*	*Codelist and values*
association healthcare activity element health condition	According to the cluster “association”. Specification of the association between the activity element and health condition(s) (observed or potential conditions) e.g. as specifying the indication, a complication to and/or the result of an activity element e.g. association between a high blood pressure and a healthcare treatment with an antihypertensive drug. FHIR:procedure. Complication**	Association	0..*	
association activity element and care plans	Specifies the associations between the activity element and one or several care plans. Examples of care plans that the activity element is included in: Care plan for a clinical process for specified health issues etc.	Association	0..*	
activity management	According to the cluster “activity management”. Specifies the indirect activity elements performed to change the status of the direct healthcare activity element.	Activity management	0..*	

12.5.1 Performer

Scope: All healthcare activity elements are performed by one or more healthcare actors. In ISO 13940 the type of activity element is defined by the type of actor performing the activity element. To avoid redundancy, type of activity element is not included in the basic structure for healthcare activity element beside the attribute for performer.

The identity of a performer can be coded if there is a register of i.e. healthcare personnel to be used. If not, the performer is to be identified by name.

Type of performer is specified according to the definitions of healthcare actors in ISO 13940.

Attribute	*Description and Comments*	*Format*	*Mult*	*Codelist and values*
performer	Identity and/or name of the healthcare actor who is planned to perform, is performing or has performed that activity element. The performer can be the subject of care (self-care activity), healthcare personnel (healthcare provider activity), healthcare third party and the responsibility/task could also be specified by the healthcare organisation within which assignment the condition was identified. National or local person registers	Healthcare personnel Healthcare organization Subject of care Healthcare third party (demographic)	0..*	
role	A code that identifies a role of the performer of the healthcare activity element The role of the performer also determines the type of activity that is performed: — healthcare provider activity; — self-care activity; — healthcare third party activity; — automated activity. Related to FHIR:procedure.performer.role**	Codeable Concept	0..*	

12.6 Pharmacological treatment

Figure 6 defines the information structure for pharmacological treatment.

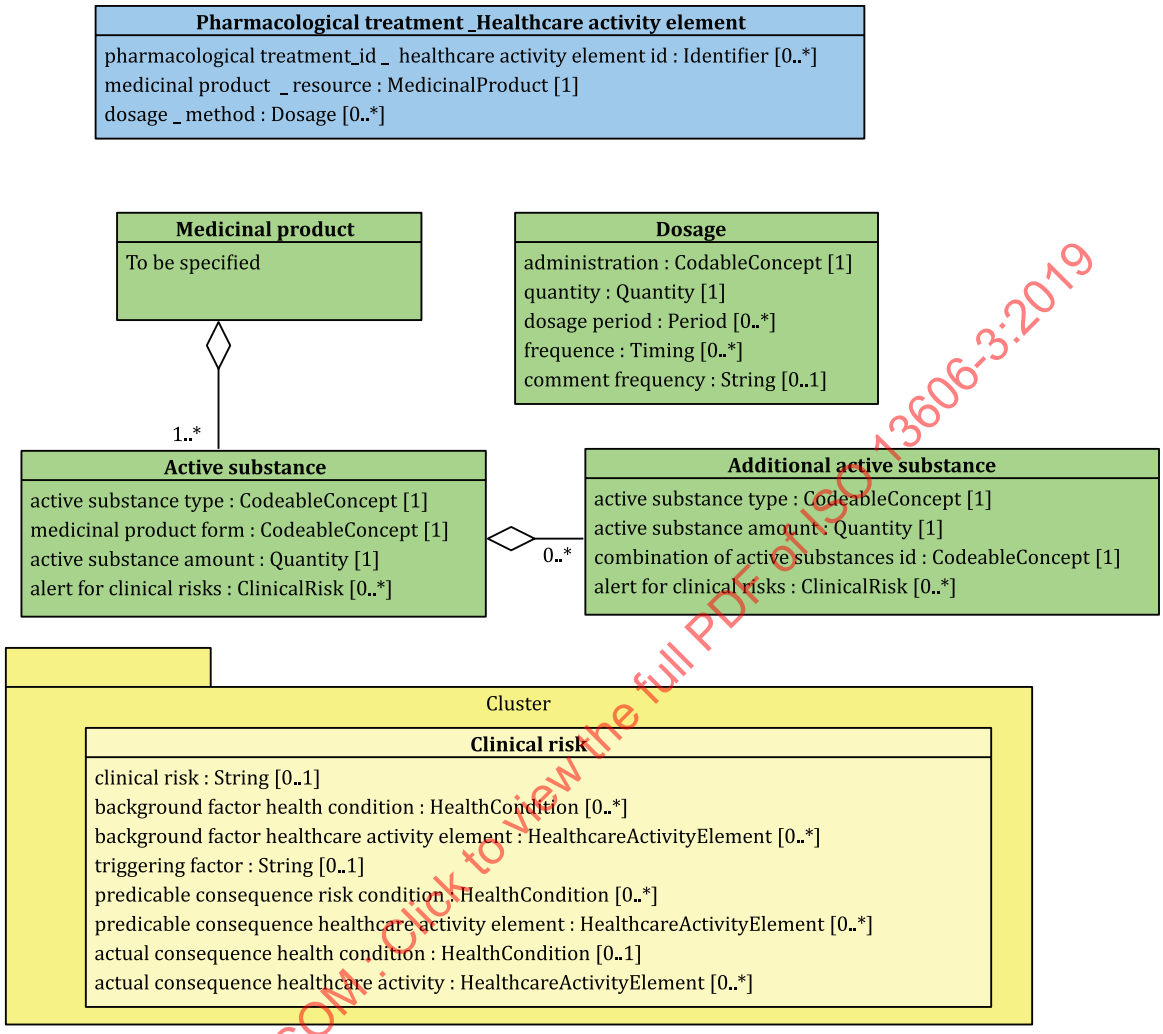


Figure 6 — UML diagrams of the clinical reference information structure for pharmacological treatment

12.6.1 Pharmacological treatment

Scope: The information structure for "pharmacological treatment" describes a specialization of healthcare activity element and the category healthcare treatment. The reason for describing this specialization separately is the magnitude of pharmacological treatments in healthcare.

The pharmacological treatment is specified according to the clinical reference information structures "Healthcare Activity element". The medicinal product is a type of resource in the activity element specification. Specification of the medicinal product refers to the reference archetype in Clause 11.

The method specification for the activity element includes the dose specification. Alert information should be specified according to the clinical reference information structure for clinical risk.

Duration of the pharmacological treatment is defined in the attribute healthcare activity period in the clinical reference information structure for healthcare activity element.

Attribute	*Description and Comments*	*Format*	*Mult*	*Codelist and value*
pharmacological treatment id	Refers to the attribute "healthcare activity element id" in "Healthcare activity element". Identity of the specification of the activity element.	Identifier	0..1	
medicinal product	Refers to the attribute "resource" in "Healthcare activity element". Specified by the reference archetype "pharmacological product" defined in Clause 11.	Medicinal product	1	
dosage	Refers to the attribute "method" in the structure for healthcare activity element. Specified in cluster "dosage".	Dosage	0..*	

12.6.2 Dosage

Scope: "Dosage" specifies characteristics/information concerning the method for a pharmacological treatment by specifying amount and frequency for the administering of a medicinal product.

Attribute	*Description and Comments*	*Format*	*Mult*	*Codelist and value*
administration	Specifies the method for administration of the medicinal product to the subject of care e.g. orally, intravenously	CodeableConcept	1	
quantity	Specific the amount for each occasion e.g. 1 á 10 mg.	Quantity	1	
dosage period	Specifies the time interval for the given dosage.	Period	0..*	
frequency	Specification of the number of occasions per time interval for the administering each dose of the medicinal product e.g. every 8th hour, daily, once a week etc.	Timing	0..1	
comment frequency	Further information to clarify the frequency.	String	0..1	

12.7 Indirect healthcare activity elements

Scope: In ISO 13940:2012 indirect *healthcare activity elements* are defined. These are *healthcare activity management* including *healthcare planning, healthcare assessment, healthcare evaluation, healthcare documenting* and *healthcare-communication*. For the content in an EHR, and for purposes of interoperability, healthcare activity management including healthcare planning, healthcare assessments and healthcare evaluations are of special importance. Information structures for these concepts are included in this clinical reference information structure. For healthcare assessment three subtypes are specified. Figure 7 defines the information structure for indirect healthcare activity elements.

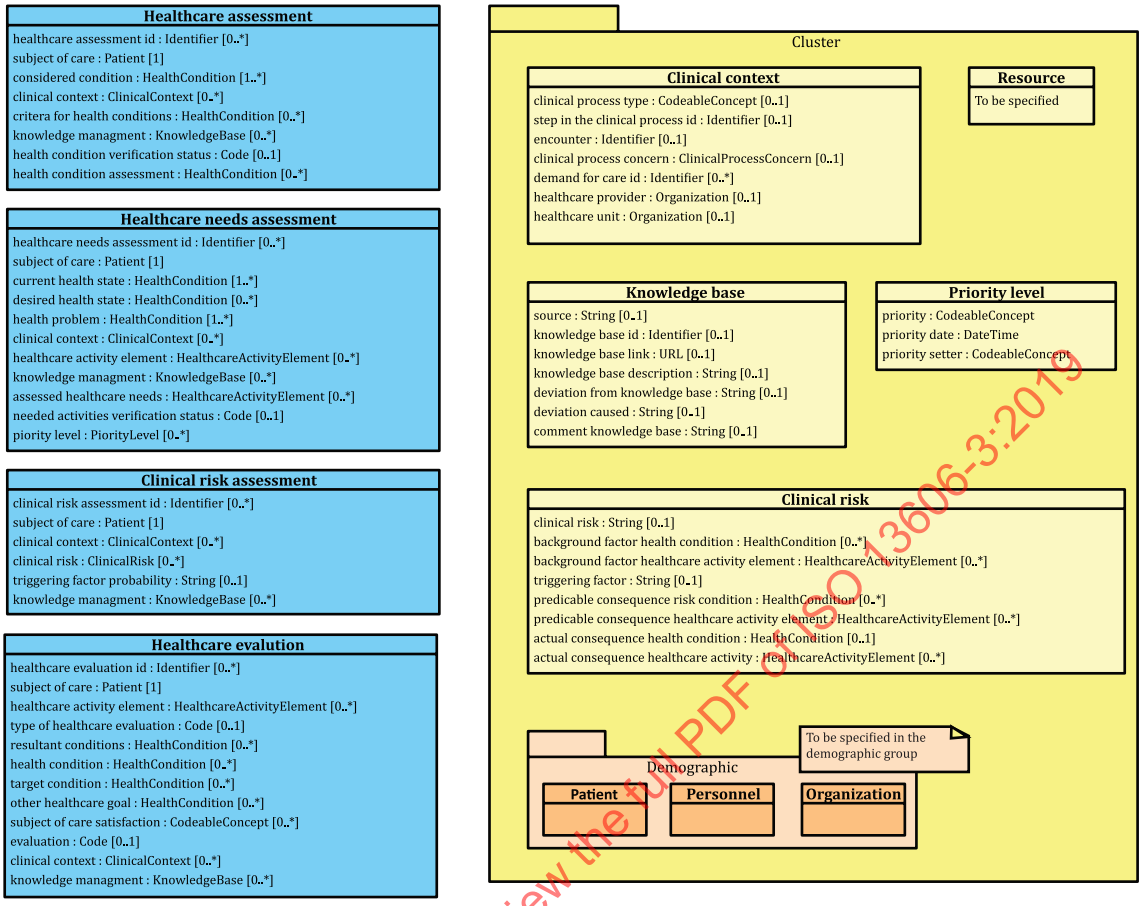


Figure 7 — UML diagrams of the clinical reference information structure for indirect healthcare activity elements

12.7.1 Healthcare assessment

Scope: *Healthcare assessment* is in ISO 13940 defined as: "*healthcare activity element* where an opinion related to *health conditions* and/or *healthcare activities* is formed".

In clinical practice different kinds of assessments are required. Three main purposes with assessments can be identified: assessments of:

— the probability of existence or a specific health condition/verified diagnosis;

— the indication for specified direct healthcare activity elements to be performed – Healthcare needs assessment;

— the probability of events that could trigger adverse reactions and the consequences of these - clinical risk assessment.

12.7.2 Assessments to conclude or exclude health conditions

Scope: Identification of *health conditions* is a basic task in clinical practice. Observations such as symptoms, signs an findings are inputs to *healthcare professional actors* for assessments of which type of health conditions that could be considered concluded or excluded based on medical knowledge. This